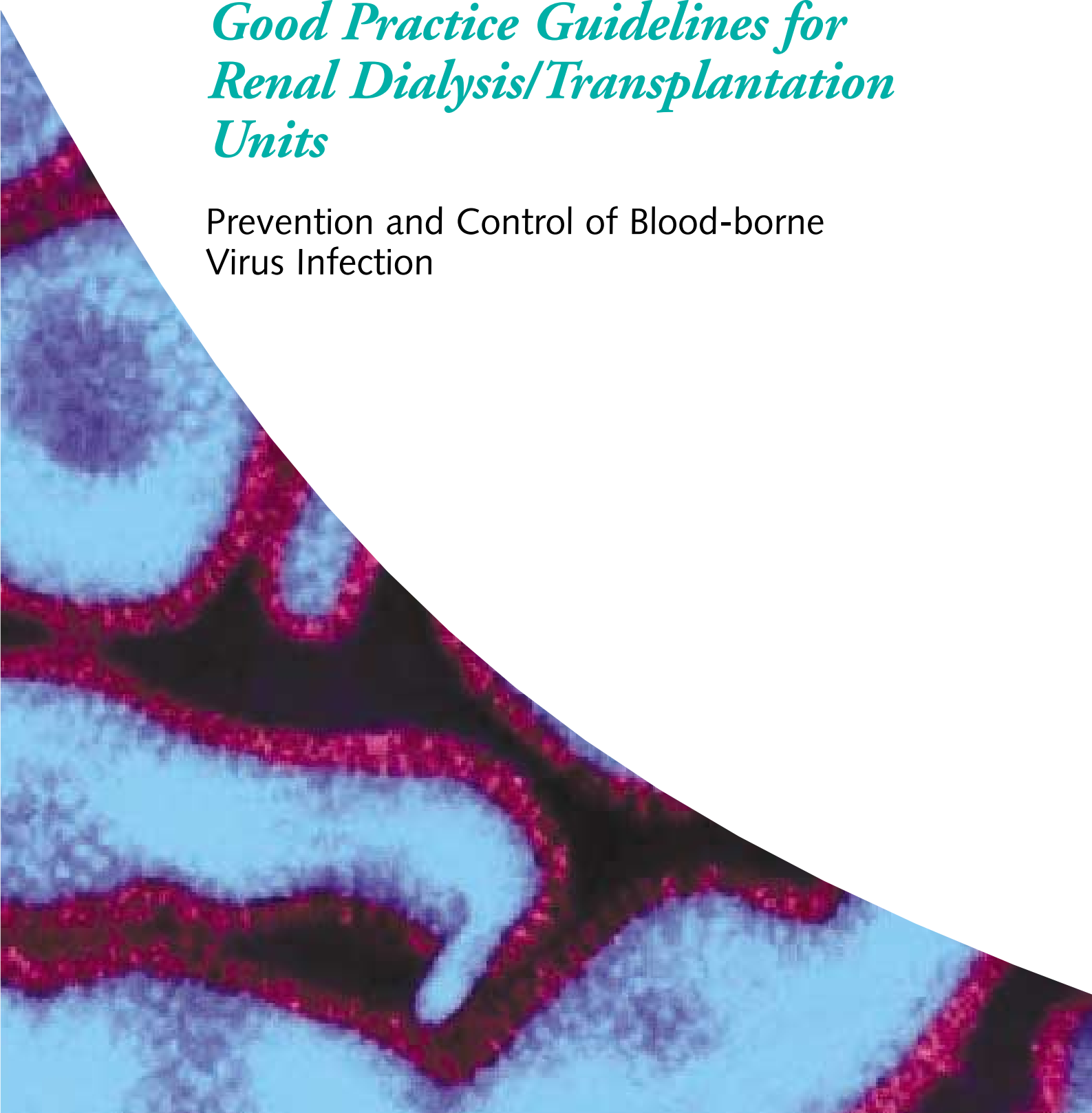
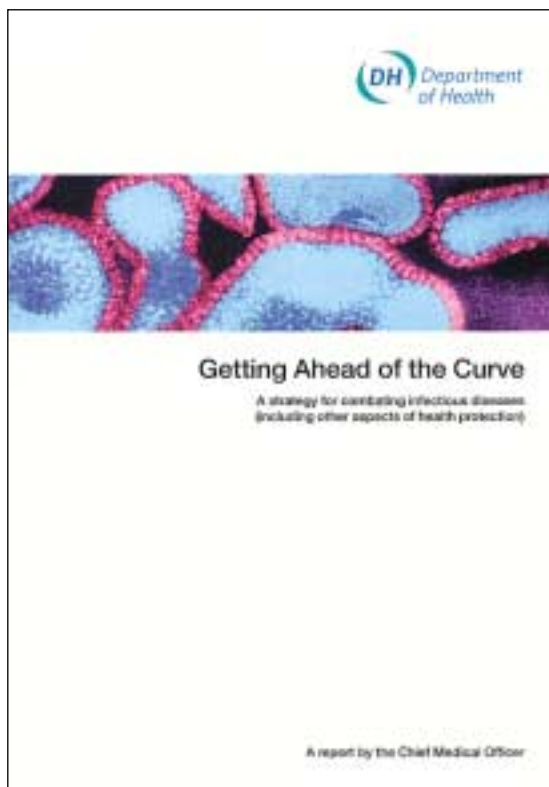


*Good Practice Guidelines for
Renal Dialysis/Transplantation
Units*

Prevention and Control of Blood-borne
Virus Infection



Implementing 'Getting Ahead of the Curve': action on blood-borne viruses



Good Practice Guidelines for Renal Dialysis/Transplantation Units

Prevention and Control of Blood-borne Virus Infection

Recommendations of a working group convened by the
Public Health Laboratory Service (PHLS) on behalf of the Department of Health

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Foreword

In 1972, the Rosenheim Advisory Group issued good practice guidelines to prevent the transmission of hepatitis B virus in renal dialysis and renal transplantation units. New blood-borne viruses, including hepatitis C and human immunodeficiency virus, have been identified since then, but additional guidance has not been issued. The Department of Health therefore asked the Public Health Laboratory Service (PHLS) to prepare good practice guidelines on the precautions that should be taken by renal units to prevent the transmission of blood-borne viruses generally. The PHLS set up a working group to review current practice and to prepare these guidelines. The working group was also able to take account of comments from the Advisory Group on Hepatitis, the Expert Advisory Group on AIDS, the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, and the Microbiology Advisory Committee. These guidelines and the forthcoming Renal National Service Framework will be crucial in driving up standards of care and providing a safe environment for patients and staff.

A handwritten signature in black ink, reading "Brian I Duerden". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Professor Brian I Duerden
Director of the Service
Public Health Laboratory Service
September 2002

Membership of the Public Health Laboratory Service (PHLS) working group

Members

Professor B I Duerden (Chairman)

Director of the Service, formerly Deputy Director of the Service and Medical Director, PHLS

Professor J E Banatvala

Formerly Professor and now Emeritus Professor of Clinical Virology, Guy's, St Thomas' and King's College School of Medicine, London, St Thomas's Hospital, London

Dr J Craske

Formerly Consultant Virologist, PHLS, Withington Hospital, Manchester

Ms S Falvey

Formerly Transplant Co-ordinator, Addenbrooke's Hospital, Cambridge

Dr M Farrington

Consultant Microbiologist, Clinical Microbiology and Public Health Laboratory, Addenbrooke's Hospital, Cambridge

Ms J Gill

Communicable Disease Nurse Specialist, Wigan and Bolton Health Authority and formerly Clinical Nurse Specialist, Nephrology, Cumberland Infirmary, Carlisle

Dr P E Gower

Consultant Physician, Charing Cross Hospital, London

Dr C C Harling

Consultant Occupational Physician, Bristol Royal Infirmary

Dr J Heptonstall

Formerly Consultant Microbiologist, PHLS Communicable Disease Surveillance Centre, Colindale

Dr P Mortimer

Consultant Virologist, PHLS Virus Reference Division, Central Public Health Laboratory, Colindale

Dr J Neuberger

Consultant Physician, The Queen Elizabeth Hospital, Birmingham

Mr T Ray

Laboratory Services Manager, United Kingdom Transplant Support Service Authority

Professor R S Tedder

Consultant Virologist, Royal Free and University College Medical School, London

Contributions to papers were made by Dr A Cockcroft, formerly Consultant in Occupational Medicine, The Royal Free Hospital, London. The analysis of the results of the survey of renal units was provided by Dr M Ramsay, Consultant Epidemiologist, PHLS Communicable Disease Surveillance Centre.

Economic Adviser

Mr R Anderson

Department of Health

Observer

Dr H Nicholas

Senior Medical Officer, Department of Health

Secretariat

Dr T Wreghitt (Scientific Secretary)

Honorary Consultant Virologist, Clinical Microbiology and Public Health Laboratory, Addenbrooke's Hospital, Cambridge

Mr J Canavan (Administrative Secretary)

Department of Health

Chapter 1

Executive summary

- 1.1 This guidance applies primarily to renal haemodialysis units. Aspects of this guidance will also apply to other units (e.g. wards in which haemodialysis is undertaken, including intensive therapy units). In such units, a risk assessment using this guidance should be carried out.

Main conclusions

- 1.2 Since the time of the Rosenheim Report (1972), the number of patients being treated in dialysis units has increased very substantially, and the range of known blood-borne virus (BBV) hazards has also increased with the identification of new viruses. Nevertheless, the risk of patients or staff acquiring BBV infection in dialysis units in the UK remains low. The basic precautions recommended by Rosenheim have been effective against hepatitis B (HBV), and probably against the other BBVs which are less efficiently transmitted in the hospital setting.
- 1.3 A survey of renal units in the UK in 1996 showed that units generally followed the Rosenheim recommendations for the prevention and control of HBV infection. However, many units were not immunising haemodialysis patients against HBV, contrary to current guidance. Practices for identifying and managing patients infected with hepatitis C (HCV) or human immunodeficiency virus (HIV) were more variable than for HBV. There is also evidence worldwide that lapses in high standards of infection control practice still occur, resulting in outbreaks of BBV infection in dialysis units.
- 1.4 The recommendations in these guidelines are largely precautionary and designed to maintain the good record of dialysis units in the UK in preventing the transmission of BBV infection. Strict observance of universal precautions should minimise the risk of BBV transmission in renal units, and units should aim to implement those precautions. This will require adequate space and staffing and vigilance by staff. Local risk assessment should be undertaken to determine the further measures that may be necessary. The leading recommendation for the management of patients who are infected with BBVs is for the continued isolation of patients with HBV, and for a simple rearrangement to segregate patients with HCV (and possibly HIV) during dialysis. A summary of the main recommendations follows.

Main recommendations

Clinical governance and audit (Chapter 5)

- 1.5 Regular clinical audit of the recommendations in these guidelines should form an integral part of good practice and of a renal unit's contribution to local clinical governance initiatives.

Immunisation of patients against HBV (Chapter 6)

- 1.6 Immunisation against HBV is recommended for patients on dialysis or in transplantation programmes. Patients with chronic renal failure should be immunised as soon as it is anticipated that they may require

dialysis or transplantation. Vaccine and, if appropriate, hepatitis B immunoglobulin should be given to susceptible patients who have been exposed to HBV.

Immunisation of staff against HBV (Chapter 6)

- 1.7 Staff in clinical contact with patients should be immunised against HBV. Non-responders should be given a further course of vaccine and poor responders an additional dose.

Immunisation of carers against HBV (Chapter 6)

- 1.8 Carers should be tested for hepatitis B surface antigen (HBsAg) and those who are negative should be offered immunisation against HBV. Non-responders and poor responders should be allowed to continue to help their relative or friend with dialysis. A carer who is infected with HBV should be advised of the risk of transmission and of the precautions necessary to prevent it.

Testing patients for BBV infections (Chapter 7)

- 1.9 Testing should be carried out to allow early detection of BBV infection in a unit and rapid intervention to prevent its spread. The patient's informed consent to testing should be obtained. Those who withhold consent should be managed in accordance with the local practice for patients infected with BBVs. Infected patients should not be denied dialysis.
- 1.10 Patients admitted or re-admitted to a unit should be tested for HBsAg, and HCV and HIV antibody, unless they have been tested in the month before admission. Additionally, patients who are HCV antibody negative and are immunosuppressed, have undergone a renal transplant, or are being admitted from a unit where there has been a recent HCV transmission, should be tested for HCV RNA. Dialysis units should ensure that they have arrangements for obtaining test results rapidly, before dialysis is carried out in the main unit. A segregation facility should be used if it is necessary to dialyse a patient before test results are available.
- 1.11 Re-admitted patients who have been dialysed outside the UK should be tested and found negative for HBsAg, HCV antibody and HCV RNA before being dialysed in the main unit. A risk assessment of potential BBV exposure overseas should also be carried out, and where exposure is considered likely, enhanced surveillance for one or more BBVs should be instituted. This should involve testing for HBsAg 2-weekly for 3 months and/or for HCV RNA 2-weekly for 3 months. A risk assessment for the likelihood of HIV infection should be conducted.
- 1.12 Patients who are being treated in dialysis units should be tested for HBsAg ideally monthly but at least every 3 months. All patients should be tested for HCV antibody every 3 months. HIV antibody testing should be based on a risk assessment.
- 1.13 When a previously unidentified case of HBV infection is found, units should carry out an HBsAg test on all patients who have shared a dialysis machine or a dialysis session with the infected patient since that patient's last negative test. Those patients who have not demonstrated an anti-HBs titre ≥ 100 mIU/ml in the preceding 12 months should be re-tested weekly for 3 months, and be given a booster dose of vaccine. Hepatitis B immunoglobulin (HBIG) should be considered for non-responders to hepatitis B vaccine (anti-HBs < 10 mIU/ml). If a case of HCV or HIV infection is found, a polymerase chain reaction (PCR) test should be carried out on those patients who may have been exposed to the infection during dialysis sessions (i.e. have shared a dialysis machine or dialysis session with the infected patient) and repeated at 2-weekly intervals for 3 months. Virological advice should be obtained about the need for further tests.

Routine precautions against BBV infection (Chapter 8)

- 1.14 Renal units should regularly conduct a rigorous local risk assessment and review of their infection control policies and practices to establish the extent of the additional precautionary measures necessary.
- 1.15 Staff should observe barrier precautions against exposure to blood and adhere strictly to infection control practices to prevent cross-infection between dialysis patients.
- 1.16 The staffing levels and environmental conditions in dialysis units should be sufficient to permit safe working practices.
- 1.17 Units should review the safety aspects of the environment at regular intervals and whenever a virus transmission has been recognised.

Avoidance of risk (Chapter 8)

- 1.18 Clinicians should consider home treatment for suitable patients as a means of reducing patient exposure to BBV hazards in the dialysis unit.

Action to be taken when BBV transmission occurs in a unit (Chapter 8)

- 1.19 When there is evidence that HBV, HCV or HIV transmission has occurred in a unit, the local infection control team should be notified, infected patients should be dialysed in a segregated area and enhanced virological surveillance should be undertaken. Prophylactic immunisation against HBV should be given where appropriate. An outbreak control team should be set up.

Relatives and friends who assist patients with dialysis treatment (Chapter 8)

- 1.20 Relatives and friends who assist patients with dialysis in a renal unit should be instructed in the precautions for preventing BBV cross-infection. When appropriate, units should supply these carers with protective clothing and equipment. Units should also ask them to report any incident in which they are exposed to blood or if they develop any symptoms of hepatitis.

Management of BBV infected patients (Chapter 9)

- 1.21 Patients infected with HBV should ideally be dialysed in separate isolation facilities. Where these are not currently available, patients should be segregated in a separate area from other patients during dialysis. Patients infected with HCV should also be segregated from uninfected patients during dialysis. Segregation of HIV infected patients should be considered, based on a local risk assessment. Because of the risk of cross infection, patients with different BBV infections should not be dialysed in a single segregated area at the same time. Staff caring for infected patients should adhere rigorously to infection control precautions.
- 1.22 Units will need to consider how to achieve the necessary degree of segregation required for each BBV taking account of the layout of their units and the number of infected patients to be treated. Full advantage should be taken of all isolation and separate treatment facilities (isolation rooms, bays, side wards or moveable partitions) and by suitable rostering of infected patients for treatment.

Nursing patients in segregated area (Chapter 9)

- 1.23 Whenever possible, staff should nurse only infected or uninfected patients during a shift. If this is not practicable, more experienced staff should be assigned the task of caring for a mixed group of patients. Designated staff should nurse affected patients when there has been an outbreak of BBV infection in a unit.

Use of dedicated dialysis machines (Chapter 9)

- 1.24 Separate machines should be used for patients infected with HBV. Dedicated machines are not required for patients with HCV or HIV provided that cleaning and disinfection processes are properly carried out between patients according to the manufacturers' instructions.

Transplantation units (Chapter 9)

- 1.25 Rigorous application of procedures to prevent the risk of blood contamination and transmission of infection is essential and local risk assessments should be carried out on transplantation units. Some of the segregated areas in transplantation units should have facilities for dialysis.

Equipment and prevention of BBV transmission (Chapter 10)

- 1.26 The blood tubing set supplied for use with dialysis machines is intended for single-use and should be disposed of in an approved manner after a single session on one patient. The filter on the venous pressure monitoring line of the tubing set should be replaced if there is evidence of contact with blood. The rupture of a filter is unlikely but if it occurs, machine components which might have been contaminated with blood should be replaced or decontaminated in accordance with the manufacturer's instructions. If replacement or decontamination cannot be done locally, the machine should be taken out of service and the manufacturer's help obtained.
- 1.27 The dialysis fluid circuit of the dialysis machine should be decontaminated between patients according to the method recommended by the manufacturer. External surfaces of machines should also be disinfected after the machine has been used by a BBV infected patient. Surfaces of all machines should be disinfected daily.
- 1.28 If a dialyser is supplied for "single-use only", or equivalent, it should be destroyed by incineration or other methods approved for disposal of clinical waste, after a single dialysis session on one patient. Dialysers should not be re-used unless specified by the dialyser manufacturer.

Occupational health (Chapter 11)

- 1.29 There should be a designated occupational health department with medical cover with responsibility for renal unit staff.
- 1.30 Staff with extensive epithelial deficiency such as eczema should not work on renal units when their skin lesions are active or if there are extensive breaks in the skin surface.

Testing of staff and staff fitness for work in dialysis units (Chapter 11)

- 1.31 Staff who have clinical contact with patients should demonstrate that they are immune to, or not infected with, HBV, or that if HBsAg positive, they are not HBeAg positive or HBeAg negative with a viral load (HBV DNA) exceeding 10^3 genome equivalents per ml.

- 1.32 Staff who have not demonstrated immunity to HBV should be tested annually for HBsAg.
- 1.33 Staff who know themselves to be infected with, or who may have been exposed to, HCV or HIV should seek occupational health advice.

Confidentiality for BBV infected staff (Chapter 11)

- 1.34 Staff found to be infected with BBVs are entitled to confidentiality: information about their status should only be given to those who need to know, and only with the infected staff member's consent. Staff should be made aware of arrangements for talking to an occupational health physician or other person in confidence if they are concerned that they might have a BBV infection.

Staff training and supervision (Chapter 11)

- 1.35 Staff in renal units should be made aware of the BBV hazards and should be given adequate training in safe working practices. New and inexperienced staff should be supervised until they are considered competent to practise safely on their own.

Blood exposure incidents (Chapter 11)

- 1.36 Renal units should have a comprehensive policy for the management of blood exposure incidents and their reporting to the occupational health or other designated department. Reports of such incidents should be monitored by the designated department for indications that procedures or equipment need to be modified.

Chapter 2

Introduction

- 2.1 This guidance is primarily for renal haemodialysis units. Aspects of this guidance will also apply to other units (e.g. wards in which haemodialysis is undertaken, including intensive therapy units), and a risk assessment using this guidance should be carried out.
- 2.2 Viral hepatitis was recognised as a hazard for dialysis patients and staff in the late 1960s and several deaths occurred during outbreaks of infection. Serum hepatitis, which is now referred to as hepatitis B, and is caused by hepatitis B virus (HBV), was responsible for these outbreaks.
- 2.3 In 1970, the Health Departments for England, Scotland and Wales set up an Advisory Group under the Chairmanship of Lord Rosenheim to review the problems of hepatitis in the light of knowledge at that time, and to make recommendations. In 1972, the Rosenheim Advisory Group issued a set of guidelines for the prevention and control of HBV in renal dialysis and transplantation units¹. These guidelines, which included basic barrier precautions against exposure to blood, regular screening of patients and staff for infection and the segregation of infected patients, have formed the basis for the safe practice of dialysis in this country.
- 2.4 While the Rosenheim Advisory Group provided guidance on the management of patients and staff with HBV infection in renal units, additional guidance was not issued when the hepatitis C virus (HCV), the human immunodeficiency virus (HIV) and other newly discovered blood-borne viruses (BBVs) were identified. Other changes have occurred, including the introduction of vaccine against HBV, increases in dialysis activity and changes in dialysis technology, which could have implications for the measures necessary to prevent and control infection with BBVs in renal units.
- 2.5 The principal developments in the management of patients in end-stage renal failure that have occurred since the Rosenheim Advisory Group reported in 1972 are:
- an increase in the number of dialysis centres and the number of patients treated;
 - the development of peritoneal dialysis and decline in home haemodialysis in the 1980s and 1990s;
 - an increase in the complexity of dialysis equipment and the introduction of disposable dialysers;
 - a widening gap between the number of patients with end-stage renal failure and the number (albeit increased) treated by transplantation.

Further information is given in Annex 1.

- 2.6 Most renal units in the UK are now accepting patients of all ages, with a variety of renal problems, at an annual rate of around 96 patients per million population. As the annual transplant rate is about 30 patients per million population, there is a cumulative growth of haemodialysis-dependent patients, many of whom are elderly and have either failed peritoneal dialysis or are unable to practice this form of treatment. There is, therefore, likely to be an increasing number of patients in haemodialysis centres or satellite units and their age and co-morbidity is increasing.

- 2.7 The Department of Health decided to review the Rosenheim recommendations in the light of current knowledge and developments in dialysis practice, with the aim of developing good practice guidelines covering all BBVs. The Department asked the Public Health Laboratory Service (PHLS) to establish a Working Group to review current practice with regard to the prevention and control of BBV infection in patients and staff in renal dialysis and renal transplantation units and to produce good practice guidelines for use in these facilities.
- 2.8 A postal survey of the 82 renal units in the UK was carried out in 1996 to establish current practice for the prevention and control of BBV infection. The 55 units that responded were providing services for 31,326 patients, including 5,327 patients on maintenance haemodialysis. Eighty one patients were known to be infected with HBV, 262 with HCV and 10 with HIV; of these, 28 patients with HBV, 115 with HCV and 5 with HIV were on maintenance haemodialysis. The survey showed that units generally followed the Rosenheim recommendations for the prevention and control of HBV infection. However, many units were not immunising haemodialysis patients against HBV, contrary to current guidance. Practices for identifying and managing patients infected with HCV or HIV were more variable than for HBV.

Chapter 3

Potential viral hazards in dialysis units

- 3.1 Viruses that may present an infection hazard in renal dialysis units are those that may be transmitted by blood transfusion, parenteral inoculation or contamination of broken skin. Viruses that present the greatest cross-infection hazard are those associated with a carrier state with persistent replication of the virus in the human host and persistent viraemia. The risk of transmission is directly related to the concentration of virus circulating in the blood of the source at the time of exposure. The viruses that may be involved, and which need to be considered in this guidance, include HBV, HCV, hepatitis D virus (HDV), HIV and human T-cell lymphotropic virus type I (HTLV I). Some other viruses such as Epstein–Barr virus and cytomegalovirus may be present in blood. However, infection with, and immunity to, them is widespread and they have not been shown to cause infection control problems in dialysis units.

Hepatitis B virus

- 3.2 HBV, which has often been associated with outbreaks of infection in dialysis units, is a DNA virus. During infection the outer coat protein of the virus (hepatitis B surface antigen or HBsAg) exists in excess, relative to the complete virus particle. Tests for HBsAg are used as the screening test for viraemia. Hepatitis B e-antigen (HBeAg) is a viral antigen which is associated with increased infectivity. A small number of individuals with HBV who are HBeAg negative may also have large quantities of HBV DNA in their blood and are also very infectious.
- 3.3 Vaccines containing recombinant HBsAg are available to provide protection against HBV infection. Although dialysis patients may respond poorly to HBV immunisation, about half of such patients develop antibodies to the surface antigen (anti-HBs). There is also evidence that most patients who have a poor anti-HBs response will not become chronic carriers of the virus². Hepatitis B immunoglobulin (HBIG) may provide passive protection after parenteral exposure to HBV infection, and is used in addition to vaccine to control outbreaks in dialysis units.
- 3.4 Symptoms of hepatitis occur in 30-50% of immunocompetent adult patients with acute HBV infection³, but infections in the immunosuppressed are largely asymptomatic. The incubation period in symptomatic infection is 40–180 days (mean about 80 days) but can be prolonged in immunosuppressed patients. The infection is associated with a prolonged viraemia, especially in immunocompromised and dialysis patients. Jaundice in the acute stage is almost invariably associated with complete resolution of infection within 6 months.
- 3.5 About 5% of immunocompetent adult patients who acquire HBV infection become carriers of the virus, with chronic replication in the liver and a persistent viraemia. The tendency to become a carrier is related to the patient's immune competence. Chronic renal failure (as well as other congenital and acquired defects in cell-mediated immunity) predisposes to the occurrence of asymptomatic infection and a chronic carrier state in those who are infected with HBV. Most patients on regular haemodialysis who have not been immunised become carriers if they are infected with HBV. Such patients are usually asymptomatic even in the acute stage of infection.

- 3.6 Dialysis in centres outside the UK can pose an increased risk of infection with BBVs (especially HBV and HCV).

HBV infection in dialysis units

Evidence of patient to patient transmission

- 3.7 Soon after the introduction of haemodialysis for the treatment of chronic renal failure, outbreaks of jaundice were reported in patients and staff⁴⁻⁹. Although most patients were not severely ill, a high proportion became chronically infected and deaths occurred in patients and staff from HBV infection acquired in association with haemodialysis treatment. It was soon established that HBV infection could be acquired from blood donations and that infected patients could transmit infection within a dialysis unit to other patients and staff. In Britain, between 1965 and 1971, there were 12 documented outbreaks of hepatitis in dialysis units. A total of 206 patients acquired hepatitis and 12 died; 120 staff acquired hepatitis and six died.
- 3.8 The implementation of the code of practice set out in the Rosenheim Report in 1972¹ dramatically reduced the incidence of HBV infections in UK dialysis unit patients and staff. Similar guidelines were issued by the Centers for Disease Control and Prevention (CDC) in the USA in 1977¹⁰ and a follow up study on the impact of these recommendations revealed a significant decline in HBsAg carriage in haemodialysis patients from 3% in 1976 to 0.5% in 1982¹¹. HBsAg carriage in staff fell from 2.6% to 0.5% over the same period¹¹. This prevalence had fallen further by 1989¹².
- 3.9 Outbreaks of HBV infection in dialysis units still occur^{2,13-19}. Examination of the causes of these outbreaks highlights weaknesses in infection control procedures. Alter *et al.*¹³ reported an outbreak in a dialysis unit in California in 1981. Ten of 61 patients susceptible to HBV acquired infection. All the infected patients were dialysed on the same days on the early morning shift. All used multiple-dose local anaesthetic, and the index case was an HBeAg-positive carrier who sustained a needlestick accident while drawing up local anaesthetic in the common preparation area. Other outbreaks have been associated with the use of multi-dose vials^{16,17}.
- 3.10 Roll *et al.*² reported an outbreak of HBV in four patients in a Swedish dialysis unit. All four patients were dialysed in the same room on the same shift and they had identical or closely related HBV DNA sequences in the complete S gene. An interesting feature of this outbreak was that none of these patients developed clinical hepatitis. Three of the patients had received hepatitis B vaccine. One patient, who had been regarded as a non-responder to the vaccine, briefly seroconverted to HBsAg positivity and then developed anti-HBc and anti-HBs. The two other immunised patients produced anti-HBs and anti-HBc, but HBsAg was never found. The one non-immunised patient developed chronic HBV infection, with persistent HBsAg and HBeAg carriage.
- 3.11 This study highlights the value of immunisation against HBV of dialysis patients in preventing or minimising HBV disease and reinforces the need to screen patients regularly for HBsAg, since many will be asymptomatic if infected with HBV. Since none of the patients in this outbreak was symptomatic, a testing protocol with intervals of more than 3 months would have failed to identify the outbreak at an early stage and prevented timely measures for outbreak control. This would have been particularly important in this unit which, because of staff shortages, allowed the same staff to work on HBsAg positive and negative haemodialysis patients.

Evidence of effective infection control

- 3.12 Strict infection control procedures have resulted in a dramatic reduction in HBV infection in dialysis patients. The use of hepatitis B vaccine for dialysis patients has also contributed to the decrease in

infections in dialysis units²⁰⁻²². Although the vaccine is recommended in the UK for all patients receiving dialysis or who are likely to need chronic dialysis in the future²³, many UK dialysis units do not yet routinely immunise all their patients²⁴.

- 3.13 The serological response rate to vaccine has been shown to be lower in haemodialysis patients than in staff²⁵, and the amount of anti-HBs produced by haemodialysis patients has been shown to be lower than in medical staff²⁶. Haemodialysis patients who mount a good response to vaccine appear unable to maintain high antibody levels. Fleming *et al.* showed that 57% of haemodialysis patients who mounted a good response had lost detectable anti-HBs within 6 months of immunisation²⁷.
- 3.14 Segregation of HBsAg positive patients and their equipment has been shown to decrease the incidence of HBV infection in dialysis units^{19,28}. However, even with this segregation, transmission of HBV can occur by the contamination of equipment, environmental surfaces and the hands of staff, if the same staff care for both groups of patients in the same shift^{14,29}. Although blood may not be visible on environmental surfaces or equipment, HBsAg may be present and it may be a source of HBV infection^{30,31}.
- 3.15 In a prospective study of Brazilian dialysis patients conducted between 1987 and 1990, Cenderoglo Neto *et al.* documented 0.19 HBV transmissions/haemodialysis patient/year and 0.01 transmission/continuous ambulatory peritoneal dialysis patient/year, despite the fact that HBsAg positive haemodialysis patients were treated in a unit separate from that for HBsAg negative patients³². Most patients were infected with the same subtype and some newly infected patients had never had a blood transfusion. Environmental transmission was the most likely cause of this outbreak. Brazil has a high prevalence of HBV infection in the community. The introduction of new cases and contamination caused by blood spillages during dialysis may have contributed to infection in this unit³³.

Conclusions about the risk of HBV transmission in dialysis units

- 3.16 Although the rate of transmission of HBV infection in dialysis units has fallen since the 1970s, incidents still occur even in developed countries. Use of multi-dose vials of drugs, failure to nurse HBV infected patients as a cohort and overworking of staff, with consequent lapses in infection control practices, have all contributed to HBV outbreaks. Increase in workload also increases the potential risk of transmission occurring.

Hepatitis C virus

- 3.17 Non-A, non-B hepatitis (NANBH) was first reported in 1974 by Prince *et al.*³⁴ as a significant cause of post-blood transfusion hepatitis. The most significant NANBH virus is HCV, an RNA virus first described by Choo *et al.* in 1989³⁵. The introduction of an enzyme-linked immunosorbent assay (ELISA) for detecting HCV antibody in 1989 enabled detailed work on HCV epidemiology and diagnosis to be conducted³⁶. Since then, several improved antibody assays and RNA detection methods have been developed which have been employed in studying HCV infections. HCV is genetically variable and at least six genotypes have been described based on overall difference in RNA nucleotide sequences. Different genotypes may be associated with different biological properties, in particular, the response to antiviral therapy.
- 3.18 Less than 20% of acute HCV infections produce symptoms of hepatitis in the patient. The period between exposure and the appearance of HCV antibody can be as long as 12 weeks. Infection with the virus produces a relatively weak and inconstant immune response in the host. Diagnosis relies on the detection of specific IgG antibody, which usually appears shortly after the onset of symptoms, where these occur. Detection of HCV RNA by polymerase chain reaction (PCR) may also be used to identify HCV infection. This is particularly useful in patients (including some haemodialysis patients) who sometimes fail to mount an adequate antibody response. Up to 80% of infections become chronic, with persistence of virus in the liver, and chronic viraemia.

- 3.19 Although many aspects of the natural history of HCV remain unknown, it seems that up to 20% of chronic carriers will develop cirrhosis 15-20 years after their initial infection. Some of these patients may subsequently develop hepatocellular carcinoma. HCV infection is also associated with autoimmune hepatitis, mixed cryoglobulinaemia, and chronic glomerulonephritis in a small proportion of infected patients. In a few patients chronic HCV infection appears to resolve, but others remain asymptomatic carriers for years with no histological evidence of significant liver disease. Immune deficiency increases the titre of virus in the blood and shortens the natural history of chronic infection, with more rapid progression to cirrhosis. The largest reservoir of infection in the UK is in injecting drug users (30-80% HCV antibody prevalence). Recipients of transfused blood may have been infected in the past, but new infections have been virtually eliminated by screening of donors.
- 3.20 Sexual transmission of HCV infection is relatively inefficient. Perinatal transmission is also uncommon, with a risk of around 5%. However, this risk increases when the patient is co-infected with HIV and is related to the level of HCV viraemia. In some patients, HCV may be cleared by treatment. This should be considered for all patients, especially if they are being considered for transplantation. There is no vaccine or passive prophylaxis to protect against hepatitis C infection, but recent evidence suggests that treatment during the acute phase of the illness may prevent chronic infection (see paragraph 11.4).

HCV infection in dialysis units

- 3.21 The prevalence of HCV infection in dialysis patients varies throughout the world, with reported prevalence rates ranging from 3.9% in Glasgow³⁷ to 71% in Kuwait³⁸. The UK prevalence is similar to that in most countries in northern Europe, but infection is more common in France, Italy, Spain, Portugal and Greece. Worldwide, the highest prevalence rates are in the Middle and Far East. HCV seroconversion rates among dialysis patients varied from 1%³⁹ to 16%⁴⁰ per year. Several studies have demonstrated a lower HCV prevalence in patients receiving peritoneal dialysis^{41,42}.
- 3.22 Two factors are consistently reported to be associated with increased prevalence of HCV infection in dialysis patients – the number of blood transfusions received⁴³⁻⁴⁵ and the length of time on dialysis⁴⁶⁻⁴⁸. These two factors are often co-variable, since patients who have been on dialysis treatment longest are likely to have received the most blood transfusions, but this is not always the case. Reports from Poland⁴³, Saudi Arabia⁴⁴ and Hong Kong⁴⁵, suggested that receiving more than five units of blood was a significant risk for being HCV infected, but these are locations where there is a high prevalence of HCV infection and not all blood had been screened for HCV antibody. In several studies, the number of blood transfusions received did not correlate with HCV positivity in the dialysis unit⁴⁶⁻⁴⁸. In all of the reports of HCV infections in dialysis units, length of time on dialysis was associated with HCV infection.

Evidence of patient to patient transmission

- 3.23 Several reports provide evidence of patient to patient transmission of HCV in dialysis units^{40,46,49-52}. Allander *et al.* used genotypic analysis to show that five patients had been infected with the same HCV strain and two other patients were infected with another HCV strain⁵¹. Transmission was not related to blood transfusions and patients infected with similar strains had not shared dialysis machines. However, patients infected with similar strains had been dialysed on the same shift, thus implicating nosocomial spread by patient to patient transfer. There was a low prevalence of HCV infection among staff in this unit. In another study of patients on a haematology ward, Allander *et al.* found five clusters of patients infected with identical or closely related viruses, involving 2, 3, 4, 6 and 15 patients respectively⁵³. Transmission from patient to patient seemed likely as all patients in each cluster had been treated in the ward during overlapping periods.

- 3.24 Corcoran *et al.* presented evidence of intra-unit transmission of HCV⁴⁶. Genotypic analysis showed that five patients were infected with genotype 1 and a further two were infected with genotype 4, which is extremely uncommon in Western Europe. In a prospective study of HCV infections in a dialysis unit in Belgium, Jadoul *et al.* documented a 1.7% annual seroconversion rate⁴⁹. All three patients who seroconverted for anti-HCV during the study period were dialysed next to HCV infected patients. Seroconversion was not associated with re-use of dialysers. Neves *et al.* reported that 8 of 27 HCV antibody-negative patients dialysed in Portugal between 1991 and 1992 seroconverted for anti-HCV⁵⁰. Sharing the same dialysis machine with an HCV infected patient was not found to be a risk factor for the acquisition of HCV, but being dialysed next to an HCV infected patient was a significant risk factor. More recently, Furusyo *et al.* have shown an annual incidence of newly acquired HCV infection of 2.6% in a Japanese haemodialysis unit where HCV infected patients were not segregated from non-infected patients⁵⁴.

Evidence of effective infection control

- 3.25 In some dialysis units, particularly in those with a higher prevalence of HCV infected patients, attempts have been made to reduce the risk of transmission by dialysing patients in a separate room or area. Arici *et al.* established a programme to prevent HCV transmission in a dialysis unit in Italy⁵⁵. In 1986, following an outbreak of NANBH in their dialysis unit, patients with suspected infection were dialysed in a separate section of the unit. Following this change in policy, there was a significant reduction in NANBH transmission. Vagelli *et al.* reported similar success in preventing the steady increase in HCV prevalence among haemodialysis patients (from 23% to 72% over 18 months) by dialysing infected patients in an isolation section. No new infections were detected in the 18 months after the isolation procedure was introduced⁵⁶.
- 3.26 Some dialysis units have used separate machines for HCV infected patients in an attempt to reduce transmission within the unit. Calabrese *et al.* showed that a striking reduction in the incidence of infection followed the dialysis of HCV infected patients in a dedicated area⁵⁷. Blumberg *et al.* reported similar results when they cohorted HCV infected patients into a dedicated area of their dialysis unit⁵⁸. The dialysis machines in this area were used only on the infected patients. Although there is no convincing evidence that dialysis machines have been implicated in the transmission of HCV in dialysis units when machines and dialysis stations are properly decontaminated, a recent report documented transmission of HCV to seven patients who were dialysed on a machine immediately after an HCV positive patient⁵⁹. Numerous instances of blood contamination of the machines and other environmental surfaces were identified. However there is evidence that cohorting infected patients reduces transmission.

Conclusions about the risk of HCV transmission in dialysis units

- 3.27 There are sufficient well conducted studies to show that HCV can be transmitted to haemodialysis patients by nosocomial transmission in dialysis units. Several studies have shown that patients dialysed in the treatment station next to an HCV infected patient may acquire infection. In order to minimise this infection risk, scrupulous attention should be paid to hygiene and the decontamination of equipment and surfaces. The staffing levels and space between patients should be sufficient to allow observation of good infection control practices, especially hand hygiene. There is evidence that dialysing HCV infected patients in a separate room or area in a dialysis unit reduces the risk of transmission to other patients. Patients on continuous ambulatory peritoneal dialysis are at lower risk of acquiring HCV infection.

Hepatitis D virus

- 3.28 HDV is a defective RNA virus and causes infection only in those who have active HBV infection. HDV is transmitted by parenteral inoculation and transfusion. Infection can occur either as co-infection with HBV or superinfection of an HBV carrier. Since HDV depends on an HBV infected host for replication, prevention of HBV infection by immunisation will also prevent HDV infection. The prevalence of

HDV infection in Europe has declined⁶⁰; its prevalence in the UK population and its role in outbreaks of hepatitis in renal units are at present unknown.

Human immunodeficiency virus

- 3.29 HIV is the virus associated with AIDS. The virus is transmitted by transfusion, parenterally, perinatally and by sexual intercourse. Infected patients have a persistent viraemia throughout the course of the infection. Antibodies to HIV usually become detectable 1 to 3 months after infection. Approximately 10% of acutely infected patients develop a glandular fever like illness and up to 50% have more minor acute illness. There is no effective vaccine or passive immune prophylaxis. However, post-exposure prophylaxis (PEP) with combination antiviral therapy is available (see paragraph 11.4).
- 3.30 In the mid 1980s, an HIV infected health care worker, identified retrospectively, was shown to have managed dialysis machines for periods of up to 3 years with no transmission of infection to patients⁶¹.

HIV infection in dialysis units

- 3.31 The worldwide prevalence of HIV infection in dialysis units varies from 0% to 39% in some inner city areas^{62,63}. Despite this, there have been only a few reports of transmission of HIV in dialysis units⁶⁴. Nine (39%) of 23 susceptible haemodialysis patients in a Colombian dialysis centre seroconverted for HIV between January 1992 and December 1993⁶⁵. These patients acquired HIV infection shortly after a new patient who was HIV positive was dialysed in the unit. Dialysers used in the unit were reprocessed separately with 5% formaldehyde. Infection is thought to have been transmitted by reprocessed wide-bore haemodialysis access needles. Four pairs of needles were placed in one pan and disinfected with benzalkonium chloride before being re-used. This created the possibility of cross-contamination and use of the needles of one patient on another, but inadequate disinfection could also have been a factor.
- 3.32 Other than the incidents above, studies of HIV infection in dialysis patients have failed to show transmission of the virus⁶⁶⁻⁷⁷. A study of HIV antibody prevalence in Italian dialysis centres in 1991 revealed that 0.22% of patients were infected with HIV⁷⁸. Infection did not correlate with longer time spent on haemodialysis. To date, HIV transmission caused by the sharing of dialysis machines has not been reported, but it must remain a potential risk.
- 3.33 HIV status is important for those patients being considered for renal transplantation, which may be contraindicated in HIV infected patients⁷⁹. HIV-associated nephropathy has characteristic clinical and pathological features and causes irreversible renal failure⁸⁰. The prevalence of HIV-related renal failure in HIV infected patients varies from 1 to 5.7% and is common in non-white injecting drug users^{80,81}. However, the availability of more effective anti-HIV drugs and drug combinations have improved the survival of HIV infected patients.

Human T-cell lymphotropic virus type I

- 3.34 Human T-cell lymphotropic virus type I (HTLV I) causes a persistent infection with a chronic viraemia. The virus is found almost exclusively in peripheral blood leucocytes (T-cells). It causes a rare but aggressive human T-cell leukaemia/lymphoma after many years. Less frequently, it may cause spastic paraparesis some years after infection. Transfusion transmissions are well described in Japan and other countries, and are associated with fresh blood transfusions. HTLV I prevalence in the UK is low (studies in blood donors report rates of approximately 1 in 20,000 in North London and 1 in 80,000 in Yorkshire) and it is not considered a sufficient hazard in renal dialysis units in the UK to warrant screening of patients. There have been no reports of HTLV I transmission in dialysis units.

Risk of blood-borne virus (BBV) transmission

- 3.35 The risk of transmission of BBV infection is directly related to the concentration of the virus in the blood of the source patient at the time of exposure.
- 3.36 The high level of virus found in patients during acute HBV infection and in the HBeAg carrier state is such that very small volumes of blood can transmit infection and there is considerable potential for transmission via environmental contamination.
- 3.37 Concentrations of virus in patients with acute HCV infection are transiently high but are not sustained and are then lower than for HBV. HCV is therefore less infectious in the hospital setting. For the same reason, transmission rates in households are low. Concurrent immunosuppression may increase viral replication and enhance infectivity and this may be relevant to dialysis patients.
- 3.38 HIV also appears to be less infectious than HBV in the hospital setting and in households. High concentrations of virus are found in the blood during acute infection and late-stage disease when patients may be more infectious. The present lack of evidence of HIV transmission in renal units should not be interpreted as absence of risk.
- 3.39 The risk of transmission of a BBV to a health care worker from an infected patient following a single open-bore needlestick injury has been shown to be around 20-30% for HBV where the inoculation source is HBeAg positive; approximately 3% for HCV from an anti-HCV positive source; and approximately 0.3% for HIV from an anti-HIV positive source.
- 3.40 Subsequent chapters of this document deal with strategies for identifying and reducing the risk of BBV infection in dialysis units.

Chapter 4

Survey of practice in UK dialysis units

4.1 In order to survey practice in UK renal dialysis units, a questionnaire was distributed in December 1995 to the 82 renal units in the UK and 55 units returned completed questionnaires. A full analysis of the results is set out in Annex 2 and the main findings are summarised in the following paragraphs.

Numbers of patients and cases of BBV infection

4.2 The 55 units that responded to the survey were, on 1 December 1995, providing services for 31,326 patients, including 5,327 patients on maintenance haemodialysis (Annex 2, Table 1). The number of patients on maintenance haemodialysis in each unit varied considerably, with a median of 80 (interquartile range 48 to 128). In total, 81 patients were known to be infected with HBV, 262 with HCV and 10 with HIV; the patients on maintenance dialysis included 28 with HBV, 115 with HCV and 5 with HIV (Annex 2, Table 6). Six cases of HCV were thought to have been acquired in UK renal units; the other infections were acquired elsewhere, or the source was unknown.

Immunisation of patients against HBV

4.3 HBV immunisation policy for patients varied between units, with 49% of the units not offering vaccine to any patient group (Annex 2, Table 8). This was contrary to national guidance²³ and the precise reason for the failure to follow this policy was unclear. However, doubts about the efficacy of immunisation in dialysis patients may be a factor.

Testing patients for BBV infection

4.4 The survey showed that 96% of renal units were screening patients for HBV markers before commencing dialysis and regularly during maintenance haemodialysis. Fewer units screened for HIV and HCV and, where they did, intervals between screening were generally longer than for HBV (Annex 2, Table 5 and Figure 1). In the UK, where the prevalence of HIV in the general population is low, the number of known HIV infections on renal units is small and confined to hospitals in the Thames regions. HIV screening was performed in only 40% of the units. In the survey, the commonest blood-borne infection reported from renal units was HCV. Although policy on HCV screening was not universal, some 80% of units did screen for anti-HCV before commencing haemodialysis and at intervals while the patient remained on dialysis.

Management of infected patients

4.5 The management of known HBsAg positive patients was relatively consistent between units and common policies included the designation of machines (for use either by an individual or by all patients with HBV infection) and dialysis of infected patients in a separate room or area. In contrast, although

most units would designate a single machine for use by HBV infected patients, working practices for HIV or HCV infected patients were less consistent.

- 4.6 The low prevalence of HCV infection shown by the survey was consistent with previous studies in the UK^{82,83}. However, the reported acquisition of HCV from haemodialysis in UK renal units suggests that a more effective control policy is required. As the prevalence of HCV infection is higher than that of HBV infection, dialysis of HCV infected patients in single rooms may not always be feasible. Some units were already dialysing HCV infected patients in a separate area and with designated staff (Annex 2, Table 7). A widening of this policy would require both adequate floor space and sufficient numbers of trained staff within units.
- 4.7 The provision of adequate space for staff to perform their duties around each patient being dialysed is essential to good clinical practice. In the survey the median estimated floor space available per patient was 8.7m² in the main units and was similar in satellite units. From the survey results it is unclear how easily areas for segregating patients with BBV infection could be provided. However, the median floor space per patient in those units which dialysed BBV positive patients in a separate area was similar to that in units without this policy. Staffing levels in main units were estimated to be a median of 0.5 staff per patient, of which 0.32 carers per patient were trained nurses. Staffing levels in satellite units were lower, with an estimated median of 0.38 staff per patient, of which 0.33 were trained. The staffing ratios in those units which designated nurses for HCV infected patients were similar to that in units without such a policy.
- 4.8 In contrast to staffing and accommodation arrangements, procedures and practices with equipment were found to be more uniform. Many units had policies of designating machines for use by infected patients (Annex 2, Table 7). Methods of decontamination should follow manufacturers' instructions and most units (78%) decontaminated machines after each use. Single-use of dialysers was found to be routine practice in nearly all units (89%) and only one unit re-used dialysers (after appropriate disinfection) on patients with BBV infections.

Immunisation and testing of staff

- 4.9 The policy of immunising staff against HBV was followed and coverage of renal unit staff was generally high (Annex 2, Table 9). Most units (85%) screened new staff for HBsAg but fewer (65%) were screening at regular intervals in the absence of a needlestick injury. Screening of staff for HCV and HIV was performed in some units after a needlestick injury, but, otherwise, screening for HCV and HIV markers was uncommon (Annex 2, Table 10).
- 4.10 The results from this survey confirmed the need for revised guidance to harmonise practice in UK renal haemodialysis units.

Chapter 5

Health and safety requirements and principles of clinical governance

Responsibilities under health and safety law

- 5.1 The Health and Safety at Work etc. Act 1974 places duties on employers to ensure, so far as is reasonably practicable, that they do not expose their employees to risks to their health and safety whilst they are at work. Employers also have a duty to carry out their undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in their employment (for example, members of the public, patients and contractors) are not exposed to risks to their health and safety.
- 5.2 Furthermore, the Control of Substances Hazardous to Health (COSHH) Regulations⁸⁴ require employers to assess both the risks to the health of employees and other persons from work with substances hazardous to health, including biological agents. Any such risks should then be prevented or, where this is not reasonably practicable, adequately controlled.
- 5.3 Ultimate responsibility for health and safety lies with the Chief Executive of each NHS Trust who must ensure that all parts of the organisation have a suitable health and safety policy and that its implementation is monitored regularly to ensure its effectiveness.
- 5.4 Renal units should take account of the guidance in this document when preparing their own detailed local guidelines for the prevention and control of BBVs. These local guidelines should be prepared in collaboration with the hospital infection control team, and implementation should be monitored regularly.

Clinical governance and audit

- 5.5 Regular clinical audit of recommendations in this document should be integral to good practice, comprising part of a renal unit's contribution to local clinical governance initiatives. This is additional and complementary to the provision of data to national initiatives such as the UK Renal Registry, which is organised through the Renal Association and held at Bristol (www.renalreg.com).
- 5.6 National summary data relevant to the prevention and control of BBVs in renal units are available from the Registry and these include types of dialysis in use, numbers of new patients starting dialysis, numbers of satellite units, staffing, factors restricting necessary developments, and the prevalence of hepatitis B and C. These data, and others to be added in the future, may be useful as norms against which to measure local performance.
- 5.7 The Renal Association's Renal Standards Document (www.renal.org) also discusses the data requirements for audit in renal units and the call for improved data collection is supported, especially relating to the prevalence and control of BBVs.
- 5.8 Clinical audits in this area may be appropriately performed at the local or regional level, and they may involve renal unit staff alone or be performed in collaboration with others, notably local Infection Control Teams and departments of microbiology and virology. Audit may be performed of structure, process and outcome issues; most audits relevant to these guidelines will be of structure or process.

- 5.9 The following areas are offered as a guide to suitable audit measures that may be useful to local units. The list is not intended to be prescriptive or comprehensive. Some of the simpler measures may usefully be included within routine good nursing practice checklists or could be included as part of a more comprehensive clinical audit project.
- 5.10 A number of these standards (indicated by *) could conveniently be included in a local Infection Control Team's regular external audit of a renal unit's infection control performance.
- Presence of a copy of this document on the renal unit; staff knowledge of its location.*
 - Staff knowledge of local policies for action in the case of exposure to BBVs, and the use of post-exposure prophylaxis (PEP) etc.*
 - Compliance of local renal unit clinical care policy with all recommendations in these guidelines.
 - Observation of care practices by Infection Control Team during audit visit, preferably unannounced: – isolation and segregation of appropriate patients, hand washing, use of appropriate protective clothing, disposal of waste and sharps, presence and use of appropriate cleaning and disinfection agents, cleaning and disinfection of machines at the end of treatment sessions.*
 - Collation of critical incident and 'near miss' reports; evidence of action being taken as a result (increasingly, this area is becoming part of hospitals' critical incident and clinical risk management procedures).
 - Evidence of recommended routine screening and immunisation of patients on dialysis.
 - Evidence of recommended screening of patients before they are admitted to the main part of the unit.
 - Evidence of recommended screening and isolation/segregation of patients returning from 'holiday' dialysis.
 - Evidence of healthcare workers being screened appropriately for BBVs (bearing in mind the need for appropriate confidentiality).
 - Timeliness of receipt of laboratory results.
 - Evidence of appropriate liaison with the Infection Control Team over local policy issues, exposure incidents etc.*

General principles for safe practice

- 5.11 Since the Rosenheim Advisory Group made its recommendations for the prevention and control of HBV infection, awareness of hazards to patients and staff in dialysis units has increased with the identification of new BBVs. However, the precautions designed to prevent the spread of the efficiently transmitted HBV would also prevent the transmission of other, less easily transmitted BBVs. Many of the precautions mentioned in these guidelines were recommended by the Rosenheim Advisory Group and have been practised by staff in renal units for many years.
- 5.12 Nevertheless, 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. This is reflected in this guidance, although it is recognised that some

differences in approach based upon differences in risk of transmission are necessary. In outline, the recommended measures are:

- immunisation of dialysis patients (and relatives who assist them) and staff against HBV;
- testing to monitor potential sources of BBV infection in a unit;
- routine cross-infection precautions;
- measures to reduce patient exposure to the BBV hazards in dialysis units;
- consideration of isolation, segregation and other measures for managing known HBV, HCV and HIV infected patients.

Chapter 6

Immunisation against hepatitis B

- 6.1 Patients with renal failure potentially remain at increased risk of HBV infection because of their need for long-term haemodialysis. Due to impaired cellular and humoral immune responses, HBV infection in haemodialysis patients may frequently be sub-clinical, and such patients are also more likely to become chronic carriers of the virus. Prevention of HBV in haemodialysis patients is therefore highly desirable.
- 6.2 The response rate to hepatitis B vaccine among patients with renal failure is less than among healthy adults. Studies have shown that 45-66% of patients with renal failure develop an anti-HBs response with conventional doses of vaccine and, compared with immunocompetent individuals, levels of anti-HBs may decline more rapidly. However, increased response rates of 75-85% have been reported when 40 µg doses of vaccine have been used.
- 6.3 Guidance on the administration, dosage and immunisation schedules of hepatitis B vaccine is given in the UK Health Departments' publication *'Immunisation against Infectious Disease'*²³.
- 6.4 Antibody responses to hepatitis B vaccine vary widely between individuals. The preferred outcome is to achieve anti-HBs levels above 100 mIU/ml. Some anti-HBs assays may not be specific at lower levels, and levels above 100 mIU/ml provide greater confidence that a true response has been obtained. Antibody responses should be checked 1-4 months after a course of vaccine has been completed in patients and health care workers on renal dialysis units.
- 6.5 An antibody level below 10 mIU/ml is classified as a non-response. Responders with anti-HBs between 10-100 mIU/ml measured 1-4 months after the completed course should receive a booster dose of vaccine, and in non-responders a repeat course of vaccine should be considered. Those with anti-HBs levels below 10 mIU/ml 1-4 months after the completion of the primary course of immunisation will require hepatitis B immunoglobulin (HBIG) for protection if exposed to infection.

Immunisation of patients with chronic renal failure

- 6.6 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 a 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.

Immunisation of staff

- 6.7 The COSHH Regulations⁸⁴ require that, where appropriate, effective vaccines should be made available to those employees who are not already immune to the biological agent to which they are or are liable to be exposed. Immunisation against HBV should therefore be made available to all health care workers, including students, trainees and staff working in laboratories attached to renal units, who have direct contact with patients' blood or blood-stained body fluids or with patients' tissues.

- 6.8 Staff working on renal units in clinical contact with patients or their treatment environment should also be screened for HBsAg and found negative before working with patients. Further required testing of those found to be positive, and the appropriate management of such individuals, is dealt with in Chapter 11. Non-responders and poor responders to hepatitis B vaccine who are HBsAg negative need not be restricted from employment in renal units, but non-responders (i.e. those with anti-HBs levels of less than 10 mIU/ml) should be tested annually for HBsAg.

Immunisation of carers

- 6.9 Immunisation is also recommended for carers of patients with chronic renal failure, particularly those involved with the dialysis process. Additionally, carers should be offered testing for HBsAg. Any carer found to be infected with HBV should be advised of the potential risks of transmission and of the precautions that should be taken to prevent it, but should be allowed to continue to help the individual patient with dialysis.

Post-exposure prophylaxis

- 6.10 Post-exposure prophylaxis with hepatitis B vaccine and/or hepatitis B immunoglobulin (HBIG) as appropriate should be considered for patients, staff and carers exposed to HBV infected blood or blood-stained body fluids. After performing a risk assessment, staff and carers who have previously responded to vaccine, and patients with anti-HBs levels above 10 mIU/ml should be offered a booster dose of vaccine. Those who have failed to respond to immunisation (i.e. have never had anti-HBs levels of 10 mIU/ml or above) should be given HBIG. Patients whose anti-HBs levels have fallen to below 10 mIU/ml should be given HBIG and a dose of vaccine. For maximum effectiveness, HBIG should be given within 48 hours of exposure to HBV infected blood; if an anti-HBs level is not known or cannot be determined within that time frame, HBIG should be given. Where immunisation has not taken place, HBIG should be given and an accelerated course of hepatitis B vaccine commenced.

Booster doses of vaccine

- 6.11 The duration of protection afforded following immunisation with recombinant hepatitis B vaccines remains unclear. There is increasing evidence in immunocompetent individuals of persisting immunological memory for 10-15 years or more in successfully immunised individuals, even after anti-HBs levels have fallen or are undetectable. However, the limits of this immunological memory are unknown. Current advice on the routine use of booster doses is to be found in *Immunisation against Infectious Disease*²³.
- 6.12 Booster doses of vaccine are recommended for immunised individuals following direct exposure to HBsAg positive blood, unless they have received a booster within the preceding 12 months.
- 6.13 The role of immunological memory in patients with chronic renal failure on renal dialysis does not appear to have been studied and protection may persist only as long as anti-HBs levels remain above 10 mIU/ml. Anti-HBs levels should therefore be monitored annually and a booster dose of vaccine given if antibody levels fall below 10 mIU/ml.
- 6.14 Booster doses of vaccine should also be considered for patients intending to visit countries with a high endemicity of hepatitis B, particularly if they are to receive haemodialysis, and have not received a booster in the last 12 months.

Chapter 7

Testing patients for BBV infection

- 7.1 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. The hazard which BBVs present in renal units has been well known since the time of the Rosenheim Report. With the same patients attending the unit several times a week, infection might spread to a number of patients before it is detected, unless there is a system of testing in place. Apart from the harm to the patients, such outbreaks cause considerable operational difficulties for units and have significant cost consequences. Regular testing will allow rapid detection of new infections and intervention to prevent their spreading to other patients. Such testing will also provide reassurance for patients and will help maintain staff awareness of the potential risks.

Consent, counselling and confidentiality

- 7.2 The reasons for testing should be explained to patients and their informed consent must be obtained before it is carried out. Any patient who withholds consent should be managed as though they are BBV infected. Patients who are known to be infected with a BBV should be counselled about the significance for their health (and that of their sexual partners and close household contacts) and their treatment, and should also be referred for assessment of disease and clinical management. Infected patients should not be denied dialysis treatment because of their virological status. Patients are entitled to confidentiality and information on test results should be limited to the staff who need to know for the purpose of treating the patient or preventing the spread of infection. Department of Health guidance about consent, pre-test discussion and confidentiality in relation to HIV testing is given in *Guidelines for pre-test discussion on HIV testing*⁸⁵.

Testing patients on first admission

- 7.3 Patients should be tested for HBsAg, and HCV and HIV antibody immediately before they are dialysed in a unit, unless they have been tested in the month before admission. Additionally, patients who are HCV antibody negative and are immunosuppressed, have undergone a renal transplant, or are being admitted from a unit where there has been a recent HCV transmission should be tested for HCV RNA. Annex 3 gives detailed information about the tests currently available for detecting BBV infections. Dialysis units should ensure that arrangements are in place to obtain test results rapidly so that the patient's status can be known before dialysis is carried out in the main unit. When there is an exceptional need to dialyse a patient before test results are available, dialysis should be carried out in a segregation facility.
- 7.4 Peritoneal dialysis patients or kidney transplant recipients returning to haemodialysis treatment should be tested for HBsAg and HCV antibody unless they have been tested in the month before re-admission. As an antibody test result may not be reliable in immunosuppressed patients, transplant patients who are found to be HCV antibody negative should also be tested for HCV RNA before being dialysed in the main unit. A decision on whether testing for antibodies to HIV is needed should be based upon a risk assessment.

Testing patients on re-admission to a dialysis unit

- 7.5 Patients should be tested for HBsAg and HCV antibody (and HCV RNA if they are HCV antibody negative and immunosuppressed, have undergone a renal transplant, or are being admitted from a unit where there has been a recent HCV transmission). A risk assessment for the likelihood of HIV infection should be carried out, and HIV antibody testing undertaken if indicated.
- 7.6 Patients re-admitted to a unit after dialysis elsewhere in the UK should be asked for a copy of any laboratory reports from the other unit confirming their BBV status. The exporting unit should provide the test results directly to the importing unit.

Holiday dialysis

- 7.7 There is an increased risk of the acquisition of BBV infection associated with dialysis abroad. Units should advise patients who will be dialysed while outside the UK about the risk of BBV infection.
- 7.8 Before travel, patients should be tested for HBsAg, HCV antibody and HIV antibody, as recent results may be required by some (overseas) renal units before they will accept patients for holiday dialysis.
- 7.9 Re-admitted patients who have been dialysed outside the UK should be tested and found negative for HBsAg, HCV antibody and HCV RNA before being dialysed in the main unit. A risk assessment of potential BBV exposure overseas should also be carried out, and where possible exposure is considered likely, enhanced surveillance for one or more BBVs should be instituted. This should involve testing for HBsAg every 2 weeks for 3 months (although units may elect to defer this testing in patients with high levels of anti-HBs (> 100 mIU/ml) at the time of return to the UK) and/or for HCV RNA every 2 weeks for 3 months.
- 7.10 On return from dialysis abroad, a risk assessment of the likelihood of HIV infection should be conducted, and HIV testing carried out if indicated.

Regular testing for infection

- 7.11 Patients who are being treated in dialysis units should be tested for HBsAg ideally monthly, but at least every 3 months. All patients should be tested for HCV antibody every 3 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).
- 7.12 Whatever frequency of testing patients is adopted, monthly archived serum specimens have proved invaluable for retrospective testing when new cases of BBV are detected on a unit, or in the investigation of outbreaks.

Outbreak of infection

- 7.13 When a previously unidentified case of HBV infection is found, units should carry out an HBsAg test on all patients who have shared a dialysis machine or dialysis session with the infected patient since that patient's last negative test. Those patients who have not demonstrated an anti-HBs titre ≥ 100 mIU/ml in the preceding 12 months should be re-tested weekly for 3 months, and be given a booster dose of vaccine. HBIG should be considered for non-responders to hepatitis B vaccine (anti-HBs < 10 mIU/ml).

- 7.14 If a new case of HCV or HIV infection is found, a PCR test should be carried out on those patients who may have been exposed to the infection during dialysis sessions (i.e. have shared a machine or a dialysis session with the infected patient), as this will allow earlier detection than an antibody test, and repeated every 2 weeks for 3 months. The recommended protocol is set out below. A virologist's advice should also be obtained about the need for further tests. Some units monitor ALT levels in their patients, and a raised ALT level may provide the first indication that a patient has been infected with HCV. When a raised ALT result is found in a patient, an HCV PCR test and an HBsAg test should be done.

Protocol for enhanced surveillance following a new case of BBV infection

HBV	<p>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 3 months after the last exposure to the index case.</p> <p>For patients who have previously been immunised and shown to have responded, a booster dose of vaccine should be considered.</p> <p>In non-responders, or where status is unknown, HBIG and an accelerated course of vaccine should be considered.</p>
HCV	<p>The exposed cohort should be tested for HCV RNA by PCR at 2-weekly intervals until 3 months after the last exposure to the index case, particularly if the index case seroconverted whilst receiving dialysis on the unit (i.e. when (s)he would have had a high viral load during the acute phase of infection).</p>
HIV	<p>Undertake a risk analysis. If the index case seroconverted whilst 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 at 2-weekly intervals until 3 months after the last exposure.</p>

Chapter 8

Routine precautions against BBV infection

Transmission hazards in dialysis units

- 8.1 The dialysis process facilitates the transmission of BBVs because of the considerable potential for exposure to blood. All blood is potentially infectious and, to prevent exposure, the barrier and other cross-infection precautions set out in this chapter should be strictly observed in the treatment of all dialysis patients.
- 8.2 Transmission of a BBV from a patient receiving dialysis to other patients or to staff is most likely to occur by percutaneous injection of blood or other body fluid directly to the recipient. It should be remembered that BBVs may be transmitted between patients and staff via hands and fomites. Contamination of the environment or of the external surfaces of medical equipment without sharp areas is less likely to lead to percutaneous exposure, but transmission from environmental surfaces cannot be entirely disregarded, especially since haemodialysis patients always have broken skin. Such transmission is most likely to occur through contamination of staff hands.
- 8.3 Patients spend short periods of time in dialysis units, they are usually ambulant and generally have not recently undergone major surgery. Their skin lesions are usually restricted to dialysis needle punctures. Hence the risks of transmission of BBV are related directly to the process of haemodialysis and not usually to other procedures.
- 8.4 The infection control recommendations below are aimed primarily at minimising the direct percutaneous risks, and also the risks associated with the clinical environment in which BBV infected patients are treated. They are intended to reduce the risks of gross exposure to blood, and also to create an environment in which staff and patients are reminded continually of the need for special precautions to reduce percutaneous and other exposures.
- 8.5 It is recommended that all units should regularly conduct a rigorous local risk assessment and review of their infection control policies and practices, in collaboration with the hospital infection control team, to establish the extent of the additional precautionary measures necessary.

General good practice guidelines

- 8.6 These guidelines should be read in conjunction with all other good practice guidelines which are relevant to maintaining safety in renal units; these include *Protection against blood-borne infections in the workplace: HIV and hepatitis*⁸⁶, and *Guidance for clinical healthcare workers: protection against blood-borne virus infections*⁸⁷. Guidance for ensuring the safety of transplanted organs is given in *Guidance on the microbiological safety of human organs, tissues and cells used in transplantation*⁸⁸.

Ensuring a safe clinical environment

- 8.7 Protection of patients and staff rests heavily on the use of safe working practices which prevent their exposure to potentially infected blood. It is particularly important that hepatitis B immunisation does

not result in a relaxation of the highest standards of infection control. Under the COSHH Regulations⁸⁴, employers have a responsibility to assess the risks from hazards at work and take necessary steps to reduce those risks. Biological hazards are explicitly covered in the regulations.

- 8.8 The working environment of renal units should be assessed with this in mind. Aspects likely to be important include layout, operating space, lighting, flow of 'traffic', heat and noise. Inadequacies in any of these areas can increase the risks of accidental exposure to blood (e.g. sharps injuries). Staffing levels should be adequate not only to ensure good care for patients, but also because staff who are rushed and under pressure are more at risk of having accidents, including blood exposure incidents.
- 8.9 In treatment areas there should be adequate space between beds for staff to perform their clinical duties and use equipment in a safe manner. Accidental disconnection of dialysis lines can result in blood spraying for considerable distances, and breaks in the blood circuit, although uncommon, risk direct and indirect contamination of patients and staff. For example, in an Italian study, accidental disconnections accounted for 10.2% of 579 skin or mucous membrane exposures to blood among dialysis unit workers⁸⁹.
- 8.10 There should be adequate supplies of protective clothing readily available at the point of use, wash hand basins readily available, and adequate supplies of sharps containers (complying with the appropriate specifications) at convenient locations. The supply and collection of sharps containers should be arranged to avoid the filling of containers to more than two-thirds capacity. The safety of equipment should be a consideration in deciding upon equipment purchase.
- 8.11 Units should review the safety aspects of their environment at regular intervals and whenever a virus transmission has been recognised in the unit. Aspects related to the risk of blood exposure should be included in these reviews. Standard operating policies should cover safety issues and, in particular, the risk of blood exposure. The Director of the Unit should appoint a member of staff of the unit as the Safety Officer, to advise on any safety problems and actions to remedy them, including problems relating to blood exposure. In addition, there should be a Safety Committee which meets regularly and, whenever there has been a virus transmission, the committee should review safety procedures. The Safety Committee should report to the Trust Chief Executive through the Infection Control Committee.

Infection control procedures

- 8.12 In 1998, the Department of Health commissioned the first phase of national evidence-based guidelines for preventing health care associated infections. These focused on developing a set of standard principles for preventing infections in hospitals. *Standard Principles for Preventing Hospital Acquired Infections*^{90 ‡} provide guidance on infection control precautions that should be applied by all health care practitioners to the care of all hospital in-patients at all times. The recommendations cover four distinct areas: hospital environmental hygiene; hand hygiene; the use of personal protective equipment; and the use and disposal of sharps. These recommendations may be read in conjunction with the present guidelines.
- 8.13 The procedures described below should be followed at all times in all renal dialysis and renal transplantation units regardless of whether or not they dialyse BBV infected patients regularly.

‡ Available at <http://www.doh.gov.uk/hai/epic.htm>

8.14 The primary measures for prevention of BBV transmission are:

- all staff should cover cuts and abrasions with waterproof dressings;
- staff should wear protective clothing (gloves, aprons, and facial protection) whenever there is a risk of exposure to blood or body fluids;
- staff should change gloves and aprons and decontaminate their hands between attending to different patients, or different caring activities for the same patient;
- all exposed surfaces in and adjacent to each patient's treatment station should be washed with neutral detergent and hot water and thoroughly dried between patient treatments; where there is visible blood, disinfection should be carried out;
- care should be taken to avoid injury with sharp instruments;
- multi-use vials should only be used for individual patients;
- adequate treatment space and staffing should be provided to ensure safe working practices (see paragraphs 8.8-8.9).

These measures are more fully described below.

Skin protection

8.15 All staff in renal units should cover any cuts and abrasions with waterproof dressings while they are within the unit. Staff who come into direct contact with patients or dialysis machines who have extensive untreated cuts or chronic skin disease, such as eczema, should not work in renal units when their skin lesions are active, or if there are extensive breaks in the skin surface. Occupational health advice should be obtained. Disposable, well-fitting gloves and a disposable plastic apron should be worn while performing procedures that may lead to contamination of the hands or clothing with blood and/or other body fluids.

Protective clothing

8.16 Care should be taken at all times to avoid splashing of blood and blood-stained body fluids. Protective clothing (such as disposable plastic aprons and gloves), facial-wear (such as visors, safety spectacles and masks) should be worn when mucosal splashes are likely to occur, for example when putting patients on and taking them off dialysis. Protective clothing should be changed at the earliest opportunity if they become visibly splashed with blood. Gloves and aprons should be changed and hands decontaminated between each patient and between different caring activities for the same patient.

Staff hand hygiene

8.17 There should be easy access to wash-hand basins for staff caring for patients in renal units. It is recommended that at least one wash-hand basin should be provided in the main dialysis area for every 3 dialysis stations, and at least the same ratio (with a minimum of one basin) in the area for treating BBV infected patients. Where possible, there should also be one in the BBV sluice area (if available), and one immediately outside each single isolation room. Renal units need to have a variety of hand hygiene products available to cover the range of necessary uses inherent in safe patient care. These products will include liquid soap and paper towels for use when hands are visibly soiled with dirt or organic material, and a surgical scrub preparation for use prior to invasive procedures. Alcoholic handrubs may also be used when the hands are not visibly soiled. Alcoholic handrubs have advantages of staff acceptability and speed of use, and their use is far preferable to the alternative of hand hygiene not being performed. (See also *Standard Principles for Preventing Hospital Acquired Infections*⁹⁰.)

Disinfection of surfaces

- 8.18 Exposed surfaces, including the outer surfaces of dialysis machines, should be washed with neutral detergent and hot water, and dried thoroughly after each patient treatment. After each BBV infected patient's session at a treatment station, surfaces of dialysis machines and furniture that have been touched by the patient or staff should be disinfected. In addition, daily disinfection of surfaces should take place when stations are used by non-BBV infected patients. This disinfection should be carried out with a chlorine-based disinfectant (1000 ppm available chlorine). Surfaces should be wiped over with a disposable cloth with neutral detergent and hot water, and dried before the area is used again. Particular care should be taken to remove chlorine residues from metallic surfaces. Units should confirm with the manufacturer whether the use of chlorine-based disinfectant is compatible with their machines; if not, units should follow the manufacturer's advice as to the appropriate method of disinfecting surfaces between patients. Advice may also be sought from the Infection Control Team. (For disinfection of machines, see Chapter 10.)

Sharps

- 8.19 Care should be taken to avoid injury when dealing with any sharp instruments but particularly when they are contaminated with blood and other body fluids, such as dialysis needles. Whenever possible, needleless collection systems should be used when collecting samples of blood and other body fluids. Needles should not be resheathed. Sharps should be discarded immediately in a safe manner into "sharps containers" which should conform to British Standard 7320:1990. Containers should not be filled to more than two-thirds capacity and should then be disposed of safely. This should involve closing and labelling the bin with its place of origin, storing it temporarily in a safe place, and arranging its transport for disposal in an approved manner. For the purposes of transportation, containers must also conform to UN3291 to meet the requirements of the Carriage of Dangerous Goods regulations. Each staff member performing procedures in which sharp instruments are used is responsible for ensuring immediate safe disposal.

Wound care

- 8.20 Occlusive dressings should be used to cover all wounds and puncture sites in dialysis patients until they have healed.

Multi-use vials

- 8.21 Multi-use vials have been identified as a route of transmission of BBVs on renal units, and this risk should be minimised by avoiding multiple use of containers of parenteral liquids whenever possible. If multi-use containers have to be used, each should be used only on a single patient and should be labelled with the patient's name and for use by that patient only. A fresh sterile syringe and needle should be used each time liquid is aspirated.

Good hygiene

- 8.22 Staff on renal units should not smoke, eat or drink except in designated staff rest areas, and they should remove protective clothing and decontaminate their hands upon leaving the clinical area of the unit for any purpose.

Contaminated clothing and linen

- 8.23 Guidance on the handling and laundering of contaminated clothing and linen is given in Department of Health guidance *Hospital laundry arrangements for used and infected linen*⁹¹.

Disinfection of spillages

- 8.25 Only staff who have been trained in the correct disinfection procedures should deal with spillages of blood and blood-stained body fluids. Disposable gloves and a plastic apron should be worn, and lesions on exposed skin should be covered with waterproof dressings. If the spillage is extensive, rubber boots should be worn.
- 8.26 Small spills should be wiped up with a paper towel soaked in a chlorine-based disinfectant (10,000 ppm available chlorine). Larger spills should either be covered with dichloroisocyanurate granules and left for at least two minutes before clearing up with paper towels or covered with paper towels and the contaminated area gently flooded with hypochlorite solution (10,000 ppm available chlorine) and left for at least two minutes before clearing up. Afterwards the area covered by the spillage should be washed with neutral detergent and hot water and allowed to dry. Paper towels and disposable protective clothing should be placed in a waste bag for disposal in an approved manner (see paragraph 8.30). Hands should then be washed. Similarly contaminated clothing should be disinfected and/or laundered as per local policy.

Other precautionary measures

Routines for patients

- 8.27 Where appropriate, patients should be encouraged to become as independent of assistance as possible for the dialysis process. They should also be fully instructed in unit procedures and in the precautions necessary to minimise the risk of transmission of BBVs.

Blood exposure incidents

- 8.28 Patients should be asked to report blood exposure incidents in which they are involved. Units should have a policy for the management of such incidents (see also paragraph 11.16).

Unit cleaning

- 8.29 Domestic staff should understand the cross-infection precautions. Those allocated to the dialysis treatment area should wear protective clothing while working and should remove it before leaving the area.

Waste

- 8.30 Clinical waste from dialysis units should be regarded as a hazardous substance unless rendered safe before disposal. Clinical waste is subject to stringent controls. Clinical waste should be double bagged before being taken out of a segregated BBV area. Any waste contaminated by blood or body fluids or other potentially infectious material should be treated as clinical waste. Full guidance on the definition of clinical waste and the requirements for its disposal, are given in *Safe Disposal of Clinical Waste*⁹².

Fluid disposal

- 8.31 Used haemodialysis and peritoneal dialysis fluids may contain BBVs and should therefore be disposed of directly to the drain or by pouring carefully into a sluice. Guidance on disposal of such effluents is given in *Protection against blood-borne infections in the workplace: HIV and hepatitis*⁸⁶.

Record keeping of treatment sessions

- 8.32 Patients should have their bed location and machine identity logged at each treatment session.

Avoidance of risk

- 8.33 The Rosenheim Advisory Group advocated the use of home haemodialysis as a means of reducing the exposure of uninfected patients to the BBV hazard in dialysis units. Clinicians should give careful consideration to the use of peritoneal dialysis (or home haemodialysis) for suitable patients. Successful transplantation could also serve this purpose or remove from the dialysis unit an infected patient who could be a potential source of BBV infection to others. However, the use of transplantation as a prophylactic measure depends on the availability of a suitable kidney at the right time, and it is recognised there is a need to increase the supply of organs to meet demand. Also, transplantation for BBV infected patients is not always clinically appropriate. For these reasons, transplantation will not generally be a practicable means of reducing risk.

Laboratory practice

- 8.34 Guidance on the procedures to be followed by laboratories to prevent BBV infection is given in *Protection against blood-borne infections in the workplace: HIV and hepatitis*⁸⁶.

Summary of action when BBV transmission occurs in a unit

- 8.35 Whenever a transmission of HBV, HCV or HIV infection is suspected within a unit, precautionary measures need to be taken to prevent further spread. Many of the measures recommended are mentioned elsewhere in this document but are included here also, for ease of reference:
- arrangements should be made for the infected patient(s) to be dialysed in the designated segregated area, and in the case of HBV, a dedicated machine should be used while the patient(s) remains infected. Patients affected by an outbreak of BBV infection should be nursed by designated staff;
 - the director of the unit should alert the staff in the unit, the hospital infection control team, the Chief Executive or Deputy as having statutory responsibility for safety, the Consultant in Communicable Disease Control and any others who need to be informed in accordance with local requirements. The Regional Epidemiologist and PHLS Communicable Disease Surveillance Centre should also be notified. An outbreak control team should be set up;
 - elective transfers of patients out of the unit should be stopped and visitors should be discouraged;
 - if a patient transfer is necessary, or has occurred in the last 3 months and during the potential incubation period, the other unit involved should be told of the outbreak;

- patients who have shared a dialysis machine or a dialysis session with the infected patient since the last routine test for the virus concerned should be screened. If there is an outbreak of HBV, patients should be tested for HBsAg weekly for 3 months; if an outbreak of HCV or HIV occurs, a PCR test for infection should be carried out on patients and the unit should obtain specialist advice from a virologist about the need for further testing (see 7.14). Patients who have been transferred elsewhere should be followed-up. The increased surveillance should also be implemented for patients transferred in from a unit where a BBV outbreak has occurred;
- staff and any other carers who have had contact with the infected patient in the unit should also be screened for HBsAg, HCV antibody and HIV antibody, as appropriate;
- prophylactic immunisation against HBV should be given where appropriate;
- the director of the unit, in collaboration with the unit's safety committee and the hospital's infection control team, should review the unit's precautions against the transmission of BBVs and remedy any deficiencies.

Relatives and friends who assist in dialysis treatment

- 8.36 Relatives and friends who attend a unit to assist a patient with dialysis are potentially at risk of acquiring or transmitting BBVs. Units should instruct these carers in the precautions to be taken to prevent cross-infection, and should provide them with protective clothing and equipment where it is appropriate for the task they are performing. Units should also make carers aware of the importance of reporting blood exposure incidents and of the arrangements for obtaining urgent advice following any incident (see paragraphs 11.15-11.18). Guidance on the immunisation of carers against hepatitis B is contained in Chapter 6.

Chapter 9

Management of BBV infected patients

Measures to ensure safety

- 9.1 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. The survey results (see Chapter 4 and Annex 2) show that units have adopted various measures or combinations of measures for the management of BBV infected patients, including reliance on universal precautions, segregation or use of separate dialysis machines.
- 9.2 Recommendations for the effective implementation of segregation and other special measures and strict observance of the infection control practices recommended in Chapter 8 should minimise the risk of BBV transmission in renal units. Units should aim to implement these measures effectively. This requires adequate space and staffing and vigilance on the part of the staff.

Segregation of infected patients

- 9.3 The following paragraphs recommend varying degrees of segregation of patients infected with different BBVs. Segregation may be achieved by the use of existing isolation facilities, use of bays or side wards, use of moveable partitions or a combination of these arrangements. Directors of dialysis units will need to consider how to achieve segregation, taking account of the layout of their own units and the number of infected patients to be treated. The findings of the survey of dialysis units indicate that most units should be able to provide the necessary degree of segregation or isolation required for each BBV, by the use of existing facilities and the suitable rostering of treatment for infected patients. Full advantage should be taken of all the isolation and separate treatment facilities available in a unit.

HBV

- 9.4 When considering dialysis of patients infected with HBV, the Rosenheim Advisory Group recommended segregating infectious and non-infectious patients; with segregation between infective and clean areas being functionally complete and direct traffic between the two being impossible. A review of the literature shows that such an approach has proved effective for the control of HBV infection on renal dialysis units. The results of the survey of dialysis units show that this degree of segregation has been most frequently achieved by the use of single room isolation facilities or separated areas designated for HBV infected patients (see Annex 2, Table 7). Given the risks of transmission of HBV in the dialysis setting (high amounts of circulating virus present in many patients and the possibility for environmental contamination) this degree of segregation should, where possible, continue. Where separate isolation rooms are not available, patients with HBV should be dialysed in areas separated from all other patients not infected with this virus.

HCV and HIV

- 9.5 The results of the survey also show that it is the policy of a considerable proportion of units to segregate HCV and HIV infected patients. Again, a review of the literature supports segregation as an effective

form of infection control for HCV. 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. Many units may wish to continue to segregate HIV positive patients, and any alternative approach should only be taken after local risk assessment.

- 9.6 Patients infected with one BBV remain susceptible to other BBV infections, and HIV positive patients who are significantly immunosuppressed are more likely to become chronic carriers should they acquire HBV or HCV. To avoid the risks of further infection, where BBV infected patients are dialysed in a single area segregated from the main dialysis area, patients should be rostered so that those with different infections are not dialysed together on the same shift.
- 9.7 All invasive, percutaneous procedures on patients with BBV infection should be carried out within the BBV areas. Other staff-patient contacts can be carried out in the unrestricted areas of the unit.

Acute dialysis patients

- 9.8 The Rosenheim Advisory Group advised separate facilities for new “acute” dialysis patients from those having “chronic” dialysis. With the introduction of rapid and sensitive diagnostic tests for the majority of BBVs, and the establishment of regular screening protocols, this separation is not considered necessary.

Facilities for segregation

- 9.9 In units which regularly dialyse BBV infected patients, a designated segregation area is recommended, and flexibility of provision is encouraged by adjacent siting of the segregation area and single room isolation facilities. When BBV infected patients are not being dialysed, the area may be used for uninfected patients after cleaning and disinfection.
- 9.10 In dialysis units with a small proportion of BBV infected patients (i.e. in which most dialysis sessions do not include an infected patient), the most efficient use of space will be achieved by having a combined segregation area and source isolation cubicle(s) which can be used flexibly for isolation of patients colonised or infected with air or hand-borne pathogens (such as methicillin-resistant *Staphylococcus aureus*, varicella-zoster virus, or *Salmonella* spp.), as well as BBV infected patients.
- 9.11 There should be adequate storage space for sterile supplies, fluids and other items adjacent to segregated areas and isolation cubicles. Where possible, there should be a designated sluice and disposal area adjacent to these areas, and sufficient space for separate storage of blood-stained fluids and equipment awaiting disposal and removal. It is not necessary to have separate lavatories for BBV infected and uninfected patients on renal units.

Partitioning of segregation areas

- 9.12 In renal units the separate areas for BBV infected and uninfected patients ideally should be demarcated with clear boundaries, which may include permanent walls or glass partitions, or more adaptable arrangements such as tall moveable, washable, screens.
- 9.13 Fixed partitions should comply with the guidance in *Health Technical Memorandum 56, Building Components, Partitions*⁹³, and any moveable screen should be constructed and fixed to comply with the strength, stability and finishing requirements of the guidance (sections 2.3 and 3). Finishes should be capable of withstanding regular decontamination with strong hypochlorite (10,000 ppm available

chlorine). It is not necessary for the areas to have doors fitted between them, or for existing doors to be kept closed. However, to ensure the distinction between the areas, the junction between them should ideally be wide enough only for single beds or other large pieces of apparatus to pass easily and safely. When labelling the areas, consideration should be given to preserving patient confidentiality while taking the opportunity to remind staff of the distinctions between areas.

- 9.14 Staff should not have to cross between areas to collect equipment or to perform other tasks; there should be sufficient storage space within the BBV area for sterile items, fluids and other equipment for staff to perform the majority of their daily duties without having to leave the area. Similarly, the BBV area should contain a telephone, and other services such as computer terminals that are needed regularly by staff.

Construction of segregation areas used for BBV infected patients

- 9.15 Areas where dialysis is carried out should be constructed with impermeable floors and other horizontal surfaces that are capable of withstanding repeated exposure to high concentrations of hypochlorite (10,000 ppm available chlorine). Carpets and floor mats should not be used in clinical areas. There should be no non-essential items in the segregation area.

Nursing infected patients in segregation area

- 9.16 Whenever possible, staff should be assigned to work only with patients infected with BBV in the segregation area, or with uninfected patients, in any one shift. This will reduce the risks of transmission of BBVs. Most units should be able to make the necessary arrangements for this and should seek to maximise the opportunities for doing so. When infected and uninfected patients have to be cared for by the same staff, this should be done by experienced staff who should adhere rigorously to infection control procedures. Designated staff should nurse the affected patients whenever there is an outbreak of infection in a unit.

Use of dedicated dialysis machines

- 9.17 There is a significant risk of HBV being transmitted via environmental surfaces and, therefore, a separate machine should be used for infected patients. When a machine is no longer required for such patients, it can be returned to general use after standard cleaning and disinfection procedures have been carried out. The risk of environmental transmission of HCV and HIV is lower than for HBV, and there is no firm evidence implicating dialysis machines in their transmission. Consequently, it is not considered necessary to have separate machines for patients infected with HCV or HIV, provided that cleaning and disinfection processes are properly carried out between patients. Many other items of medical equipment are safely used for all patients with appropriate reprocessing between uses.

Infected patients dialysed in transplantation or other hospital units

- 9.18 Patients who have recently received organ transplants, particularly renal or liver transplants, sometimes require a period of post-operative haemodialysis while renal function recovers. This dialysis is usually performed on transplantation units because these patients often suffer complex medical problems in the post-operative period. Many transplantation units nurse all types of transplant patient together on the same ward, and some patients undergo renal transplantation at the same time as receiving other organ transplants. Because liver transplant recipients have a high rate of carriage of hepatitis viruses, and the same clinical staff are often involved in performing dialysis and managing patients on both dialysis units

and transplantation units, it is recommended that the same standards of care to avoid the transmission of BBVs be applied in both types of unit.

- 9.19 Patients on transplantation units often remain in hospital for long periods and may be immunocompromised. Many will be receiving post-operative care and have healing wounds, surgical drains, intravenous lines and other lesions that increase their risk of acquiring or transmitting BBVs. Owing to this higher level of risk, recommendations for transplant units differ in some details from those made for renal units.
- 9.20 Rigorous application of procedures to prevent the risk of blood contamination and transmission of infection are essential and local risk assessments should be carried out on transplantation units. These should take into account the local provision of isolation facilities, the number of post-operative dialysis and other patients, the likelihood that patients may bleed, and the numbers of patients carrying BBVs who are treated in the unit.

Precautions during surgery

- 9.21 Guidance on the precautions to be taken against BBV during surgery is included in *Guidance for clinical healthcare workers: protection against blood-borne virus infections*⁸⁷.

Segregation in transplantation units

- 9.22 A transplantation ward will need designated areas for BBV infected patients and single rooms for source isolation of patients with a range of infections. Some of these segregated areas or rooms will need facilities for dialysis. The hospital's infection control team should be involved in the decisions about which patients with conflicting requirements for BBV isolation and source isolation for other organisms are nursed in which rooms and areas.

Use of BBV area

- 9.23 All invasive, percutaneous procedures on BBV patients on transplantation units should be performed within the BBV area, and patients should remain there while they are bleeding or are likely to bleed except while they are being transported to other hospital areas for specialist investigations, treatment or surgical operations. In these cases, the receiving departments should be informed in advance of the patient's BBV status so they can take appropriate precautions. Once infected patients are judged unlikely to bleed, they may leave the BBV area for social interaction on the ward, but they should return to the BBV area for all clinical interventions and procedures. Clinical waste should be double bagged before being removed from the area.

Chapter 10

Equipment and prevention of BBV transmission

Dialysis machines

Blood circuit

- 10.1 The dialysis process is controlled and monitored by the dialysis machine which has safeguards to minimise the risk of transmission of BBV. Dialysis machines have separate circuits for the patient's blood and the dialysate fluid, which come together in the dialyser ('artificial kidney') separated by a semi-permeable membrane. The tubing in the blood circuit is supplied for single-use and should be destroyed by incineration or other method approved for disposal of clinical waste (see *Safe Disposal of Clinical Waste*⁹²). The blood tubing set includes a venous pressure monitoring line (VPML) which is fitted with a filter to protect the pressure monitor and other components of the machine from contamination with blood.
- 10.2 Some machines also have an internal filter mounted immediately behind the VPML connector on the machine. Should blood come into contact with the VPML filter, the machine operator will be alerted and the filter should be replaced. In the unlikely event that the VPML filter ruptures, any machine components which might have been contaminated with blood (e.g. the internal filter and the tubing between it and the VPML connector) should be replaced or decontaminated in accordance with the manufacturer's instructions. If replacement or decontamination cannot be carried out locally, the machine should be taken out of service and help obtained from the manufacturer.
- 10.3 There is little evidence to implicate haemodialysis machines in the transmission of BBVs through contamination of an internal component. A more likely risk for transmission between successive patients using the same machine is a failure to adequately clean its external surfaces between dialysis sessions. However, a recent paper describing an outbreak of HCV infection has drawn attention to the possibility of blood contaminating the pressure monitor of the dialysis machine and of the need to ensure that, should such an event occur, the machine is adequately decontaminated before it is put back into service⁹⁴ (see paragraph 10.2).

Dialysis fluid circuit

- 10.4 The dialysis fluid circuit of the machine may be contaminated if the semi-permeable membrane leaks, and contamination may also occur during assembly of the system. However, the design of machines is such that contamination would be very unlikely to enter or remain within the dialysis circuit upstream of the artificial kidney, and there would also have to be a leak in the semi-permeable membrane of a subsequent artificial kidney for contamination to gain access to another patient's circulation. The manufacturer's recommendations for assembly and use of the equipment should always be followed.

Decontamination

- 10.5 It is the responsibility of the dialysis machine manufacturer to provide information on the compatibility of the equipment they supply with methods and agents for its decontamination. This information should be incorporated into local codes of practice and be kept under review. The entire dialysis fluid circuits of the dialysis machine should be decontaminated between each patient use by heat or chemical disinfection, according to the manufacturer's instructions.

- 10.6 Dialysis machines should be cleaned with neutral detergent and hot water between each use by non-BBV infected patients. Surfaces of dialysis machines should be disinfected after each BBV infected patient's session at a treatment station. In addition, daily disinfection of surfaces of each work station should be performed when stations are used. This disinfection should be carried out with a chlorine-based disinfectant (1000 ppm available chlorine). Surfaces should be wiped over with a disposable cloth with neutral detergent and hot water before the area is used again, and particular care should be taken to remove chlorine residues from metallic surfaces. Units should confirm with the manufacturer whether this use of chlorine-based disinfectant is compatible with their machines; if not, units should follow the manufacturer's advice as to the appropriate method of disinfecting surfaces between patients.
- 10.7 Generic advice on the decontamination of medical devices, including dialysis machines and other equipment used in renal units, is available in *Sterilisation, disinfection and cleaning of medical equipment: Guidance on decontamination*⁹⁵. Guidance on legal responsibilities related to equipment which is or is potentially contaminated is given in *Decontamination of equipment prior to inspection, service or repair*⁹⁶ and this guidance should be followed when such equipment is sent for servicing, repair or disposal.

Dialysers ('artificial kidneys')

- 10.8 If a dialyser is supplied for "single-use only", or equivalent, then, in accordance with the guidance from the Medical Devices Agency, *Single-use medical devices: implications and consequences of reuse*⁹⁷, it should be destroyed by incineration or other methods approved for disposal of clinical waste (see paragraph 8.30) after a single dialysis session on one patient. Dialysers should not be reused unless specified by the dialyser manufacturer.

Reporting of adverse incidents involving dialysis equipment

- 10.9 The Medical Devices Agency has issued guidance on the reporting of adverse incidents involving medical devices, including dialysis equipment⁹⁸.

Chapter 11

Occupational health and staff fitness to work in dialysis units

- 11.1 General guidance on protection against BBV infections in the workplace has been issued by the Advisory Committee on Dangerous Pathogens and the Advisory Groups on AIDS and Hepatitis^{86,87,99}. Good working practice in renal dialysis and transplantation units should ensure the protection of staff against BBVs in their work. It is essential that renal units be provided with specialist occupational health advice in accordance with the relevant Department of Health guidance¹⁰⁰.

Occupational health arrangements

- 11.2 Each renal unit should receive advice from a designated occupational health unit, which should include a specialist occupational health physician experienced in health care work, charged with responsibility for that renal unit. Ideally, this would be the occupational health department of the hospital where the renal unit is located, though difficulties may arise with satellite units; nevertheless, clear and explicit arrangements should be in place.

Skin conditions that make staff unsuitable for work in dialysis units

- 11.3 Few medical conditions render staff unsuitable for work in renal units. However, extensive epithelial deficiency such as eczema, particularly if affecting the hands or forearms, may offer an additional portal for infection and make repeated hand washing difficult. Such staff should not work on renal units when their skin lesions are active or if there are extensive breaks in the skin surface.

Immunisation and post-exposure prophylaxis

- 11.4 Immunisation and post-exposure prophylaxis to protect against HBV infection are dealt with in Chapter 6. There are no vaccines currently available for HCV or HIV. Post-exposure prophylaxis is available for HIV. If occupational exposure occurs, the UK Health Departments' guidelines on HIV post-exposure prophylaxis should be followed¹⁰¹. There is no passive prophylaxis against HCV. The PHLS Advisory Committee on Blood-borne Viruses has produced guidance on the appropriate management of occupational exposures to hepatitis C¹⁰². A recent study suggests that early treatment of acute hepatitis C may prevent chronic infection¹⁰³.

Testing for BBV

- 11.5 This section sets out the position on the testing of staff current at the time of publication. Guidance in this area may change and up to date advice should be sought from the supervising occupational health physician.

HBV

- 11.6 The activities undertaken by staff in a renal dialysis unit would not normally be regarded as exposure prone procedures as defined in UK Health Departments' guidance^{99,104}. However, the possibility of transmission from staff to patients cannot be entirely ruled out in the particular circumstances of a renal unit where all patients have repeated bloodstream access as the key part of their treatment. There is a minimal risk of contamination of the patient by blood or body fluids from staff.
- 11.7 It is therefore recommended that staff who work or are being recruited to work in a renal dialysis or renal transplantation unit and who will have clinical contact with patients (i.e. are concerned directly with the haemodialysis process) should be tested for HBsAg. If found to be HBsAg positive, they should be further tested for HBeAg. Any found to be HBsAg positive but HBeAg negative should have their HBV DNA levels determined. Health care workers who are either HBeAg positive or are HBeAg negative with an HBV DNA level exceeding 10^3 genome equivalents per ml should not undertake clinical duties on renal dialysis units^{99,104}. Such restrictions do not apply to staff who have no close patient contact, e.g. secretarial or laboratory staff.
- 11.8 All health care workers employed on renal units should be immunised against HBV and their response to vaccine checked (see Chapter 6). Staff who have not demonstrated immunity to HBV and have clinical contact with patients should be tested for HBsAg annually.
- 11.9 A finding of HBsAg positivity in a member of staff should lead to a thorough investigation of the HBV status of the dialysis patients with whom they have had contact. During this period, the member of staff should not work on a renal unit in clinical contact with patients. Staff may only resume work in the unit when found to be HBeAg negative with a viral load not exceeding 10^3 genome equivalents per ml.

HCV

- 11.10 At present, renal units do not need to screen prospective staff for HCV. Applicants who declare themselves to be HCV infected should be referred to occupational health for advice but there is at present no bar to employing them on the unit. However, in line with other guidelines, HCV infected health care workers who are viraemic (i.e. HCV RNA positive by PCR) should not perform exposure prone procedures¹⁰⁵.

HIV

- 11.11 Routine screening for HIV of prospective staff for work in renal units is not indicated. However, individual health care workers who have any reason to believe that they may have been exposed to HIV, in any circumstances whatsoever, have a responsibility promptly to seek and follow confidential professional advice on whether they should be tested for HIV. This is in line with statements from the General Medical Council and the UK Central Council for Nursing, Midwifery and Health Visiting (now the Nursing and Midwifery Council) about the responsibilities of individual practitioners. General guidance from the UK Health Departments on the management of health care workers infected with HIV recommends that they should not perform exposure prone procedures; however, as pointed out in paragraph 11.6, routine activities undertaken by staff in a renal dialysis unit would not normally be regarded as such.

Confidentiality for BBV infected staff

- 11.12 Staff found to be infected with a BBV, whether through an accidental blood exposure incident at work or otherwise, are entitled to confidentiality. Where such staff need to have their working practices

limited or to be redeployed, the information about their status should be limited to those who need to know and only given with the staff member's explicit consent. For work modification it is often possible to avoid making it obvious why this is being done. For HCV and HIV, the responsibility rests with the individual to declare their status and they are more likely to do this if there are policies in place to protect their confidentiality and interests as far as possible. Staff should be made aware (on the renal unit and throughout the hospital) of the arrangements that allow them to talk to someone in confidence if they are concerned that they might be infected with a BBV, or know themselves to be infected. Ideally, the person they can talk to should be the supervising occupational health physician or, by arrangement, an experienced occupational health physician from another hospital.

Staff training and supervision

- 11.13 Providing information, instruction and training for staff working with hazardous substances is a requirement under the COSHH Regulations⁸⁴. Staff should be made aware of the hazards and they should be given adequate training in safe working practices. New and junior staff should be supervised until they are considered competent to practice safely without supervision. In practice, this means that all new staff should attend an induction into the working and layout of the renal unit: this is required even for experienced staff coming from other units. New staff should meet the unit safety officer and should be given a copy of the safety policy of the unit, including standard operating policies for different procedures, which they should sign to confirm they have read it. Particular attention should be given to pointing out the location of sharps containers and the locations for protective clothing and equipment.
- 11.14 Temporary, locum, agency or inexperienced staff should not work in the renal unit until they have had appropriate training. Staff training should include the procedure to follow in the event of an accidental blood exposure. All such incidents should be reported to the supervising occupational health department or other designated department.

Management of blood exposure incidents

- 11.15 Blood exposure incidents are those accidents where there is a possibility that blood from the source patient (or much less likely, a member of staff) may have entered the body of the injured person. The majority of these accidents are needlestick injuries where a sharp object such as a needle or blade that is contaminated by blood pierces the skin. The term also includes accidents where blood from a source patient (or staff) contaminates an open wound, area of eczematous skin or a mucous membrane.
- 11.16 The dialysis unit should ensure that there is a comprehensive policy for the reporting and management of blood exposure incidents. Staff sustaining injuries should be aware of how to report such incidents to the occupational health department or other designated department, and of the need for prompt reporting since there are time constraints on implementing post-exposure prophylaxis for HIV or HBV. The physician in charge of the dialysis unit should also be informed of all blood exposure incidents. There should be clear policies for management of the incidents (which should be under the control of the supervising occupational health physician or other designated physician), including follow-up of staff and access to post exposure prophylaxis for HIV or HBV as necessary, in line published guidance^{101,102,106}. Policies for the management of incidents should also take account of the potential exposure of patients and relatives who assist them.
- 11.17 There is usually no need to limit the practice of staff who have been exposed to BBV infected blood during the follow-up period, provided they agree to report any relevant symptoms to the designated person (such as the occupational health physician) immediately, and to undergo appropriate serological testing.

- 11.18 The occupational health department (or other designated department for reporting blood exposures) should keep a database of incidents in order to identify patterns that might indicate that a particular procedure or piece of equipment has a high risk of blood exposures and needs to be modified. There should be provision for immediate investigation of the circumstances of particularly 'high risk' incidents (e.g. an accidental deep intramuscular injection of blood).

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Annex 1

Developments in the management of patients since the report of the Rosenheim Advisory Group

Numbers and types of dialysis patients in the UK

- 1 Between 1975 and 1998 (see Table 1), the number of patients on dialysis in the UK increased from 2218 to 16,100 and the number of renal units increased from 53 to 71. Over this period, the rate of acceptance of new patients for dialysis increased from 15.3 to 96 per million population (pmp). Most of the increase in numbers was due to more patients over the age of 55 being treated, but dialysis programmes were also extended to patients with diabetes and other complicated renal and urological problems. In 1998 47% of patients on dialysis were over the age of 65, and 19% of patients were diabetic.
- 2 In 1972, virtually the only methods of treatment available for patients in end-stage renal failure were haemodialysis and transplantation, and since the availability of organs for transplant could not match the demand and the number of renal units was small, the increasing patient numbers could be accommodated only by home haemodialysis. Now, by contrast, most patients on haemodialysis are being treated in central or satellite renal units in hospitals, with few on home haemodialysis and many more on peritoneal dialysis. Most of the latter patients are on continuous ambulatory peritoneal dialysis and only a few on overnight automated peritoneal dialysis.

Table 1: Number of renal units, mean age of new patients and number of patients on different methods of dialysis treatment

Year ending 31 Dec	Number of main renal units	New patients accepted per million population per annum	Average age of new patients	Number of patients on:			Total dialysis
				Home peritoneal dialysis	Centre haemo-dialysis	Home haemo-dialysis	
1975	53	15.3	37	50	741	1427	2218 ¹
1998	71	96	Not available	5927	9571	602	16,100 ²

Sources:

¹ Garland *et al.* *Nephrology, Dialysis, Transplantation* 1976; 3:58.

² The 1999 Renal Survey. Third Annual Report of the UK Renal Registry. December 2000.

Dialysis methods and techniques

- 3 Changes which have occurred since 1972 in the methods and techniques of dialysis include:
 - (a) replacement of Scribner A/V shunts with A/V fistulae, polytetrafluoroethylene or other synthetic grafts and indwelling venous catheters for vascular access;

- (b) modernisation of proportionating machines with the inclusion of sophisticated electronic fail-safe devices and the capability to adapt to a range of dialysis processes;
 - (c) replacement of non-disposable Kiil dialysers with disposable dialysers, using various membranes with a variety of clearances and ultrafiltration characteristics.
- 4 These changes in technology have reduced the duration of dialysis from approximately 20 hours to 12 hours or less per week, and treatment is tailored to the needs of individual patients according to their size, residual renal function and type of dialyser used. There is, however, considerable variation in current haemodialysis practice in the UK; most units use dialysers containing Cuprophane (bio-active membranes) and long (12 h/week) dialysis but a few use high flux bio-inert membranes and high blood flows with shortened dialysis hours.
- 5 Peritoneal dialysis has largely replaced home haemodialysis as the method of choice for dialysis in the community. Haemodialysis and peritoneal dialysis should be considered as complementary treatments, and many patients transfer from one type of treatment to the other during the course of their life on dialysis. No blood access is required for peritoneal dialysis, and so the risks of acquiring BBV infections are reduced. The risks of BBV cross-infection from contaminated peritoneal dialysis fluid are unknown but are clearly low.

Number of transplants

- 6 There was a substantial increase in the annual number of kidney transplants between 1975 and 2001 (see Table 2). Also these were more successful due to better matching, lower steroid doses, the use of Cyclosporin A and more recently tacrolimus (FK506) and mycophenolate mofetil. Although there has been a three-fold increase in the annual rate of transplantation, it has not been sufficient to meet the rising demand and transplant waiting lists have grown. Furthermore, there has been no increase in the annual rate of kidney transplantation per million population since 1990.

Table 2: Number of kidney transplants in 1975 and 2001, cumulative total of surviving recipients and number awaiting a re-graft (UK Transplant)

Year	Patients transplanted in year	Number of kidney graft recipients alive	Number of recipients awaiting a re-graft
1975	646	1356	306
2001	1473	20,000 estimate	1620

Management of patients undergoing transplantation

- 7 Before transplantation, all patients are usually tested for HBV surface antigen (HBsAg), HCV and HIV antibodies. Most transplantation units will not accept HIV infected patients for transplantation because of their lower survival rates, and some may not accept patients who are HBV infected. There is insufficient knowledge about the outcome in patients who are HCV infected, but most transplantation units are prepared to accept such patients for transplant. Some units treat HCV infected patients with interferon prior to transplantation. It is known that both cytomegalovirus (CMV) and Epstein-Barr virus (EBV) may be acquired by blood-borne infection, but there is no evidence of their spread by nosocomial routes within renal units. However, both viruses cause serious complications after transplantation including EBV-related lymphoproliferative disease and a wide spectrum of CMV-associated clinical disorders.

- 8 There is a need to continue haemodialysis in some patients after transplantation. Dialysis usually takes place within the transplantation unit but the same precautions are taken with BBV infected patients as in a dialysis unit. The follow-up of transplant patients who are uninfected with BBVs does not require frequent testing for BBVs, except to exclude the risk of infection associated with immunosuppression. Patients with failing renal function returning to dialysis are usually tested for HBsAg, HCV and HIV antibodies before restarting treatment.

- 9 Patients who have received transplants and are known to be infected with BBVs require careful follow-up as immunosuppression may accelerate progressive liver disease, including development of hepatocellular carcinoma.

Annex 2

Analysis of results of survey of renal units

- 1 The Working Group commissioned a survey of all renal units in the UK to establish their current policies and practices to prevent the transmission of BBV infection to patients and staff. The survey was carried out in early 1996 by the Immunisation Division of the PHLS Communicable Disease Surveillance Centre.

Methods

- 2 Postal questionnaires were sent to the heads of 82 renal units in England, Wales, Scotland and Northern Ireland. Respondents were asked to return the questionnaire in a pre-paid envelope which was provided. Reminders were sent to those units who had not returned questionnaires within 8 weeks of the target date.

Results

- 3 Questionnaires were returned from 59 units (72%) but four were not completed (one unit was no longer open, one unit only offered haemofiltration and two units had merged to become satellites of larger units). Therefore this analysis was performed on a total of 55 completed questionnaires.
- 4 Completed questionnaires were returned from 40 units in England (Oxford & Anglia 4, North Western 4, South Thames 6, North Thames 3, South Western 7, Trent 4, West Midlands 3, Northern & Yorkshire 9), from 3 units in Wales, 10 in Scotland and one in Northern Ireland. The remaining questionnaire was returned without an identifying hospital.

Number of patients and patient turnover

- 5 As at 1 December 1995, the 55 units were providing services for 31,326 patients, including 5327 patients on maintenance haemodialysis. The number of patients in each unit varied considerably (Table 1).

Table 1: Number of patients receiving treatment in renal units on 1 December 1995

	N	Total patients	Median number (interquartile range) patients per unit
Maintenance haemodialysis	55	5327	80 (48–128)
Maintenance peritoneal dialysis	55	4515	73 (29–123)
Home dialysis	54	1092	6 (0–17)
Functioning renal transplant	55	11835	155 (30–324)
Chronic renal disease (no dialysis)	47	8166	80 (45–200)
Acute renal failure (on dialysis)	54	441	4 (2–200)

- 6 The turnover of patients in 1995, as indicated by the numbers commencing dialysis, receiving transplants and stopping dialysis or dying was also variable (Table 2). In addition to new patients commencing haemodialysis, a total of 355 patients (median of 3 patients per unit) returned to maintenance dialysis after failed transplants, and 46 returned to the UK after commencing dialysis overseas.

Table 2: Dialysis patient turnover per year in renal units

	N	Total patients	Median number (interquartile range) patients per unit
Began maintenance haemodialysis	54	2676	41 (23–65)
Began maintenance peritoneal dialysis	54	1840	24 (12–49)
Received renal transplant	54	1499	24 (10–39)
Died or ceased maintenance dialysis	53	2016	35 (16–56)

- 7 Each unit treated a median of 14 (interquartile range 10–18) haemodialysis patients in each daytime session and 6 (interquartile range 0–12) patients in each night-time session. Of those units which provided information, only 4 (8.5%) of 47 were providing haemodialysis to fewer patients than the maximum capacity of the unit at each session.

Accommodation available for haemodialysis

- 8 There were 314 single rooms available for haemodialysis, a median of 2 rooms for each unit. Very few two-bedded areas were available. Otherwise, the median estimated floor space available per patient dialysed in the main body of the unit was 8.7m² (interquartile range 7.0–11.8m²).

Staffing levels for haemodialysis units

- 9 The staffing levels varied between units with a median of 6 staff (including 4 trained nurses) for each daytime session of haemodialysis and 4 staff (3 trained) on the night-time sessions. This was estimated to comprise a median of 0.5 (interquartile range 0.40–0.67) staff members per patient of which 0.32 (interquartile range 0.24–0.41) carers per patient were trained nurses.

Satellite units

- 10 Twenty four (44%) centres had one or more satellite units (10 had one, 13 had two and 1 had four satellites). In each daytime session the satellites performed haemodialysis for a median of 8 patients (interquartile range 6–10). In the satellite units, the average floor space per patient was similar to that in the main units – with a median of 8.7m² (6.1–13.3m²) per patient. Staffing levels were lower than those in the main units, with a median of 0.38 (0.33–0.50) members of staff per patient of which 0.33 (0.22–0.40) carers were trained. Only 2 satellite units offered night-time sessions.

Services to other patient groups

- 11 Fifty two units provided services to patients from other medical and surgical specialities (Table 3). Patients from intensive care units were the most common users of renal unit facilities.

Table 3: Number of units that provide dialysis/haemofiltration services to patients from other specialties

Providing dialysis/haemofiltration to patients from	Number (%) providing Service (n=55)
Liver transplant unit	4 (7.3%)
Renal transplant unit	26 (47%)
Liver failure unit	6 (11%)
Intensive care unit	48 (87%)
Cardio-pulmonary transplant unit	4 (7.3%)
Medical/surgical ward	37 (67%)

Equipment and procedures

- 12 Seven makes of dialysis machine were used by the units and many units owned different makes and models of machines (Table 4). Most units used circulating hot water to decontaminate these machines routinely but chlorine-containing disinfectants were also commonly used. Most of the units that responded, 42 (78%) of 54, decontaminated the machines after each use and a further 10 units decontaminated at least once every 24 hours. The two remaining units decontaminated the dialysis machines on two or three occasions per week.

Table 4: Types of dialysis machine in operation and routine methods for decontamination

Type of dialysis machine		Number of units using (number of machines)	Number of units using routine decontamination by:		
Make	Model		Heat	Chlorine	Other
Althin	1000	12 (124)	9	2	0
Cobe	All models	21 (351)	4	15	2
	Century 3	21 (330)			
	Century 52	2 (21)			
Dylade	DII	1(1)	1	0	0
Fresenius	All models	18 (290)	12	3	2
	2008	3 (44)			
	2008C	6 (67)			
	2008D	5 (49)			
	4008	2 (24)			
	4008D	3 (17)			
	4008E	6 (41)			
	Unspecified	4 (48)			
Gambro	All models	31(700)	29	2	0
	AK10	24 (292)			
	AK90	6 (84)			
	AK100	25 (324)			
Hospal	All models	10 (111)	5	4	0
	Monit S	4 (29)			
	Monit SC	4 (27)			
	Monit SC30	3 (14)			
	Unspecified	6 (41)			
Redy	2000	1 (7)	1	0	0
TravBax	All Models	2 (4)	1	0	1
	SPS 550	1 (3)			
	Unspecified	1 (1)			

Dialysers

- 13 The most commonly used dialyser was the hollow-fibre normal flux dialysers. These were used by 45 units, each unit using a median of 10,000 (interquartile range 4200–14,761) per year. Nine units used flat plate normal flux dialysers (a median of 10,000 were used by each unit per year). Twelve units used hollow-fibre high flux dialysers but these were used in smaller quantities (median of 1000 per unit per year).
- 14 Only 6 (11%) of 55 units ever re-used dialysers. All of these six units only re-used dialysers for the same patient and only one unit would re-use a dialyser for a patient with HBV, HIV or HCV infection.

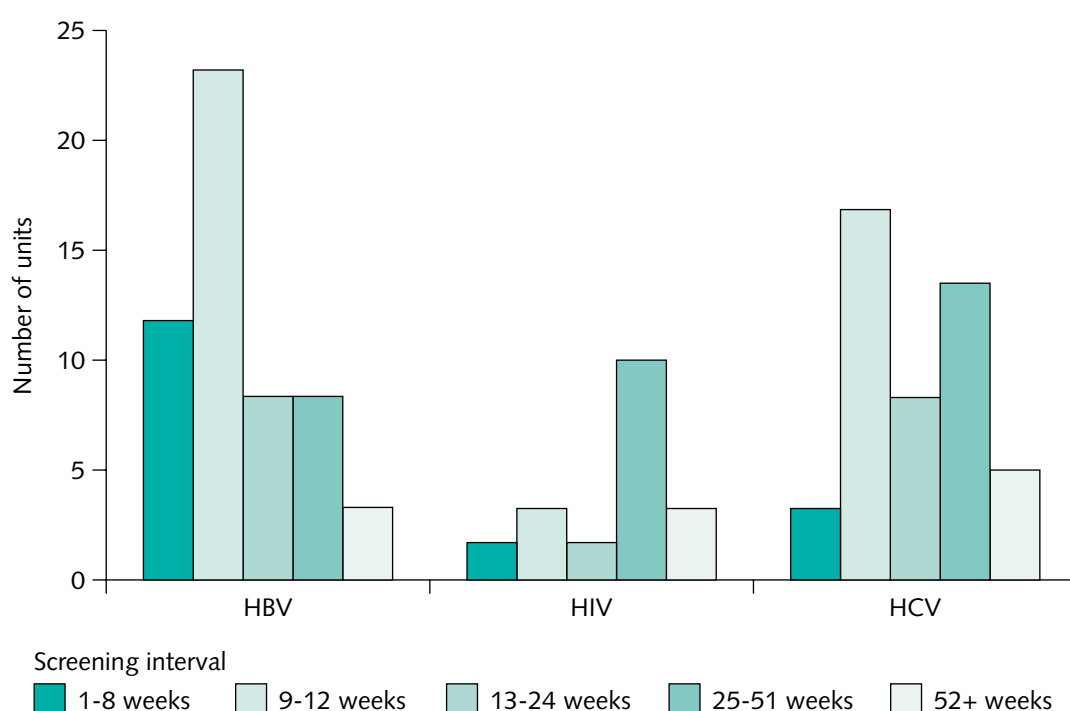
BBV screening for patients

- 15 Most units screened patients prior to commencing dialysis and regularly during maintenance dialysis for HBV (Table 5) but the screening interval was variable between units. Fewer units screened haemodialysis patients for HIV and HCV and where they did the interval between screening tests was longer than for HBV (Figure 1). Screening of patients in other risk groups was less commonly performed.

Table 5: Indications for screening patients for HBsAg, HIV and HCV

Indication	HBsAg (n=55) N (%)	HIV (n=55) N (%)	HCV (n=55) N (%)
At initial presentation	34 (62%)	9 (16%)	23 (42%)
Before commencing maintenance haemodialysis	53 (96%)	22 (40%)	44 (80%)
Before commencing maintenance peritoneal dialysis	49 (89%)	17 (31%)	36 (65%)
At regular intervals during maintenance dialysis	53 (96%)	23 (42%)	46 (84%)
After return from dialysis outside UK	38 (69%)	22 (40%)	32 (58%)
At regular intervals after return from dialysis outside UK	42 (76%)	19 (34%)	35 (64%)
For clinical/diagnostic purposes	41 (75%)	37 (67%)	38 (69%)
After involvement in needlestick exposure	43 (78%)	29 (53%)	32 (58%)
Before dialysis for acute renal failure	49 (89%)	16 (29%)	30 (55%)
Before joining transplant list	48 (87%)	49 (89%)	46 (84%)
Immediately prior to any transplant	23 (42%)	21 (38%)	21 (38%)
At regular intervals after transplantation	14 (25%)	3 (5.0%)	11 (20%)
After transplant failure before dialysis	42 (76%)	14 (25%)	33 (60%)

Figure 1: Screening of patients on maintenance haemodialysis for HBV, HIV and HCV infections



Prevalence of BBV infections

- 16 There were 81 patients known to be HBsAg positive (range 0–6 per unit) (Table 6) and at least one HBsAg positive was reported from every English region, Wales and Scotland. The unit in Northern Ireland reported no HBsAg positive patients. Only 10 HIV positive patients were reported and all were from units in the Thames regions. Forty-one units reported a total of 262 patients who were positive for anti-HCV. Patients infected with HCV were reported from all English regions, Wales, Scotland and Northern Ireland. The highest number of HCV infections were reported from units in North and South Thames and from Scotland.

Table 6: Prevalence of blood-borne virus infections (units with denominator information only)

Risk group	Number (estimated prevalence) of		
	HBsAg positive	HIV positive	HCV positive
Maintenance haemodialysis in hospital	28/5246 (0.53%)	5/5190 (0.10%)	115/5190 (2.2%)
Maintenance peritoneal dialysis	24/4472 (0.54%)	5/4213 (0.12%)	46/4213 (1.1%)
Functioning renal transplant	21/10,370 (0.20%)	0/10,743 (0.0%)	79/10,743 (0.74%)
Chronic renal disease	7/5376 (0.13%)	0/5176 (0.0%)	2/5176 (0.04%)
Maintenance haemodialysis at home	1/1092 (0.09%)	0/1075 (0.0%)	5/1075 (0.47%)

Acquisition of BBV infection

- 17 Nine units reported that one or more patients under their care had acquired HBV infection, 19 reported acquisition of HCV infection and 2 reported acquisition of HIV infection in the period 1991–1995.
- 18 Twelve cases were described who had acquired HBV, although one infection was acquired before the survey period (in 1990). Of the remaining 11, five were thought to have been acquired during transfusion or dialysis overseas. One infection was thought to be due to reactivation of an old infection following a transplant. The remaining six cases were thought to have been acquired in the UK, one from sexual contact, one from IV drug use, and in the remaining four cases the source of the infection was not known.
- 19 Thirty three separate acquisitions of HCV were described of which 4 were known to have been acquired prior to 1991, and 3 were found to be anti-HCV positive on the first test. Of the remaining 26, eight were thought to have been acquired from dialysis, transfusion or transplant overseas. Of the remaining 18 cases, six were thought to have been acquired from haemodialysis in a UK renal unit (three in 1992, two in 1994 and one date unspecified), four were thought to have been acquired via blood transfusion (no dates were specified for these cases), one from a transplant in 1994, and one by IV drug use. In the remaining cases the information was not available.
- 20 Two cases of HIV acquisition were reported, one was in a patient on continuous ambulatory peritoneal dialysis with no known exposure. The second case was in a patient was Afro-Caribbean origin but it was unclear whether infection had been acquired in the UK or overseas.

Management of BBV infected patients

- 21 Few units managed patients with BBV infections in the same way as uninfected patients (Table 7). Only one unit managed patients who were infected with HBV or HIV the same as uninfected patients but 7 (13%) of 52 units had no special management policy for HCV infected patients. Amongst those units with special management policies for infected patients, there was no consistency in the policies across all the units. Designation of machines for use by that patient, or for all patients with that infection, and dialysis in a separate room were common approaches to patients who were infected with HBV but policies for patients with HCV or HIV were less consistent across the units.

Table 7: Managing patients with HBV, HCV and HIV

Management policies	HBV	HIV	HCV
Designate a dialysis machine for individual patient or only for patients with that virus	44/52 (85%)	39/54 (72%)	37/54 (69%)
Dialyse the patient in a separate room or in separate area for patients with that infection	39/52 (75%)	21/54 (39%)	31/51 (61%)
Prefer to treat by peritoneal rather than haemodialysis	32/51 (63%)	23/52 (44%)	29/51 (57%)
Designate a nurse to treat only that patient during a session	21/53 (40%)	9/54 (17%)	12/52 (23%)
Refer the patient for treatment in a renal unit elsewhere	13/53 (24%)	4/54 (7.4%)	7/52 (14%)
Never offer that patient a renal transplant	13/47 (24%)	10/50 (20%)	33/46 (72%)

Immunisation policy for patients

- 22 Few units offered hepatitis B vaccine to all patients with chronic renal disease and 27 (49%) units did not offer vaccine to any patient groups (Table 8). Of the 23 units who offered vaccine and who responded to the question, 12 (52%) prescribed the majority of vaccine themselves, 8 (35%) left the prescription mainly up to the GP and in 3 units the volume of vaccine prescriptions was evenly split between the GP and the unit.

Table 8: Use of hepatitis B vaccine for patients

Groups of patients offered hepatitis B vaccine	No (%) of units offering
All patients with chronic renal disease (including dialysis)	9 (16%)
Patients with chronic renal disease (not on dialysis)	1 (2%)
Patients on haemodialysis and peritoneal dialysis	7 (13%)
Patients on haemodialysis only	3 (5%)
Patients who will be treated outside UK	7 (13%)
Other groups	1 (2%)

Immunisation and screening policy for staff

- 23 The majority of units reported that over 50% of staff at risk had been vaccinated and successfully immunised against HBV (Table 9). Fifty two (95%) units tested staff for anti-HBs after immunisation. Most units pursued active policies of screening new staff for HBsAg but fewer were screening staff at

regular intervals in the absence of needlestick injury (Table 10). Screening of staff for HCV and HIV infection was much less common, except at the time of a needlestick injury.

Table 9: Number of units that have staff vaccinated and successfully immunised against HBV

Staff in unit (%)	Staff groups					
	Medical Staff		Nursing staff		Technical staff	
	Fully vaccinated	Fully immunised	Fully vaccinated	Fully immunised	Fully vaccinated	Fully immunised
>90%	43	31	49	34	42	32
>50%	48	42	53	48	44	42
>10%	49	42	53	48	45	42
Total	49	42	53	48	46	42

Table 10: Number of renal units testing staff for HBV, HIV and HCV

Indication	Screening test	No. (%) of renal units
Prior to employment	HBsAg	47 (85%)
	anti-HIV	0 (0%)
	anti-HCV	3 (5%)
At regular intervals during employment	HBsAg	36 (65%)
	anti-HIV	0 (0%)
	anti-HCV	1 (2%)
During needlestick injury follow up	hepatitis B markers	46 (84%)
	anti-HIV	11 (20%)
	anti-HCV	20 (36%)

Annex 3

Tests for BBV infection in renal units

- 1 The viruses which are known to present the greatest risks, and for which adequate serological and other tests available, are HBV, HCV and HIV. A theoretical risk exists of transmission of other viruses, e.g. human T cell lymphotropic viruses I and II but, in the absence worldwide of frequent reports of their transmission in the context of the treatment of renal disease, screening for these viruses is not justified. Summaries follow of the laboratory tests available for the investigation of HBV, HCV and HIV 1 and 2.

Description of serological markers

HBV

- 2 The basic screening test for HBV infection is for its surface antigen, HBsAg, and current HBsAg ELISAs are extremely sensitive. Tests for antibody to HBsAg (anti-HBs) are indicative of immunity to HBV whether naturally acquired or the result of immunisation. Most recipients of hepatitis B vaccine make an anti-HBs response greater than 10 mIU/ml within 1 month of completing a full course of vaccine. However, patients in renal units often fail to make an anti-HBs response after repeated doses of vaccine, even though they may be partially protected. Moreover, under immunosuppressive treatment, anti-HBs positivity may be lost, and a patient may then become HBsAg positive either through recrudescence of latent infection or through re-infection.
- 3 Tests for antibody to the core antigen of HBV (anti-HBc) are useful in two situations. IgM antibody (IgM anti-HBc) is present at high titre in acute HBV infection, whether jaundice is present or not; IgG antibody to the core antigen (IgG anti-HBc) is a more persistent antibody and is seen both in carriers of HBV (almost all of whom are also HBsAg positive), and in those who have recovered from HBV infection. Anti-HBc is not found in vaccinees who have never been exposed to natural infection.
- 4 The remaining serological markers of HBV infection are the e-antigen and its antibody (HBeAg and anti-HBe). These are found in carriers of HBV infection and they are a qualitative measure of viraemia. Almost all high-titre carriers of HBV are HBeAg positive. Those who, though HBsAg positive, are also anti-HBe positive are, with rare exceptions, a much lower infection risk to others. In the case of renal patients, especially those who are immunosuppressed, high-titre carriage of HBV is relatively common.
- 5 In addition to these serological tests for HBV, the DNA of the virus can be detected using the polymerase chain reaction (PCR) or other DNA amplification procedures. Amplification and sequence analysis, or comparable procedures that detect minor variations in nucleotide sequence, are the basis of modern HBV sub-typing and finger-printing investigations and they show how a particular strain of HBV has spread in a clinical unit. These techniques have superseded serological sub-typing of HBsAg.
- 6 Both tests for HBsAg and anti-HBs are usually available at a local level and they are sensitive, and relatively specific. Nevertheless, positive reactions for HBsAg should be confirmed by neutralisation or by another HBsAg assay, and by testing a second specimen. Truly HBsAg positive specimens are also almost invariably anti-HBc positive unless they have been collected in the prodromal phase of HBV infection, a point which can be established by follow up. All PHLS Group and some university hospital and other laboratories offer a fuller range of serological tests for HBV including IgM and IgG anti-HBc, and HBeAg/anti-HBe assays. These laboratories will also provide advice and refer specimens to specialist centres for HBV sequence analysis.

HCV

- 7 Tests for HCV infection have developed progressively since 1989 when the virus was first characterised. The most recent tests for antibody to HCV (anti-HCV) are generally sensitive and specific enough to be a firm basis for diagnosis and control of infection in renal units. However, serum samples from patients receiving haemodialysis may give weakly reactive results in HCV antibody assays and results should be interpreted with caution; they may be non-specific. In tests on serum from the main risk group, intravenous drug users, there is a close correlation between anti-HCV positivity and presence of the other HCV marker, HCV RNA.
- 8 HCV RNA is usually detected in serum or plasma by reverse transcription and PCR amplification (see below). Studies of acute HCV infection following infection by transfusion suggest that conversion to anti-HCV positivity (as measured by the latest generation of ELISA) usually occurs within 4 to 6 weeks of exposure, but by other infection modes, e.g. needlestick, seroconversion may be delayed for up to 12 weeks. Positive anti-HCV reactions should be confirmed by testing a second specimen and using complementary ELISAs and/or the RIBA immunoblot. HCV RNA tests should be done if there is doubt about the validity of HCV antibody test results. These tests are available in PHLS Group laboratories and at some university hospital centres. Since 1999, an HCV antigen assay has become available which detects antigen in the absence of HCV antibody. It becomes positive several weeks before anti-HCV appears, and may be useful in the investigation of a suspected outbreak of HCV.
- 9 There is no validated assay for IgM antibody to HCV, which is probably a weak serological response. The earliest marker of HCV infection to appear is HCV RNA in serum or plasma, which is detectable by PCR within 2 to 3 weeks of exposure. Other tests for HCV RNA (e.g. NASBA, branched chain DNA) are not yet fully evaluated. As HCV RNA may persist in plasma and serum after acute infection, a positive test result is consistent with but not indicative of acute infection.
- 10 Up to 80% of infections with HCV become chronic, with persistence of virus in the liver and viraemia. This carrier state is characterised by anti-HCV positivity which lasts for several years (and may often be lifelong) and persistence of HCV RNA.
- 11 The interpretation of changes in HCV RNA is controversial. In general, the loss of positivity correlates with normalisation of liver function tests and on liver biopsy absent or only mild hepatitis without fibrosis. This may signal recovery, with elimination or suppression of the virus and possibly loss of anti-HCV at a later stage. Conversely, persistent high-titre HCV RNA (for HCV quantification, see below) may be associated with abnormal liver function and active hepatitis. There is evidence that renal patients, perhaps due to immunosuppression, may retain a high titre of HCV RNA in the absence of severe liver damage.
- 12 In the absence of blood screening for HCV before 1991, some renal patients, especially those receiving long-term haemodialysis, were infected with HCV. Transmission from them to other renal patients may have occurred, though this is rare in the UK. Renal patients may have some intrinsic immunosuppression and those who are chronically infected with HCV are more likely than other carriers to have a high-titre viraemia, especially if they are receiving immunosuppressive treatments. These patients usually remain anti-HCV positive, except when HCV infection may have been acquired in the course of transplantation. It is therefore generally unnecessary to use PCR as well as anti-HCV assays to screen for infection in renal units.
- 13 PCR will, however, be needed if there is evidence of a recent introduction of infection and if, therefore, new infections are being sought. PCR confirmation should also be carried out if there are doubts about the validity of anti-HCV assay results, particularly if weakly positive reactions are found. It is not known how long seroconversion may be delayed in renal patients, but it is possibly longer than in other HCV risk groups (e.g. injecting drug users). This would justify the use of the much more expensive PCR assay and the HCV antigen assay to investigate possible new introductions of infection into a renal unit. There

may be other situations in which PCR needs to be used even though it is not generally recommended for screening purposes. Where PCR assays are used, they should be of proven specificity and quantifying PCR assays for HCV RNA may also be employed. There is a need to obtain a repeat specimen to confirm HCV RNA positive results, otherwise unjustified and costly interventions intended to control cross-infection may ensue.

HIV

- 14 The diagnostic test of choice for HIV infection is an antibody test. Intensive study of the progressive immunosuppression that develops during HIV infection, culminating in AIDS, has shown that seropositivity is very rarely if ever lost. It may therefore be assumed that HIV infected renal patients, even if immunosuppressed, will remain anti-HIV positive.
- 15 No known outbreak of HIV has yet occurred in a UK renal unit, and little information is available about the possible pattern of spread if such an introduction were to occur. The rapidity of development of markers of HIV infection following transmission to a renal patient may depend on the dose and the route of contamination, as well as on the degree of pre-existing immunosuppression. Unlike HCV, PCR tests for HIV RNA become positive only 1 to 3 weeks before the most sensitive anti-HIV tests, and tests for anti-HIV are therefore adequate to detect HIV infected renal patients except at the earliest stage of infection. To investigate a suspected introduction of HIV into a renal unit, therefore, the patient should first be screened using sensitive anti-HIV ELISAs. Any initial positive reaction should be repeated. If reactivity is still present, this should lead to collection of another sample and confirmatory tests on both samples. In the case of renal patients this should include both a Western blot and PCR amplification of HIV RNA. A high index of suspicion of an outbreak might lead to immediate tests of patients for HIV RNA.
- 16 Serum tests for the p24 antigen of HIV are inferior to PCR for early diagnosis, although they might have a role in assessing the potential infectivity of an HIV infected renal patient. The quantitative assays for HIV RNA are probably better for this purpose. A full range of confirmatory assays, which should always include testing of follow-up specimens, is available in PHLS Group and some university hospital laboratories.

Choice of test and laboratory

- 17 Tests for markers of HBV, HCV and HIV infection are the subject of regular evaluation, both by the Medical Devices Agency and as reported in studies published in scientific journals. Although single rapid test devices are increasingly being introduced that allow 'near-to-patient' testing, these are in general less accurate than ELISAs and comparable assays developed for transfusion and diagnostic laboratory use. It is therefore advisable for renal units to use the services of a virological laboratory that can offer a full range of ELISA tests and access to PCR assays. In any case the unit should communicate regularly with a virologist or microbiologist familiar with their work to discuss appropriate immunisation, testing and screening strategies, and infection control.
- 18 The specimens collected from patients for virological tests should be appropriate and drawn into the correct containers, and transported without delay to the laboratory. Interpretation of the results of serological and viral genomic tests in renal patients may not be straightforward. A long-term partnership between the clinical team and a virologist or microbiologist with a special interest in the needs of renal patients will help prevent BBV infections in the renal unit. It will also mean that control measures are rapidly put into effect if a BBV infection is inadvertently introduced.



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