

THE PREVENTION OF TRANSMISSION OF BLOOD-BORNE DISEASES IN THE HEALTH-CARE SETTING



DEPARTMENT
OF HEALTH AND
CHILDREN
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**THE PREVENTION
OF TRANSMISSION OF
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IN THE HEALTH-CARE
SETTING**

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Foreword



As Tánaiste and Minister for Health and Children, I am very pleased to publish and endorse this report as health policy on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting. The Department of Health and Children established the Standing Advisory Committee to provide a code of practice which should underpin the approach to patient and health care worker protection from blood-borne viruses. The protocols contained in the report meet that requirement and it is my intention that the report will be updated in keeping with developments and best practice in this area on an ongoing basis.

The incidence of blood-borne viral infections has increased in Ireland in recent years. In the health-care setting, it is well documented that health-care workers are at risk of infection by blood-borne viruses. Patients may also be at risk of infection from an infected health-care worker. Health care should always be provided with compassion and dignity in compliance with best practice in relation to safety and standards of care. Health-care workers, especially those involved in exposure-prone procedures, should take all appropriate precautions in order to prevent the transmission of blood-borne diseases and promote a safe and healthy work environment to protect themselves, their patients and their co-workers. This requires the implementation and application of the best practice protocols contained in this report. It is the responsibility of both employers and employees to take appropriate steps to prevent the potential exposure of health-care workers and patients to blood-borne diseases.

Since the last report in 1999, there have been significant developments in the prevention of these infections. Based on previous experience, new ways of co-ordinating look-back exercises are recommended in this report. New protocols include a requirement to test health-care workers for hepatitis B virus and, where indicated, to vaccinate them. Testing for hepatitis C virus for health-care workers involved in exposure-prone procedures is also required so as to reduce transmission in the health-care setting.

Recommendations on improved safety devices to reduce the risk of needle-stick injuries are included and there is an increased emphasis on precautionary measures to protect the health and safety of health-care workers. A chapter on reducing blood-borne virus transmission in the dialysis setting is included for the first time. These measures should be taken with all patients in all health-care facilities at all times by all staff in both the public and private health-care sectors.

The report also provides practical advice on procedures following the identification of infected health-care workers and on measures to be taken to reduce the risk to patients. The importance of respecting the confidentiality and employment rights of infected health-care workers is highlighted. Patients and health-care workers are entitled to expect the highest standards in relation to the prevention of blood-borne virus infections. These protocols provide advice in the area of risk management and infection control and should apply across the public and private health-care sectors.

On behalf of the Department of Health and Children, I would like to thank the Standing Advisory Committee and the many organisations which contributed to the report. The Health Strategy Quality and Fairness: A Health System for You highlighted the need for quality and continuous improvement to be embedded in daily practice to ensure consistently high standards. The implementation of these protocols will provide a standardised quality system that supports the safety of both patient and health-care worker by minimising the transmission of these infections. I am confident the result will be a significant reduction in the risk faced by health-care workers and by patients, of contracting blood-borne infections in the health-care setting.



Tánaiste and Minister for Health and Children

Acknowledgements

This report of the Standing Advisory Committee on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting reflects a significant commitment on behalf of members of the group.

The Standing Advisory Group consulted with many organisations and individuals and appreciates the submissions that have been made which have enhanced the quality of the report.

I would like to thank the members of the Advisory Committee for all their efforts in preparing this report. In particular, I wish to express my gratitude to Dr Brian O’Herlihy as vice chair and to Dr Patrick O’Sullivan for acting as medical secretary to the committee. Finally, a special word of thanks to Ms Pauline Brady for seeing this report to its final form.

Our intention is that these protocols will contribute towards better patient and health-care worker protection from blood-borne virus infections in the health-care setting.



Dr John Devlin

Deputy Chief Medical Officer (Chair)

EXECUTIVE SUMMARY

The risk of transmission of blood-borne pathogens in the health-care setting has become a matter of increasing concern in Ireland in recent years. Health-care workers undertaking exposure-prone procedures are at risk of contracting blood-borne diseases from the patients they are treating and there is also a small risk that patients who are undergoing such procedures may become infected by the health-care workers who are treating them. An Advisory Group on the Transmission of Infectious Diseases in the Health-Care Setting was established in 1995 to advise the Minister for Health on the prevention of the transmission of such diseases. The Advisory Group published its report in 1997. It was realised at that time that this matter would need to be kept under review and a Standing Advisory Committee was established. Guidelines on this subject were published by the Advisory Committee in June 1999. In the current document, these guidelines have been substantially revised in the light of recent information and technical developments and are now considered to be a Code of Practice in the area of prevention of the transmission of blood-borne pathogens in the health-care setting.

For the purposes of this report, exposure-prone procedures (EPPs) are considered to be those procedures where there is a risk that injury to the health-care worker may result in exposure of the patient's open tissues to the blood of the worker. They have been more precisely defined as procedures which involve surgical entry into tissues, cavities or organs or repair of major traumatic injuries, vaginal or Caesarian deliveries or other obstetric procedures during which sharp instruments are used; the manipulation, cutting or removal of any oral or perioral tissues including tooth structure, during which bleeding may occur. EPPs include situations where the worker's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space, where the hands or finger tips may not be completely visible at all times. EPPs would not usually include giving injections, taking blood, setting up IV lines, minor surface suturing, the incision of abscesses or uncomplicated endoscopies.

The viruses identified as risks for transmission to patients in the health-care setting include hepatitis B, hepatitis C and human immunodeficiency virus (HIV). The possibility of the transmission of other as yet unidentified viruses cannot be dismissed. This document reviews the risk of transmission, looking at the nature, duration and severity of that risk and the probability of transmission, both from health-care workers to patients and vice-versa, for each of the identified viruses. It concludes that, provided infection control procedures are adhered to, contact between health-care workers and patients carries little or no risk of transmission of blood-borne pathogens.

The document examines in more detail the risk management and infection control policies that are most effective in preventing the transmission of blood-borne pathogens in the health-care setting. Hepatitis B prevention must be based on the vaccination of all health-care workers at risk of infection. This is of particular importance for those undertaking exposure-prone procedures. The Code of Practice advocates the adoption of a risk management approach that not only encourages the active compliance of the health-care worker with infection control procedures but also requires an analysis of the working environment, conditions and practices that might contribute to the transmission of blood-borne diseases. While the protocols relate generally to preventing transmission of BBVs from HCWs to patients, they can also be adapt-

ed to situations involving potential transmission between patients or from equipment to patients. The risk management process involves the identification of risk, the analysis of risk, the elimination or reduction of risk, the ongoing evaluation of the risk management process and occurrence management. In reducing risk, the appropriateness of screening and vaccination should be considered. Standard precautions **must** be observed and improved safety devices and technology should be used.

An occurrence management strategy **must** be in place to examine accidents and infections that occur. This should include provisions for the support of the infected health-care worker concerned, including retraining or redeployment, where appropriate. Occurrence management should also include a look-back policy where risk of patient exposure has occurred. In that situation, a Local Expert Group should be convened by the Director of Public Health to consider the need for a look-back exercise. However, no look-back exercise should be undertaken without informing the national Standing Advisory Committee.

A policy for the prevention of transmission of the blood-borne pathogens under consideration is defined in this document. In general, hepatitis B prevention should be based on the screening and vaccination of health-care workers who are not already immune to the infection. Health-care workers who are infected with hepatitis B virus should submit to further testing to clarify their infectivity. **The immune status of health-care workers involved in EPPs must be established and then vaccination performed as appropriate.** Hepatitis C prevention should likewise be based on the screening of all health-care workers who undertake EPPs for antibodies to HCV and, if positive, proceeding to PCR testing for hepatitis C RNA, to further determine their infectivity. This screening process should be introduced on an incremental basis. Screening of health-care workers for HIV is not considered a desirable option but this will be kept under review. There are currently no vaccines available for hepatitis C or HIV. Prevention of transmission of these viruses relies on good infection control procedures. Such procedures are extremely significant in the dialysis and transplant settings, where patients may be particularly at risk of infection because of prolonged and often repeated exposure to situations where transmission is possible. There is need for strictly observed standard precautions in these settings.

The process to be followed on identification of an infected health-care worker involves several parties, including the infected health-care worker, the Occupational Health Physician, the Infectious Diseases Consultant, the Director of Public Health and the CEO of the employing authority. Retraining, redeployment and the provision of a support package for infected health-care workers are seen as significant aspects of the process.

Since there are other potential risks for the transmission of blood-borne pathogens in a health-care setting, hospitals should have a comprehensive infection control programme. Such programmes include infection control practices specifically designed for various settings and procedures, surveillance systems, training and education. Within an institution, specific protocols should be in place in relation to infection control for procedures where there is an increased risk of transmission, e.g. dialysis or the use of endoscopy equipment.

The adoption of these recommendations will minimise the risk of transmission of blood-borne pathogens in the health-care setting, and protect the patients who are being treated and the health-care workers who are treating them.

RECOMMENDATIONS

A Risk management and infection control

- 1 The development of risk management and infection control strategies is essential for the prevention of transmission of blood-borne pathogens in the health-care setting. Each hospital/institution or medical/dental practice should develop and adopt risk management and infection control policies that are monitored for effectiveness.
- 2 In order for risk management and infection control policies to be implemented, access to specialist advice in relation to occupational health, microbiology, infectious diseases and infection control should be made available to each hospital/institution and medical/dental practice.
- 3 Education on infection control and the application of standard precautions must be made available to all health-care workers who may be exposed to blood or other body fluids potentially contaminated with blood-borne pathogens.
- 4 Education programmes on infection control should be incorporated into the general training of medical, dental and nursing students.
- 5 Training programmes and information sessions must be provided upon initial employment and at least annually thereafter by individuals who are knowledgeable in the subject matter being presented.
- 6 Health-care institutions should apprise themselves of developments in safety devices, e.g. needle-less technology, and should invest in appropriate devices related to the pattern of risk within their organisation.
- 7 The protocols contained in this report generally apply to potential transmission of BBVs from HCWs to patients. They should be adapted for analogous situations including potential transmission of BBVs from equipment or between patients.
- 8 Standard precautions should be taken with all patients in all health-care facilities at all times by all staff.
- 9 Health-care workers should keep themselves up to date with information about developments in the area of blood-borne diseases and be aware of the risks of contracting or spreading these diseases.
- 10 Additional precautions apply to haemodialysis units – please refer to Chapter 5.
- 11 All HCWs who perform/intend to perform exposure-prone procedures should complete a BBV risk assessment to reduce potential transmission.
- 12 Contact and standard precautions should be applied to patients positive for a blood-borne virus who have uncontrolled bleeding (see Chapter 3).

B Prevention of transmission of hepatitis B virus

- 1 Health-care workers who are at risk through contact with blood or body fluids should be vaccinated against hepatitis B virus (HBV) unless immunity to the virus has already been established or the vaccine is contraindicated. Where health-care workers claim to have acquired immunity to HBV, they must satisfy their employer or the relevant Occupational Health Physician that this is the case.
- 2 **All health-care workers who undertake EPPs must be tested for HBc antibody and HBsAg, to ensure that they are not infectious carriers of hepatitis B. The interpretation of positive results, including levels of immunity after vaccination, requires professional advice such as that of an occupational health physician and/or a virologist as appropriate.**
- 3 **All health-care workers who perform exposure-prone procedures, and all medical, dental, nursing and midwifery students must be immunised against HBV, unless immunity to HBV as a result of natural infection or previous immunisation has been established.**
- 4 **The immune status of health-care workers who might, at any time, perform exposure-prone procedures (EPPs) must be established. Where such workers are identified as not having immunity to HBV, they should be vaccinated and tested to ensure that they establish immunity to HBV.**
- 5 An appropriate pre-employment occupational health assessment programme should be introduced for health-care workers. No offer of employment should be made unless this has been complied with.
- 6 Records of immunisation of health-care workers should be maintained on a confidential basis. These records may be used by the health-care worker as part of an 'occupational health history' or by employers for the purposes of establishing limits to look-back exercises.
- 7 The 'occupational health history' should be issued to individual health-care workers as a record of their immunisation. It is envisaged that the health-care worker will be able to produce this history to potential employers as evidence of such immunisation.
- 8 Health-care workers who are HBsAg positive and who perform EPPs should be tested for HBeAg. If they are positive, they are at risk of transmitting HBV to their patients and therefore should not perform exposure-prone procedures.
- 9 All HBsAg positive and HBeAg negative health-care workers should have their hepatitis B viral loads determined on three sequential samples at approximately two weekly intervals over a six-week period and the presence of HBV pre-core mutants investigated. Those health-care workers identified with viral loads in excess of 10^4 copies/ml must not perform exposure-prone procedures. This threshold will be reviewed periodically by the Standing Advisory Committee.
- 10 A look-back policy is required where the risk of patient exposure to HBV has occurred.

A Local Expert Group, convened by the Director of Public Health, may recommend a look-back exercise. However, no look-back exercise should be undertaken without informing the national Standing Advisory Committee. Occurrence management should also include a prepared strategy in respect of public relations policy and the reassurance of patients and health-care workers, where such an accident or incident has arisen.

C Prevention of transmission of human immunodeficiency virus and hepatitis C virus

- 1 Protecting health-care workers and patients from human immunodeficiency virus (HIV) and hepatitis C virus (HCV) relies on good general infection control procedures. There are no vaccines to protect health-care workers from HIV or HCV. It is recommended that screening of health-care workers who perform EPPs for infection with HCV is now initiated. This should be introduced on an incremental basis, with new trainees, new entrants and re-entrants to the Irish health system, as the initial cohort for testing. This phase should be evaluated and the outcome should inform the subsequent implementation of the process.
- 2 The HCV screening referred to above involves testing for hepatitis C antibodies (anti-HCV) and, if positive, to proceed to PCR testing for hepatitis C RNA, to establish if the HCW is an infectious carrier of hepatitis C. The need for screening of health-care workers for infection with HIV will be kept under review. Health-care workers infected with HCV who are PCR positive must not carry out EPPs until the risk has been assessed. This assessment should include measurement of viral load. The interpretation of positive results requires professional advice such as that of an occupational health physician and/or a virologist as appropriate.
- 3 Any health-care worker who suspects that he/she may have been exposed to infection with HIV or HCV through his/her work, or through other risk behaviours, must seek professional advice and diagnostic HIV or HCV testing.
- 4 A health-care worker known to be infected with HIV must not perform exposure-prone procedures.
- 5 Testing health-care workers for infection with HIV should not be instituted at present.
- 6 A look-back policy is required where risk of patient exposure to HIV or HCV has occurred. Local Expert Groups, convened by the Directors of Public Health, may recommend a look-back exercise. However, no look-back exercise should be undertaken without informing the national Standing Advisory Committee. Occurrence management should include a prepared strategy in respect of public relations policy and the reassurance of patients and health-care workers, where such an accident or incident has arisen.

D Dialysis and renal transplant settings

- 1 BBV prevention and control in the dialysis and renal transplant settings require comprehensive implementation of infection control guidelines, together with segregation of infected patients and their equipment.
- 2 Screening and vaccination protocols should be implemented before commencing dialysis as well as when on treatment.

E Identification of infected health-care workers

- 1 Voluntary disclosure of risk of infection is considered to be the most effective method of identifying infected health-care workers. It is important that employers have in place a supportive environment to facilitate this. On commencement of employment, all employees should be made aware of the risk factors for acquiring blood-borne diseases and of their ethical duties to disclose to an appropriate physician any blood-borne infection or risk of infection. The employing authority should ensure that health-care workers have read and understood their ethical duty to inform the appropriate authorities, if they might be infected or at risk of infection.
- 2 Once notified by an infected health-care worker of his/her status, the physician should inform the Director of Public Health on an anonymous basis, who should then decide what action, if any, needs to be taken. If there is any possibility of risk to patients, at present or in the past, the Director of Public Health should convene a small team of relevant experts, the Local Expert Group, to anonymously assess the case. If there is no current or past risk to patients, no further action is taken. If there is a current risk to patients, a restriction in work practices will be recommended. The infected health-care worker and also the CEO of the employing authority should be told of the need for restriction. It is important that these restrictions are adhered to by the HCW and the employing authorities. The local Expert Group will also assess the need for a look back exercise.

F Redeployment, retraining and/or support

- 1 Every effort should be made to retrain or re-deploy infected health-care workers, where appropriate.
- 2 The Training bodies should be cognisant of the difficulties posed by the identification of an infected health-care worker who requires retraining and should take these into consideration when organising training positions.
- 3 Appropriate support arrangements should be instituted for permanent employees who are unable to work as a result of being infected with a blood-borne pathogen.
- 4 A mentoring system that would provide support and information on the financial, medical and career consequences of infection would be of benefit to an infected

health-care worker. The specialist faculties should set up such a system that the infected health-care worker could avail of, if he/she so wished.

- 5 The medical, dental and nursing schools, as well as the faculties of the colleges, should take account of national guidance in developing policies for students and members of faculties.



CHAPTER 1: INTRODUCTION

1.1 Background

The transmission of blood-borne pathogens in the health-care setting has become a matter of increasing public interest and concern over the past number of years. There have been several reports of health-care workers (HCWs) infected with blood-borne pathogens, who had been involved in exposure-prone procedures. There have also been reports of infections being transmitted due to contaminated equipment. Look-back exercises, where patients are notified that they may have been exposed to a risk of infection from an infected health-care worker or for other reasons, have been undertaken amid much public alarm and media coverage.

While the emphasis in this Code of Practice is on the prevention of person-to-person transmission of blood-borne diseases, there are many other circumstances within the health-care setting where transmission can occur, for example from contaminated equipment. The principles set out in the Code of Practice must also be followed in such instances.

An Advisory Group on the Transmission of Infectious Diseases in the Health-Care Setting was established by the Minister for Health in February 1995 to 'advise the Minister for Health regarding the prevention of transmission of infectious diseases in the health-care setting'. Its report was published in January 1997.¹ This report stated a set of general principles that would underpin the approach to the protection of patients and health-care workers in relation to blood-borne viruses. It required all new employees whose work necessitated them carrying out exposure-prone procedures to provide evidence either that they had been vaccinated and were immune or that they were non-infectious carriers of hepatitis B virus. The group did not make recommendations regarding human immunodeficiency virus or hepatitis C virus.

On 17 December 1996, the Minister for Health announced the setting up of a Committee to 'report on the further measures which need to be taken in relation to a range of issues not addressed by the Advisory Group and which will also function as a central resource for the foreseeable future. The group will, inter alia, in conjunction with the Medical Council and An Bord Altranais, ensure that there is an integrated and complementary approach to dealing with the service, personnel, ethical and legal matters arising for health-care workers and patients in relation to infectious diseases'.

The Committee considered the prevention of transmission of hepatitis B virus, hepatitis C virus and human immunodeficiency virus in the health-care setting. It met on 6 occasions between January and May 1997. A document was circulated for comments and submissions were received in 1997 and 1998. A guidance document was published in February 1999.² The purpose of this document was to present guidelines that would protect patients and health-care workers from the transmission of blood-borne pathogens. In so doing, the guidelines had regard to medical, legal, ethical and practical issues, and to the rights of both patients and infected health-care workers.

The National Standing Advisory Committee was reconvened to review technical developments that had taken place and to review how the guidelines worked in practice.

The following were appointed members of the group:

Dr John Devlin <i>Chair</i>	Deputy Chief Medical Officer, Department of Health and Children <i>Seconded to other duties from May-October 2001</i>
Dr Brian O'Herlihy	Specialist in Public Health Medicine, Health Service Executive (HSE)-Eastern Region (formerly Eastern Regional Health Authority) <i>Acted as Chairman from May-October 2001</i>
Dr Derval Igoe Medical Secretary	Specialist in Public Health Medicine, HSE-Health Protection Surveillance Centre (formerly National Disease Surveillance Centre) <i>Resigned</i>
Dr Patrick O'Sullivan <i>Medical Secretary</i>	Specialist Registrar in Public Health Medicine, HSE Eastern Region <i>(formerly Eastern Regional Health Authority)</i> <i>Replaced Dr Igoe as Medical Secretary</i>
Dr Karina Butler	Consultant in Paediatric Infectious Diseases, Our Lady's Hospital for Sick Children (OLHSC)
Dr Mary Cronin	Specialist in Public Health Medicine, HSE-Health Protection Surveillance Centre
Professor Denis Cusack	Director, Department of Legal Medicine, University College Dublin (UCD)
Dr Stephen Flint	Senior Lecturer/Consultant in Oral Medicine, Dublin Dental Hospital, Trinity College Dublin (TCD)
Dr John Gallagher	Occupational Health Physician, HSE Southern Region, Cork
Professor William Hall	Director, National Virus Reference Laboratory, UCD, Belfield, Dublin
Dr Jeff Connell	Assistant Director, National Virus Reference Laboratory, UCD, Belfield, Dublin.

Dr Blánaid Hayes	Occupational Health Physician, Beaumont Hospital, Dublin
Professor Brian Keogh	President, Royal College of Physicians of Ireland
Dr Fiona Mulcahy	Consultant in Genito-Urinary Medicine, St James's Hospital, Dublin
Ms Margaret Nadin	Infection Control Nurses Association <i>Replaced Ms Prout</i>
Ms Sheila Donlon	Infection Control Nurses Association
Dr Joan O'Donnell	Specialist in Public Health Medicine, HSE-Eastern Region <i>Resigned</i>
Dr Lelia Thornton	Specialist in Public Health Medicine, HSE-Health Protection Surveillance Centre <i>Replaced Dr O'Donnell</i>
Mr Larry O'Reilly	Principal Officer, Department of Health and Children
Ms Siobhán Prout	Infection Control Sister, St Vincent's Hospital, Dublin <i>Resigned</i>
Dr Gerard Sheehan	Consultant in Infectious Diseases, Mater Misericordiae University Hospital, Dublin

1.2 Legal and ethical background

A primary principle of health-care is that of *primum non-nocere* or 'first, do no harm'. It is of the utmost importance that no harm should be done to patients through any intervention.

It is the position of this Advisory Committee that, in relation to blood-borne disease, this principle must go further and that it is the duty of all health-care workers to actively take steps to protect themselves and their patients from disease. This includes being tested and immunised, if appropriate, and strictly adhering to standard precautions and to the Code of Practice set out in this document.

The Code of Practice set out in this document is not optional and must be followed and adhered to by all health-care workers. There exists a moral and legal obligation on both health service providers and health-care workers to ensure the protection of workers and patients alike.

The Medical Council's Ethical Guidelines for Medical Practitioners (2004) state that it is clearly unethical for doctors who consider that they might be infected with a serious contagious disease not to seek and accept advice from professional colleagues as to how far it is necessary for them to limit their practice in order to protect their patients.³ These guidelines, therefore, clearly place an ethical duty on doctors to protect patients from harm. In addition, doctors who are consulted for advice must recommend appropriate restrictions to practice, where indicated, and also ensure, as far as possible, that this advice is carried out. Failure to act on such advice must be reported to the Fitness to Practice Committee of the Medical Council. Breach of the Medical Council's Ethical Guidelines is subject to disciplinary action by the Fitness to Practice Committee, which has the power to admonish, sanction or remove doctors from the medical register.

Other health-care workers, such as dentists, dental hygienists, nurses, speech therapists and occupational therapists, are subject to guidelines, a breach of which could also be sanctioned by their appropriate regulatory bodies, for example, the Dental Council and An Bord Altranais. In 1998, the Dental Council re-issued their ethical guidelines, Professional Behaviour and Dental Ethics.⁴ This updated version of the ethical guidelines stated that the dentist has an obligation to abide by the Guidelines on the Control of Cross Infection in Dentistry. Those Guidelines were issued by the Dental Council in 1993 and amended in 1996. The 1996 amendment states that it is the ethical responsibility of dentists/dental hygienists who believe that they themselves may have been infected with HIV or another blood-borne virus to obtain medical advice, including any necessary testing and, if found to be infected, to submit to regular medical supervision.⁵ Failing to seek advice or to act on advice given may raise a question of serious professional misconduct.

An Bord Altranais issued *Guidance for Nurses and Midwives with Serious Contagious/Infectious Diseases* in 2004.⁶ It is stated that a nurse or midwife who believes that he/she may have been exposed to, or be infected with, any serious contagious/infectious disease, e.g. the hepatitis viruses or HIV, should seek specialist medical advice and diagnostic testing, and adhere to the advice received. Failure to follow specialist medical advice would be in breach of the nurse's/midwife's ethical duty of care and may amount to professional misconduct. It is unethical for a nurse or midwife to continue to practice when he/she thinks they may be putting patients at risk. Any nursing/midwifery practice involving exposure-prone procedures must cease while awaiting specialist medical advice.

A doctor or other health-care worker who knowingly puts patients at risk and who infects patients may be subjected to a medical negligence case under the standard of care heading or to prosecution for criminal negligence. However, the doctor in whom the infected health-care worker has confided may feel that it is a breach of doctor-patient confidentiality to disclose information regarding infectivity to a third party such as the CEO of the employing authority. In such a situation, where the public may be at risk, a breach of confidentiality is allowed, in accordance with the Council's own guidelines. This may apply within the current or future workplace settings. Employing authorities should consider this carefully as there might be legal consequences for non-disclosure in certain circumstances.

Doctors also have a general legal duty to protect patients from harm. Health and safety legislation states that employers have a duty to protect the health and safety of their employees and to take reasonable measures to minimise risks. Employees have a duty to co-operate with safety measures.

The Director of Public Health in his/her role as Medical Officer of Health has a statutory function in relation to the surveillance and control of infectious diseases under the Infectious Diseases Regulations 1981. Medical practitioners and clinical directors of diagnostic laboratories are required to report notifiable infectious diseases, including hepatitis B and hepatitis C, to the Director of Public Health (Infectious Diseases [Amendment] No 3 Regulations 2003).

1.3 Approaches to preventing transmission of blood-borne pathogens

In developing an approach to preventing transmission of blood-borne pathogens, the following questions need to be addressed:

- What is the nature and significance of the risk and how can it be minimised?
- How should infected health-care workers be identified?
- How should infected health-care workers be managed, having regard to patient protection, the duty of care to patients, the welfare and legal rights of the infected worker, and what is feasible or practical?

Patients should be protected from contracting blood-borne virus infections from a health-care worker and the approach to prevention should reflect this. Proportionality (e.g. the rights of a HCW including that to confidentiality) is important but **proportionality must be construed in a manner which ensures that patients are protected from risk of infection**. The approaches to identifying infected health-care workers range from voluntary disclosure of risk of infection to a compulsory policy which focuses on mandatory screening of health-care workers for blood-borne pathogens and exclusion from practice, if found positive. There are problems with this latter approach. Firstly, it violates the privacy of the individual health-care worker. In the case of testing for human immunodeficiency virus (HIV), such a policy would also be contrary to the national policy on HIV testing which advocates voluntary not mandatory testing. In addition, the tests are of limited value in that repeated testing over time is required to ensure ongoing absence of infection. In particular, for HIV infection, medical

evidence is providing greater clarity on its low infectivity and that worldwide, infection control procedures have generally proved successful in preventing transmission (see Chapter 2). Secondly, the cost involved in reducing even further an already very small risk of transmission would be high, and divert resources from other areas of greater benefit to patients. However, in the case of hepatitis B, where an effective and safe vaccine exists, there are clearly benefits in screening health-care workers for this virus and immunising all of those who are found to be non-immune, thus protecting them against any risk of being infected in the future. In the case of hepatitis C, there is increasing evidence of its infectivity (unlike the case of HIV), where there have been several cases of transmission from health-care workers to patients.

In a determination of risks of infection, it is important that the process reflects best practice. The Code of Practice has been formulated to take account of the risks of infection, the ethical, legal and practical management issues, and the rights of both patients and infected health-care workers. They apply to all health-care workers in both the public and the private sectors, including visiting health-care workers and students.

Whereas this document focuses on occupational transmission of blood-borne diseases, it is incumbent on all health-care workers to take steps to ensure that they do not put themselves at risk from such diseases in their private lives. This includes the avoidance of illicit intravenous drug use and the adoption of a responsible approach to sexual activity, avoiding or protecting themselves against unsafe sexual contact.

The Standing Advisory Committee met on 12 occasions and it was acknowledged that, as there are continuing developments in the area of blood-borne pathogens, it will be necessary to update the Code of Practice from time to time, as the situation develops.

CHAPTER 2: THE RISK OF TRANSMISSION OF BLOOD-BORNE PATHOGENS IN THE HEALTH-CARE SETTING

Most contact between health-care workers and patients does not involve the possibility of blood-to-blood contact and therefore carries no risk for transmission of blood-borne pathogens. Provided infection control procedures are adhered to, exposure-prone procedures are the only procedures associated with a risk of transmission of blood-borne pathogens to patients and that risk is extremely low.

2.1 Exposure-prone procedures

An exposure-prone procedure (EPP) has been variously defined. At its simplest it can be said to be any situation where there is a potential risk of transmission of blood-borne diseases from the health-care worker to the patient during medical or dental procedures.⁷

For the purposes of this Code of Practice, an exposure-prone procedure is defined as: 'a procedure where there is a risk that injury to the health-care worker may result in exposure of the patient's open tissues to the blood of the worker'.⁸

Exposure-prone procedures are procedures which involve surgical entry into tissues, cavities or organs or repair of major traumatic injuries, vaginal or Caesarean deliveries or other obstetric procedures during which sharp instruments are used; the manipulation, cutting or removal of any oral or perioral tissues including tooth structure, during which bleeding may occur.

EPPs relate to situations where the worker's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth), inside a patient's open body cavity, wound or confined anatomical space, and where the hands or finger tips may not be completely visible at all times.

EPPs would not usually include:

- Giving injections
- Taking blood and setting up IV lines
- Minor surface suturing
- The incision of abscesses
- Routine vaginal or rectal examinations
- Uncomplicated endoscopies.

More recent documents, while indicating situations where exposure may occur, have not developed the definition of exposure-prone procedures further, nor do they indicate any reason for altering the definition of EPPs given above.⁹

2.2 Transmission of blood-borne virus infections

The three blood-borne viruses that have, to date, been identified as risks in the health-care setting are hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). The potential exists for the transmission of other as yet unidentified viruses or agents, but the risks for this cannot be quantified at this time.¹⁰

Public perceptions of risk of transmission of blood-borne pathogens have been greatly influenced by publicity concerning HIV infection. Although this virus is the least infectious of the three viruses identified as risks, it has aroused the most interest and fear. To many members of the public and some professionals, even a low probability of transmission is seen as a serious risk.

The risk of death from HIV infection after an invasive procedure by an HIV-infected surgeon, was at one time estimated to be between 2.4 to 24 per million procedures (that is 1/400,000 to 1/40,000).¹¹ This is probably an overestimate because as more information has emerged in the course of the HIV epidemic, only two HCWs are linked with transmitting HIV to patients through their work. Despite this risk being very small, many people are fearful of HIV. Public perception of the risk of acquiring blood-borne pathogens is out of proportion to the scientific probability of transmission. To put it in perspective, the risk of a fatal reaction to an anaesthetic is 1 in 10,000; of a fatal anaphylactic reaction to penicillin between 1 in 50,000 and 1 in 100,000; and of HIV infection from an infected health-care worker during an invasive procedure between 1 in 40,000 to 1 in 400,000.¹² If the HIV status of an operating surgeon is unknown, the risk of infection is one in 20 million. The risk of dying in either a plane crash or after travelling in a car for 300 miles is 20 times greater than this.¹³

Blood-borne viruses can be transmitted from health-care workers to patients or, much more frequently, from patients to health-care workers. The risk of occupational acquisition of a blood-borne virus is related to:

- The prevalence of the virus in the patient population
- The efficiency of virus transmission after a single contact with blood
- The nature and frequency of occupational blood contact.

The risk to patients of blood-borne viruses is dependent on:

- The frequency of events leading to exposure to the health-care worker's blood
- The risk of transmission associated with each event.

The viral load in the blood is probably the most important determinant of risk. Viral load can vary between and within individuals and influence the risk of acquiring infection. While most of the scientific literature refers to the risk of person-to-person transmission of these infections, it may also occur from contaminated equipment and instruments.

As part of the overall approach to minimizing the frequency of these infections in the health-care setting, all HCWs who perform/intend to perform EPPs should complete a BBV risk assessment to reduce the potential of transmission of these infections. A sample form that may be adapted for these purposes is outlined in the Appendices.

The phenomenon of clusters of transmission of blood-borne pathogens has been described mainly in connection with HBV but also with HIV and HCV, and this complicates the estimation of risk. The risks of infection with HBV, HCV and HIV are outlined in the following sections. The risk of transmission is considered under four headings:

- Nature of the risk of transmission
- Duration of the infection
- Severity of the infection
- Probability of transmission.

2.3 The risk of transmission of hepatitis B virus (HBV)

Nature of the risk of transmission

The most efficient method of HBV transmission in health care is by percutaneous exposure to infected blood. Transmission by saliva has been documented only after percutaneous exposure (e.g. bite).¹⁴

Duration of the infection

After acute HBV infection, the outcome of infection can follow one of two courses: most infections in adults (90-95 per cent) are self-limited; symptoms last for up to several weeks are followed by spontaneous recovery and the development of immunity to re-infection within six months.¹⁵ However, between 5 and 10 per cent of adults, and more than 90 per cent of babies who become infected, develop chronic infection with the virus and become carriers. The majority of such persons remain infectious for their lifetimes and can be identified by being persistently serologically positive for HBsAg. Persons with chronic HBV infection have an estimated 20 per cent lifetime risk of dying of cirrhosis and a 6 per cent risk of dying of hepatocellular carcinoma.^{16, 17}

Severity of the infection

Approximately one-third of those infected have no clinical symptoms and are unaware of the infection. A further third of patients show signs of illness and develop symptoms between four and twelve weeks after coming into contact with the virus. Symptoms include loss of appetite, malaise, nausea and influenza. Another third develop more serious symptoms, e.g. vomiting, abdominal pain and jaundice. A small percentage (<1 per cent) of persons with acute HBV infection die from fulminant liver failure during their acute illness.

Probability of transmission of HBV

HBV transmission from patients to health-care workers

HBe antigen is a serological marker associated with higher circulating viral titres. Acutely and chronically infected persons who are positive for hepatitis e antigen are generally more infectious than persons who are e antigen negative. However, individuals infected with pre-core mutant viruses which do not produce HBeAg may also have high HBV viral loads. The risk of transmission is related to the viral load and is at least 30 per cent after a needle-stick exposure with blood from an HBeAg positive source. The corresponding risk from an HBeAg negative source has been cited as less than 6 per cent.¹⁸

The risk of transmission depends on the prevalence of HBV infection in the patient population. It is estimated that 0.3 per cent of the general population of the USA is chronically infected as opposed to 0.8-4 per cent of health-care workers.^{19,20} A seroprevalence study in Ireland in 1998-1999 estimated that 0.51 per cent of the population has evidence of past infection with HBV, that is they are anti-core antibody positive.²¹ Voluntary screening of Irish antenatal patients for HBsAg shows carrier rates of 0.02-0.1 per cent.²² In sub-groups of the Irish population, however, the prevalence of HBV is higher. In a study of the Irish prison population, a prevalence of anti-core antibody of 9 per cent was identified, and this rose to 19 per cent in prisoners who were injecting drug users.²³ A study carried out in 1993 in persons with learning disabilities in institutions in Ireland found the prevalence of HBV infection to be high, with 10 per cent of clients being HBsAg positive, and between 41 and 60 per cent having markers of previous infection.²⁴ The non-residential population with learning difficulties also had higher prevalence rates than the general population, 4 per cent being HBsAg positive.²⁵ Cross-sectional seroprevalence studies in the USA show that health-care workers have prevalence rates of past or recent HBV infection 3 to 5 times higher than the general United States population.²⁶ Cohort studies in the pre-vaccination era in the USA showed an annual rate of infection among health-care workers that ranges from 0.5-5 per cent. The corresponding rate in the general population is 0.1 per cent.^{27, 28, 29, 30}

HBV transmission from health-care workers to patients

From the 1970s to December 1994, 42 infected health-care workers were recognised as having transmitted HBV in the United States and other developed countries.³¹ The number of patients infected by each health-care worker ranged from 1 to 55. More than 375 cases of HBV transmission to patients have been recognised. Of the health-care workers whose HBeAg

status was known, all were positive except one whose virus was a pre-core mutant and unable to express eAg. However, since then, there have been reports of transmission of HBV from infected health-care workers who were HBeAg negative. In 1997, four surgeons in the United Kingdom were documented as having transmitted HBV to six patients, despite being HBeAg negative.³² They were carriers of HBV with a nucleotide substitution in the precore region of the viral genome. A single base change at codon 28 encoded a premature stop codon in place of a tryptophan residue. The mutation prevents transcription of the precore region and therefore the expression of HBsAg, but allows the continued assembly of the infectious virus.

Investigation of cases of HBV has shown that clusters of infection have occurred. A study of 10 clusters of infection associated with HBV-infected surgeons in the UK between 1984 and 1993, showed transmission rates of 0.3-9.0 per cent.³³ On average, one outbreak a year has been detected in the UK over a ten year period, whereas only two such incidents have been reported from other countries. In an investigation of two clusters of transmission of HBV in 1996, transmission rates varied from 3-17 per cent, according to operator role.³⁴ The authors estimated that, at a minimum, patients might be exposed to the blood of at least one operator once in every 6 high exposure risk cardiothoracic surgical procedures.

2.4 The risk of transmission of hepatitis C virus (HCV)

HCV was first identified in 1989. Satisfactory tests to identify it were not developed until 1991. Thus, knowledge about the disease at this point in time is not complete.

Nature of the risk of transmission

The major route of transmission in health care is by exposure to infected blood and body fluids.

Duration of the infection

The average incubation period for hepatitis C following infection by a blood transfusion or a needle-stick injury is approximately seven weeks. American studies have shown that the majority of patients with acute HCV infection develop chronic HCV infection with a persistent viraemia.³⁵

Severity of the infection

Among persons with acute HCV infection, 25 per cent or fewer have symptoms of acute hepatitis. It is estimated in US populations that 67 per cent of patients have persistently elevated liver enzymes, 26-50 per cent develop chronic active hepatitis, and depending on the population, 3-26 per cent develop cirrhosis within several years of becoming infected. The NIH estimates the risk of cirrhosis to be of the order of 10-15 per cent.³⁶ In some populations the outcome can be more benign.³⁷

Probability of transmission of HCV

HCV transmission from patients to health-care workers

The risk of transmission after a needle-stick contaminated with blood from a source with detectable HCV RNA is estimated to be 6.1 per cent.^{38,39,40,41} The risk of transmission is also related to the prevalence of HCV in the patient population. Only a few studies of anti-HCV prevalence among patients have been done. These studies have shown widely divergent results, depending on the study location and the frequency of risk factors among the study groups. This has ranged from 0.5 per cent in a Canadian teaching hospital to 18 per cent of emergency room patients at an inner-city location.^{42, 43} In the Irish prison study, 81 per cent of prisoners who were injecting drug users were positive for hepatitis C, whereas non-injecting prisoners had a prevalence of 3.7 per cent.²³

HCV transmission from health-care workers to patients

Transmission of HCV from surgeons to patients is now well documented although the numerical risk is not established. The first case report was in 1995 when an infected surgeon transmitted hepatitis C to a patient during cardiothoracic surgery.⁴⁴ A second case of surgeon-to-patient transmission was documented in Spain in 1996 and occurred during open-heart surgery.⁴⁵ Since then there have been further reports in the United Kingdom, one involving gynaecological surgery, and another two in Germany, one where an anaesthesiology assistant contracted HCV from a chronically infected patient and subsequently transmitted the virus to five other patients⁴⁶ and another where one woman was infected by an HCV positive gynaecologist.⁴⁷

2.5 The risk of transmission of human immunodeficiency virus (HIV)

Nature of the risk of transmission

The major risk for transmission of HIV in the health-care setting is associated with percutaneous exposure to blood or blood-containing body fluids contaminated with HIV. Transmission can occur rarely through mucous membranes.

Duration of the infection

Patients are presumed to be infectious early after the onset of HIV infection and to remain infectious for the rest of their lives. Infectivity may be high during the initial period after infection and again as the degree of immunodeficiency worsens.

Severity of the infection

Within several weeks to several months after infection with HIV, many people develop an acute self-limited mononucleosis-like illness lasting a week or two. Infected people may then be free of symptoms for many years before progressing to clinical immunodeficiency. The

epidemiology of HIV has changed more recently with the advent of more effective treatment and the longer-term survival has changed markedly since September 1995. Death rates in Europe in 1998 were less than a fifth of their previous level largely due to new treatment combinations.⁴⁸

Probability of transmission of HIV

HIV transmission from patients to health-care workers

National AIDS/HIV surveillance data in the US give some minimum estimates of the level of HIV infection in health-care workers. Over 11,000 health-care workers have been identified through such systems, and they comprise 4.7 per cent of all notifications.⁴⁹

The risk of transmission after a single percutaneous exposure has been found from follow-up studies of exposed health-care workers to be approximately 0.3 per cent.⁵⁰ Nearly all occurred following percutaneous injury with a hollow-bore needle. However, some percutaneous exposures to HIV-infected blood may be of higher risk than others. A case control study identified the following risk factors for sero-conversion: injury by a device visibly contaminated with blood; injury with a needle that had previously been placed directly in the source patient's artery or vein; and exposure to a source patient with late-stage HIV infection with probable high HIV viral load. There have been six cases of HIV infection in Ireland where an occupational needle-stick injury was cited as a risk factor.⁵¹

Of the cases documented worldwide, 72 per cent of definite occupationally acquired cases have occurred in nurses and clinical laboratory workers, and 14 per cent of cases have occurred in medical students and doctors (excluding surgeons).⁵²

HIV transmission from health-care workers to patients

To date, throughout the world, only two health-care workers have been identified as having transmitted HIV to their patients. The first case, reported in 1991, was that of a Florida dentist who infected six of his patients.^{53, 54} The second case, reported in 1997, occurred in France, during a traumatic and lengthy procedure when a surgeon infected a patient.⁵⁵ However, the risk of such an event occurring is very low. The Centers for Disease Control, Atlanta, has used a computer model to estimate that the average risk of death from infection with HIV from a surgeon of unknown HIV status to a patient due to a percutaneous injury during an invasive procedure is between 2.4 to 24 per million. A review of all patients who had received care from health-care workers infected with HIV was undertaken by the CDC Atlanta.⁵⁶ The look-back studies related to the practices of 64 infected workers were examined. HIV results were available for 19 per cent (22,191) of their patients. One hundred and thirteen sero-positive patients were identified. Epidemiological and laboratory follow-up did not show any health-care worker to have been a source of HIV for any of the patients tested. In the UK, a recently published consultation document provides guidance on quantifying the level of risk associated with clinical procedures that are classified as exposure-prone and also lists criteria to use when assessing whether a patient notification exercise is warranted and, if so, its extent.⁵⁷

2.6 HBV, HIV and HCV transmission to patients from practices and procedures in the health-care setting

Transmission of HBV, HIV and HCV to patients in the health-care setting has occurred as a result of inadequate decontamination procedures, reuse of single use devices, and contaminated blood products.^{58, 59, 60}

Summary

When infection control procedures are adhered to, most contact between health-care workers and patients carries little risk of transmission of blood-borne pathogens. Exposure-prone procedures are the only procedures associated with a risk of transmission from health-care workers to patients and that risk is low. The widespread public fear that exists is out of proportion to the true level of risk. No procedure in medical care is risk free and the risk of transmission of blood-borne pathogens is extremely low when compared to the risks associated with other procedures and interventions. The risk to health-care workers can be further reduced by the use of safety devices as part of a comprehensive preventive programme.

CHAPTER 3: CONTROL OF INFECTION IN THE HEALTH-CARE SETTING: STANDARD PRECAUTIONS AND RISK MANAGEMENT

The most effective way of preventing transmission of blood-borne pathogens in the health-care setting is to make the working environment as safe as possible by having good infection control practices, by the implementation of standard precautions and by the provision of effective risk management policies.

3.1 Standard precautions

Standard precautions refer to a set of precautions designed to prevent or reduce the risk of transmission of HIV, HBV, HCV and other blood-borne pathogens from both recognised and unrecognised sources of infection in health-care settings. Standard precautions combine the major features of universal precautions, which were designed to reduce the risk of transmission of blood-borne pathogens,^{61, 62} and body substance isolation, which was designed to reduce the transmission of pathogens from moist body substances.⁶³ Standard precautions apply to: blood, all body fluids, secretions and excretions except sweat, regardless of whether or not they contain visible blood; non-intact skin; and mucous membranes.^{64, 65}

Standard precautions include the use of protective barriers such as gloves, waterproof gowns and aprons, water-repellent masks and protective eyewear, which can reduce the risk of exposure of the health-care worker's skin or mucous membranes to potentially infective materials. In addition, under standard precautions, it is recommended that all health-care workers take precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices.

Establishing an adequate infection control service in every health-care institution is a fundamental part of any strategy to reduce the number of incidents that occur where there is a risk of transmission of blood-borne pathogens. This requires the formation of an infection control committee and access to infection control nursing and medical microbiologist staff. This will enable the development of surveillance strategies, the formulation of relevant policies, the provision of education at all levels of service and the setting of standards for best practice. ICNs are also important in ensuring that standard precautions are observed in all exposure-prone procedures and for the development of effective risk management policies. Occupational health expertise also plays a key role in the surveillance, prevention and follow-up of occupational blood and body fluid exposures.

Essential safety procedures in the health-care setting may be summarised as follows (Table 1):

Table 1: STANDARD PRECAUTIONS

- Observe good hand hygiene practices – see NDSC guidelines 2004.⁶⁶
- Wear gloves if contact possible with blood, body fluids, non-intact skin or mucous membranes.
- Prevent puncture wounds, cuts and abrasions in the presence of blood and body fluids.
- Use safety devices where appropriate and avoid use of or exposure to sharp instruments (needles, glass, metal, etc.) when possible but, if unavoidable, take particular care in handling and disposal.
- Protect all breaks in exposed skin by means of waterproof dressings and/or gloves.
- Protect the eyes and mouth by means of a visor or goggles/safety spectacles and a waterproof mask when splashing is a possibility. (This will also protect the eyes and mouth against bone fragments in orthopaedic surgery and post-mortem examinations).
- Avoid contamination of the person or clothing by use of waterproof/water-resistant protective clothing, plastic aprons, etc.
- Wear rubber boots when the floor or ground is likely to be contaminated.
- Footwear/rubber boots should be decontaminated by a washer-disinfector.
- Health care workers should be aware of the first aid and follow up procedures to follow in the event a percutaneous or mucotaneous exposure to blood or body fluids.
- Avoid mouth-to-mouth resuscitation by using mouth pieces or resuscitation bags.
- Control surface contamination by blood and body fluids by containment and appropriate decontamination of spillages.
- Ensure that all single use items are disposed of after use.
- Ensure appropriate decontamination of reusable medical devices by following manufacturer's instructions. The NDSC CJD guidelines provide additional advice for best practice on decontamination.⁶⁷
- Dispose of all contaminated waste and sharps safely.⁶⁸
- Ensure linen contaminated with blood or body fluids is bagged appropriately at the bedside.
- The infection control committee should develop and update annually all relevant protocols as new information becomes available on best practice.

In the event of a patient infected with BBV being admitted to a health-care facility, standard precautions ensure that the patient can be cared for safely without the use of an isolation room. However, in the event of uncontrollable bleeding, it is recommended that contact precautions (see Table 2) in addition to standard precautions, are used.⁶⁹

Table 2: CONTACT PRECAUTIONS

Standard precautions

plus

1. Single room or cohort with patients with the same infection.
2. Use gloves and apron/gowns for all patient contact.
3. If possible, dedicated non-critical equipment should be for patients' use only.
4. All equipment should be decontaminated prior to re-use.

Standard precautions are effective if applied correctly and consistently. However, many health-care workers in high-risk settings do not use adequate precautions or use them incorrectly. Much work needs to be done to educate health-care workers on the need for standard precautions and to ensure that adherence to standard precautions is monitored. Employers are obliged under health and safety legislation and the Biological Agents Directive, to provide information and training in this area.

3.2 Safety devices and technology

The prevention of transmission of blood-borne pathogens from patient to health-care worker requires a comprehensive approach that considers all aspects of the work environment, including the implementation of improved safety devices such as needle-less devices and other devices with in-built safety features. This has been reviewed in a report issued by the National Institute for Occupational Safety and Health in the US.⁷⁰ The document reported on the effectiveness of devices with safety features as follows:

- Needle-less or protected-needle IV systems reduced needle-stick injuries related to IV connectors by 62-88 per cent.
- Phlebotomy injuries were reduced by 76 per cent with a self-blunting needle, 66 per cent with a hinged needle shield and 23 per cent with a sliding-shield winged-steel (butterfly type) needle.
- Phlebotomy injuries were reduced by 82 per cent with a needle shield but a recapping device had minimal impact.
- Safer IV catheters that encase the needle after use reduced needle-stick injuries related to IV insertion by 83 per cent in three hospitals.

Health-care institutions should, therefore, review their organisational measures to incorporate:

- Risk assessment of work practices that pose a significant risk of an inoculation injury hazard

- Modification of these identified hazardous practices
- The education and training of staff on the use of new devices and the disposal of sharp instruments and health-care risk waste
- The correct and appropriate use of personal protective equipment (PPE), including gloves, as required of employees in adherence to the Safety, Health and Welfare at Work Act, 1989
- The promotion of a safety culture in the workplace
- Recording and audit of all needle-stick and sharps-related incidents and other significant body fluid exposures.

Health-care workers should adopt a safe system of work by:

- Avoiding the use of needles where safe and effective alternatives are available
- Planning the disposal of devices and sharp instruments before commencing the procedure and disposing of used sharp items promptly into the sharp instruments container
- Participating in educational training on the prevention of acquisition of blood-borne pathogens
- Reporting all needle-stick injuries, sharps-related incidents and near misses.

3.3 Risk management

Risk management not only focuses on the active compliance of the individual health-care worker with infection control measures, but also requires analysis of the working environment, conditions and practices that might contribute to the risk of transmission of blood-borne pathogens in the health-care setting. The risk management process involves the identification of risk, the analysis of risk, the elimination or reduction of risk, ongoing evaluation of the risk management process itself, and occurrence management. Precautions and policies underpin effective risk management.

Identification of risk

This involves a review of the reporting systems in relation to accidents or near misses involving the transmission of blood-borne infections in the health-care setting. It is essential that the true incidence of accidents and near misses involving health-care workers is established so that effective risk management may be put in place. Reporting systems for accidents and near misses should include the incident report, information derived from

medical and surgical audit, and data derived from the occupational health department. The issue of patient confidentiality must be addressed in any such reporting system.

Risk analysis

The risks must be addressed in relation to their frequency, cost (both psychological and financial), and whether or not they are high or low risks. Risk analysis should be applied both to functional areas within the health-care institutions, e.g. theatre, accident and emergency department, and to different categories of personnel, e.g. obstetricians.

Risk reduction

The appropriateness of screening and vaccination should be considered. The entirety of standard precautions, which now replace universal precautions, should also be addressed under this heading and must include the issue of health-care students and health-care workers. The use of improved safety devices with safety features to reduce the risk of needle-stick injuries, e.g. needle-less systems, should be included in a comprehensive approach to risk reduction, thereby eliminating needle devices where safe and effective alternatives are available.

Occurrence management

All health-care employers are required to make provision for dealing with occupational blood exposures (e.g. needle-stick injuries) and must have in place a written protocol. Specialist advice should be made available through A&E departments or via 'hotline' or other direct access to occupational health or infectious disease expertise. These injuries should be dealt with promptly as decisions regarding the need for post-exposure prophylaxis (PEP) should be taken immediately - within hours - in the case of HIV exposures and within 48 hours in relation to hepatitis B exposures. There is currently no recommended PEP for exposures to hepatitis C.

There should also be in place a management strategy to address accidents and infections which occur despite the existence of a risk management strategy. Under this heading, the issues to be reviewed should include the health requirements of the health-care worker, indemnity/insurance/social insurance, occupational injury benefits and retraining and/or redeployment of infected health-care workers where feasible.

3.4 Look-back policy

See algorithm, Chapter 6, for details of this policy. A look-back policy is essential where risk of patient exposure has occurred. Local Expert Groups, convened by the Directors of Public Health, may recommend a look-back exercise. However, no such exercise should be undertaken without first informing the national Standing Advisory Committee. It is envisaged that in many instances it will not be necessary to convene the full Committee. Occurrence

management should include a prepared strategy in respect of a public relations policy and the reassurance of patients and health-care workers, where such an accident or incident has arisen.

3.5 Information, training and education requirements for health-care workers

Education on infection control and the application of standard precautions should be made available to all health-care workers who may be exposed to blood or other body fluids potentially contaminated with blood-borne pathogens.

Educational programmes should be incorporated into the training of medical, dental and nursing students. Training programmes and information sessions should be provided upon initial employment and at appropriate intervals thereafter. This should be included in the conditions of service of the post.

The content of education sessions must ensure that all such health-care workers:

- Receive training on precautionary measures, epidemiology and modes of transmission
- Be informed regarding the location and proper use of personal protective equipment, e.g. gloves, plastic aprons, visors, etc
- Understand standard precautions
- Be aware of the role of occupational health
- Be aware of procedures to be followed, including post-exposure prophylaxis, if occupational exposure to blood or body fluids has occurred
- Have access to policies on protecting health-care workers and patients from HBV, HCV and HIV
- Be informed of and have access to protocols for infected health-care workers
- Be provided with an opportunity for interactive questions/answers with the training facilitator
- Be provided with a protocol regarding the steps to be taken immediately following a possible exposure.

Training records, including dates, content and names of attendees should be maintained.

CHAPTER 4: POLICY FOR PREVENTION OF TRANSMISSION OF BLOOD-BORNE PATHOGENS

4.1 Hepatitis B

A safe and effective vaccine is available for the protection of health-care workers from infection with hepatitis B virus. In accordance with the RCPI National Immunisation Committee's Guidelines for Ireland⁷¹, the policy for prevention of transmission of HBV in the health-care setting is based on vaccination of health-care workers who are not naturally immune to infection with HBV. This policy is applicable to all health-care workers whether they are new employees, currently in post, locums, temporary workers or supernumerary workers.

Health-care workers are defined as persons whose activities involve contact with patients or with blood or other body fluids from patients in a health-care setting. This includes doctors, nurses, dentists, dental hygienists, speech and language therapists, laboratory staff, mortuary attendants, porters and cleaners.

All health-care workers must follow general infection control guidelines and adopt safe working practices, as set out in Chapter 3, to prevent HBV transmission in health-care settings.

All health-care personnel who have direct contact with blood or body fluids, or with patients' tissues and who are therefore at risk of acquiring HBV occupationally, should have their anti-HBs status established. If the contact involves undertaking EPPs, testing should also include anti-HBc and HBsAg. Susceptible staff should be vaccinated for their own protection. Health-care workers who are unwilling to be vaccinated when it is appropriate should be considered for redeployment to a position where they will not be involved in exposure-prone procedures.

Employers should inform staff of the requirement for immunisation and the necessity to test for a response to the vaccine.

Specific categories

Transmission of hepatitis B to patients is known to occur during exposure-prone procedures. No other intervention poses a risk to patients, provided infection control procedures are adhered to.

Exposure-prone procedures are those where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker. These procedures include those where the worker's gloved hand may be in contact with sharp instruments, needle tips and sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. (For a more complete explanation of exposure-prone procedures see Chapter 2.)

The hepatitis B status of health-care workers who work in an area involving

exposure-prone procedures must be established by testing for HBsAg, anti-HBc and anti-HBs as outlined above.

All health-care workers (whether they are new employees, currently in post, locums, temporary workers or supernumerary workers) who perform exposure-prone procedures, and all medical, dental, nursing and midwifery students must be immunised against HBV, unless immunity to HBV as a result of natural infection or previous immunisation has been established or the vaccine is contraindicated.

Surgeons, dentists, dental hygienists, obstetricians, gynaecologists and midwives may be excluded from practice if infected with HBV, because exposure-prone procedures form an integral part of their work. Other workers infected with HBV may be asked to restrict certain aspects of their work practices.

Health-care workers who are both HBsAg and HBeAg positive are at risk of transmitting HBV to their patients and must not, therefore, perform exposure-prone procedures.

All HBsAg positive and HBeAg negative health-care workers who undertake EPPs should have their HBV viral loads determined and the presence of HBV pre-core mutants investigated. Those health-care workers identified with viral loads in excess of 10^4 copies/ml are at risk of transmitting HBV to their patients and must not perform exposure-prone procedures. This level also applies to retrospective situations where there is a requirement to evaluate the need for a look-back exercise. If the viral load was never shown to be above the threshold, a look-back is not considered necessary. This threshold will be reviewed periodically by the Standing Advisory Committee.

HBV viral load

A baseline HBV viral load will be determined on three sequential samples at approximately two weekly intervals using the same testing kit, collected over a six-week period. Health-care workers are not permitted to be involved in exposure-prone procedures pending the outcome of all three samples. Any difference in viral load within $0.5 \log_{10}$ can be attributable to assay variation and is not significant. Health-care workers, whose viral loads are in excess of 10^4 copies/ml, on any one occasion, are excluded from exposure-prone procedures. Individuals with viral loads below this level should undergo regular testing and, if the viral load on any occasion exceeds 10^4 copies/ml, must not perform exposure-prone procedures. In HCWs who are HBeAg negative and the viral load is $<10^4$ copies/ml, this viral load should be performed annually. HCWs are not required to stop exposure-prone procedures while the yearly tests are being carried out. However, for those HCWs whose baseline viral load is in excess of 5,000 copies/ml or if there has been a significant increase in viral load ($>0.5 \log_{10}$), more frequent testing may be necessary.

Guidance for health-care workers who have been on antiviral treatment is provided later in this chapter.

HBV pre-core mutant investigation

In parallel with the above, molecular investigation will be performed to identify the presence of HBV pre-core mutants. While this test is no longer used to exclude health-care workers from involvement in exposure-prone procedures, it serves as an important epidemiological tool and its usefulness will be reassessed in the future.

Whereas this document focuses on occupational transmission of blood-borne diseases or pathogens, it is incumbent on all health-care workers to take steps to ensure that they do not put themselves at risk from such infections in their private lives. This includes the avoidance of intravenous drug abuse and appropriate precautions in relation to sexual activity.

If a health-care worker becomes infected with hepatitis B, then s/he must seek advice from a specialist Occupational Health Physician. This advice will relate to the interpretation of the virological testing, the options for treatment and, in particular, the duties which the health-care worker may continue to perform.

Staff who perform exposure-prone procedures and who fail to respond to the vaccine, may continue in their work, provided that they are not HBeAg or HBsAg positive carriers of the virus. They should be made aware that they are at risk of acquiring infection and should sign a written declaration that they have been so advised. All inoculation incidents must be reported in accordance with standard procedures.

Health boards and employing authorities must ensure that all workers employed by them who are carrying out exposure-prone procedures are immune to hepatitis B virus either as a result of natural infection or by immunisation. This requires that the antibody status of such workers is checked and carriers who are HBsAg positive and HBeAg positive must not undertake exposure-prone procedures.

Hepatitis B is a prescribed occupational disease for health-care workers. Occupational injury benefits are available for affected health-care workers.

Physicians who are aware that infected health-care workers under their care have not followed advice to modify practice should inform, as appropriate, the Medical Council, the Dental Council or An Bord Altranais.

It is essential to accurately determine the health-care worker's response to the vaccine and that the anti-HBs level is checked 2-4 months after completion of the primary course.

- An anti-HBs level of 100miu/ml or greater is considered to reflect an adequate response to the vaccine and to confer protective immunity.⁷²
- Antibody levels of between 10 and 99miu/ml indicate a poor response. A booster dose of vaccine should be given immediately, and the health-care worker re-tested for antibody levels at 2-4 months using two assays. If both assays are >10miu/ml, this indicates an adequate response, a view supported by the European Consensus Group on Hepatitis B Immunity in their consensus statement in 2000,⁷³ and reiterated by the European Consensus Group in their consensus statement on the management of HCWs infected with the hepatitis B and C viruses in 2003.⁷⁴ A poor

response may be associated with host factors such as obesity, smoking, age or male gender, and a genetic factor has also been recognised in these individuals. Such 'poor responders' may in fact just be 'slow responders' with different kinetics of humoral response.

- An anti-HBs level of less than 10miu/ml is a non-response to the vaccine. It is important to exclude past infection or chronic carriage. Non-responders to the vaccine should be tested for anti-HBc. Anti-HBc negative persons are true non-responders and should be considered for a second course of vaccine using a different preparation in accordance with guidelines.⁷⁵ Double dosing should also be considered and the anti-HBs levels rechecked at 2-4 months post completion.⁷⁶ Anti-HBc positive persons should be tested for HBsAg. All HBsAg positive health-care workers should be tested for e markers and anti-HBc IgM.

The routine testing of individuals who have previously achieved an adequate immune response to vaccine is no longer recommended. Healthy immuno-competent individuals who have achieved good antibody titres with standard vaccination regimens should be advised that they will not need routine booster vaccines. Individuals who are immuno-compromised should be advised that they require regular testing for anti-HBs and a booster injection, if the titre falls below 10miu/ml. Such recommendations should be given on an individual basis in consultation with an Occupational Health Physician.

All cases of viral hepatitis are statutorily notifiable. It is important that all cases are actively followed up by the Director of Public Health, risk factors for infection identified and contact tracing carried out, with vaccination where appropriate to prevent secondary cases. If recent surgery or dentistry is identified as a risk factor, then the hepatitis B immunisation status of the operator involved in the procedure should be investigated to rule out health-care worker to patient blood-borne transmission of infection.

A health-care worker who suspects that he/she may have been exposed to HBV must co-operate with any look-back exercise deemed necessary, and seek professional advice including testing, if appropriate.

4.2 Hepatitis C

Previous policy for the protection of health-care workers and patients from HCV relied on good general infection control procedures. This has been largely successful, where the risk of transmission of HCV between patients and health-care workers is considered low. However, since 1995, an increasing number of HCV transmissions from health-care workers to patients have been documented in other countries. Epidemiological data, from Ireland and elsewhere, has also led to a greater appreciation of the prevalence of hepatitis C in the population.

It is now recommended that health-care workers who perform exposure-prone procedures must be tested for antibodies to hepatitis C virus and, if positive, for hepatitis C virus RNA.

It is appreciated that the implementation of this recommendation will take time and, therefore, should be introduced on an incremental basis. Health-care workers who are either (a)

commencing training for a career that involves the performance of exposure-prone procedures or (b) new entrants or re-entrants to the Irish health system and whose work involves exposure-prone procedures, should be tested initially. The definition of exposure-prone procedures is given in Chapter 2. The relevant speciality areas include the following:

- Surgery
- Obstetrics and gynaecology
- Midwifery
- Nursing involving exposure-prone procedures (e.g. in the operating theatre)
- Dentistry
- Paediatric surgery
- Medicine.

This list is intended to provide general guidance on the specialties that perform exposure-prone procedures. It is not exhaustive and occupational health advice should be obtained if further clarification is necessary.

This phase of testing should be evaluated and the outcome should inform the subsequent implementation of the process.

The infectivity of health-care workers who are PCR positive for HCV is uncertain. This is reflected in the different approaches that developed countries have taken on this issue. Current knowledge does not automatically lead to a conclusion that HCV PCR positive individuals should be restricted from performing EPPs, unless they have been shown to be a source of HCV transmission previously. However, on the precautionary principle, it is recommended that HCWs who are HCV PCR positive should not perform EPPs until they have been comprehensively assessed from an occupational, public health and medical virological perspective which should include a determination of viral load. This includes HCWs on antiviral treatment who in general should be PCR negative for 6 months before performing EPPs. This case by case assessment will determine the need for restrictions in work practice.

This policy is applicable to all health-care workers, including temporary workers, students, trainees, locums and supernumeraries, who carry out exposure-prone procedures.

Any health-care worker who suspects that s/he may have been exposed to HCV from any source should seek professional advice, including the need for testing if necessary, and must co-operate with any look back exercise deemed necessary.

An infected health-care worker must agree to abide by any restrictions imposed by the Local Expert Group who assessed their case anonymously (see Chapter 6).

Any infected health-care worker involved in clinical cases should remain under regular medical supervision and/or occupational health supervision.

A health-care worker who is antibody positive but PCR negative for HCV can continue to perform exposure-prone procedures, but should have a PCR test for hepatitis C annually while s/he continues to undertake EPPs. In such circumstances, the Occupational Health Physician of the employing institution should be made aware of the status health-care worker and of her/his need for annual PCR testing for hepatitis C.

Physicians who are aware that infected health-care workers under their care have not followed advice to modify practice must inform, as appropriate, the Medical Council, the Dental Council or An Bord Altranais. Employers need safe, effective and comprehensive systems to discharge these duties to the employee and patients.

4.3 HIV

Worldwide, there have only been two incidents of transmission of HIV from health-care workers to patients. The policy for protecting health-care workers and patients from HIV has relied on good general infection control procedures. These procedures have been further enhanced with the introduction of improved safety devices to reduce the risk of needle-stick injuries.

As there is still as yet no vaccine available to protect against HIV infection, the policy for protecting health-care workers and patients from HIV continues to rely on good general infection control procedures.

Mandatory screening for HIV is not recommended on the basis of the low levels of risk involved. This policy will be kept under review.

A health-care worker infected with HIV must not perform exposure-prone procedures.

Any health-care worker who suspects that s/he may have been exposed to HIV must co-operate with any look back exercise deemed necessary, and seek professional advice including testing, if appropriate.

An infected health-care worker must agree to abide by any restrictions imposed by the Local Expert Group who assessed their case anonymously (see Chapter 6).

Physicians who are aware that infected health-care workers under their care have not followed advice to modify practice should inform, as appropriate, the Medical Council, the Dental Council or An Bord Altranais.

This policy is applicable to all health-care workers, including temporary workers, students, trainees, locums and supernumeraries, who carry out exposure-prone procedures. The only circumstances in which transmission of HIV to patients occurs is during exposure-prone procedures. No other intervention poses a risk to patients, provided infection control procedures are adhered to.

4.4 Health-care workers who have been treated with antiviral drugs and/or interferon

Health-care workers should be asked if they are currently being treated or have been treated within the last 12 months with antiviral therapy and/or interferon. Hepatitis B infected health-care workers should be under the supervision of a specialist and inform their occupational health physician if they have been on or are currently on interferon or antiviral therapy. Those who have undergone a course of such treatment need to show that they have a viral load that does not exceed 10^4 genome equivalents per ml. If the viral load exceeds 10^4 then restrictions to work practice are necessary. Restrictions are also necessary if a HCW stops treatment on their own accord and he/she should stop performing EPPs within 48 hours of coming off treatment. HCWs who stop treatment on their own accord or under supervision may not perform EPPs until it is demonstrated that the viral load has remained below the cut-off level for twelve months after coming off antiviral treatment.

HCWs, under close supervision by an Occupational Health Physician and complying with the protocol described in this section of the report, may be allowed to return to EPPs while on antiviral therapy if the viral load is reduced to below the cut-off level. Once the viral load has been reduced below the cut-off level, the HCW should be re-tested every three months. When the HCW has been below the cut-off for at least one year, he/she should be monitored annually to ensure there is no relapse of infection.

Hepatitis C infected health-care workers should be under expert supervision, including occupational health advice, during therapy where a decision on the need for restrictions to work practice will be made on a case to case basis. This issue should be kept under review by the Standing Advisory Committee. Individuals should be monitored on a yearly basis to ensure there is no relapse of infection.

4.5 Policies for prevention

Employing authorities must ensure that a policy for infection control and risk management is in place, that employees are aware of it, that employees have undergone training in infection control, that they understand the principles of standard precautions and that adherence to good infection control practice is monitored.

Employing authorities should ensure that the resources required to implement and monitor infection control and risk management policies, and to provide adequate training in infection control, are made available.

Employers should ensure that access to specialist occupational health services is made available. Employing authorities should ensure that new employees are aware of their ethical and legal obligations to disclose infection to the Occupational Health Physician or another appropriate person, and that current employees are reminded of these obligations periodically.

Employing authorities have a duty to employees to maintain confidentiality. The procedures should take place in a supportive environment with a confidential system for record keeping which facilitates confidence in the disclosure and assessment process.

4.6 Testing for blood-borne viruses

Occupational health physicians and any other physicians who undertake blood sampling for immunity to hepatitis B and/or the presence of BBVs (HBV, HCV or HIV) must ensure that samples provided are from the health-care worker in question.

Occupational health staff should record hepatitis B immunity in a health-care worker's occupational health (OH) file only if the sample has been taken in the OH department, or can be confirmed to have been taken elsewhere by an OH professional. In practice, this may require telephone confirmation with a colleague in Ireland or the United Kingdom. Results taken from centres elsewhere are not acceptable, as they are too difficult to verify. Health-care workers presenting with such results must have the test repeated. Under no circumstances should health-care workers provide their own specimens.

When undertaking testing for viruses in an employee seeking EPP clearance, further steps must be taken to ensure that the source of the sample can in the future be validated. In testing for hepatitis B viral load and hepatitis C RNA, occupational health professionals must ensure that the sample is identifiable and validated as follows:

- 1 The health-care worker should show photographic proof of identity (e.g. hospital ID badge, driver's licence etc.) at the time of sampling
- 2 The sample should be taken in the occupational health department (OHD)
- 3 The sample should be transported to the laboratory in the normal way and not by the health-care worker
- 4 Upon receipt of results from the laboratory, the OHD must confirm that sample was taken in the OHD

The approved laboratory for such samples is the National Virus Reference Laboratory at UCD, Belfield.

Furthermore, the occupational health professional should take reasonable steps to ascertain whether the health-care worker may be receiving antiviral therapy, as this will have implications for the interpretation of the test result. A simple question to this effect (e.g. incorporated in the laboratory request form or the consent form) should suffice.

4.7 Costs

When testing is undertaken on current or prospective employees (e.g. as part of a pre-employment health assessment), the cost of testing should be borne by the employer.

CHAPTER 5: BLOOD-BORNE VIRUSES IN THE HAEMODIALYSIS, CAPD AND RENAL TRANSPLANT SETTING

5.1 Introduction

End stage renal failure requires a variety of treatment options including dialysis and transplantation, procedures where infection control is of paramount importance. It is recognised that a review of renal services has recently commenced in the HSE and that this will include service and clinical issues. It is generally accepted that there is a requirement for comprehensive renal guidelines in Ireland and it is the intention that this chapter of the report will address those aspects with respect to BBV infections. The protocols outlined in this chapter draw on best international practice which is referenced if more comprehensive information is required.

Chronic haemodialysis patients are at high risk of infection because the process of haemodialysis requires repeated vascular access for prolonged periods. Such patients are susceptible to person-to-person transmission of infectious agents, directly or indirectly, via contaminated devices, equipment and supplies, environmental surfaces or the hands of personnel.

The recommendations in this chapter outline comprehensive infection control measures for health-care professionals and organisations or institutions involved in the care of patients receiving renal replacement therapies including haemodialysis, continuous ambulatory peritoneal dialysis (CAPD) and transplantation. A summary of these recommendations is included in Table 5 at the end of this chapter.

For many years, viral hepatitis was recognised as a hazard for dialysis patients and staff.⁷⁷ In 1972, guidelines were issued in the UK for the prevention and control of HBV in renal dialysis and transplantation units.⁷⁸ In the US, recommendations for the control of HBV in haemodialysis centres were first published in 1977.⁷⁹ By 1980, their widespread implementation was associated with a sharp reduction in incidence of HBV infection among both patients and staff members. In 1982, hepatitis B vaccination was recommended for all susceptible patients and staff members.⁷⁹ New BBVs including HCV and HIV were later identified.

Hepatitis B vaccination

Recombinant vaccines are available against HBV. Compared with adults with normal immune status, the proportion of haemodialysis patients who develop a protective antibody response after vaccination (with higher doses) is lower.⁷⁹ For those who receive the three-dose schedule, the median is 64 per cent (range: 34-88 per cent), and for those who receive the four-dose schedule, the median is 86 per cent (range: 40-98 per cent). Some studies have demonstrated that higher antibody response rates could be achieved by vaccinating patients with chronic renal failure (CRF) before they become dialysis dependent.⁷⁹ Haemodialysis patients who mount a good response to vaccine appear unable to maintain high antibody levels.⁸⁰ Hepatitis

B immunoglobulin (HBIG) may provide passive protection post-exposure. For further discussion about vaccine efficacy, serological response rates, antibody persistence, response to revaccination and different protocols, please refer to the current US and UK renal dialysis guidelines.^{79,80}

Transmission of blood-borne viruses in dialysis patients

Outbreaks of both HBV and HCV infections continue to occur among chronic haemodialysis patients, mainly outside Ireland.^{79,80} Investigations in other countries have indicated significant deficiencies in infection control practices along with failure to vaccinate haemodialysis patients against HBV. Factors that have been demonstrated to contribute to HBV outbreaks include: use of multi-dose vials of drugs, failure to nurse HBV infected patients as a cohort and lapses in infection control practices. Two factors are consistently reported to be associated with increased prevalence of HCV infection in dialysis patients: the number of blood transfusions received and the length of time on dialysis. Studies show that HCV can be transmitted to haemodialysis patients by nosocomial transmission in dialysis units.⁸⁰ 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.⁸⁰ There have been only a few reports of transmission of HIV in dialysis units, with many studies failing to show transmission of the virus.^{79,80}

Prevention of transmission

Currently, there is a low incidence of BBV infections in renal units in Ireland. However, rigorous adherence to the protocols and recommendations proposed in this chapter is imperative in order to prevent transmission of these viruses. Recognised standard precautions against blood-borne viruses designed both for the protection of the staff and to prevent cross-infection between patients are essential. Patients with chronic renal failure (CRF) or acute renal failure (ARF) should be considered as potentially infected until they have been fully tested. Regular testing of patients must be part of their subsequent management within the renal unit. Staff must be continually educated and brought up to date on BBV developments.

5.2 Serological testing for blood-borne viruses

On admission to a dialysis programme, all patients should be screened for HBV and HCV infection. Testing for HIV should be based on a risk assessment. Patients' informed consent to BBV testing must be obtained. Those who withhold consent should be managed as though they were BBV infected. Infected patients should not be denied dialysis, however, every effort should be made to conform with the screening and management protocols that are outlined in this chapter.

Hepatitis B

Pre-dialysis

Pre-dialysis testing for hepatitis B should include HBsAg, anti-HBs and anti-HBc (Figure 1).

- anti-HBc positive:

This should be confirmed by a second assay on the same sample and a repeat sample sent for further testing.

If positive, review with results of HBsAg testing.

- HBsAg positive/anti-HBc positive: See below for management of a HBsAg positive patient.
 - HBsAg negative/anti-HBc positive: No isolation is necessary if HBsAg remains negative. Carry out monthly HBsAg testing.
- anti-HBc negative: proceed with HBV vaccination, if not already carried out (see below).

Regular testing

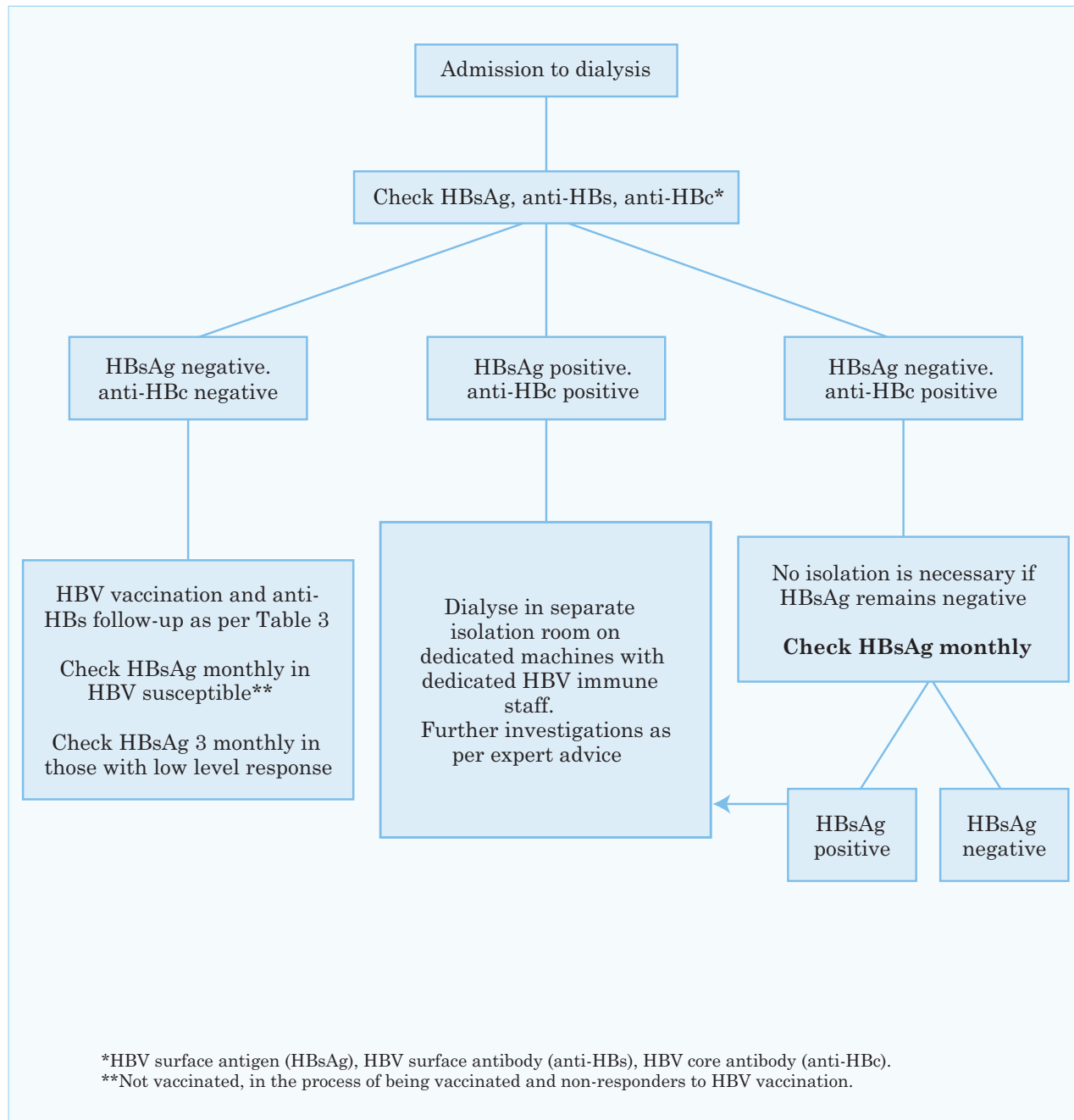
HBV susceptible patients (i.e. unvaccinated and non-responders to vaccine) should have HBsAg tested monthly (Table 3).

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

Patients who have shown a good response to vaccination (anti-HBs \geq 100 mIU/ml) should be tested for anti-HBs annually.

Patients who have shown a low level response to vaccination (anti-HBs 10-99 mIU/ml) should be tested 3-monthly for HBsAg and annually for anti-HBs.

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



Hepatitis C

Pre-dialysis screening should be carried out for anti-HCV, HCV PCR and ALT (Table 3). Testing for hepatitis C antibodies should include both an EIA anti-HCV test and supplemental or confirmatory testing with an additional, more specific assay.

Those patients who are anti-HCV negative should have monthly ALT, 3 monthly anti-HCV testing and annual PCR testing.

The need for, and the frequency of, HCV PCR testing in the following situations should be based on risk assessment and expert advice: (1) Patients who are HCV antibody negative and are immunosuppressed, (2) patients have undergone a renal transplant, (3) patients who are being admitted from a unit where there has been a recent HCV transmission.

HIV

Testing for HIV antibody should be done before starting or restarting haemodialysis, based on a risk assessment, and annually thereafter (Table 3).

Re-admitted patients

Re-admitted patients who have been dialysed abroad should be tested and found negative for HBsAg (if previously susceptible), anti-HCV and HCV RNA before being dialysed in the main unit, i.e. dialysed on separate machines and in a segregated area. The need for follow-up testing should be based on risk assessment and expert advice.

Abnormal liver function

Any patient who develops abnormal liver function tests should be screened for HBV and HCV as appropriate depending on previous test results.

Table 3: Schedule for routine testing for HBV, HCV and HIV infections

Patient status	On admission	Monthly	3 monthly	Annual
All patients	HBsAg, anti-HBc, anti-HBs, anti-HCV, HCV PCR, ALT ± anti-HIV			
HBV susceptible (unvaccinated and non-responders to vaccine)		HBsAg		
Vaccinated – good response (anti-HBs ≥100 mIU/ml)				Anti-HBs
Vaccinated – low level response (anti-HBs 10-99 mIU/ml)			HBsAg	Anti-HBs
Anti-HBc positive, HBsAg negative		HBsAg		
Anti-HCV negative		ALT	Anti-HCV	HCV PCR
Anti-HIV negative				± Anti-HIV

5.3 Hepatitis B vaccination

All long term dialysis patients should be immunised against HBV. Patients with CRF should be offered hepatitis B vaccination at the earliest opportunity, ideally before reaching the stage of requiring dialysis or transplantation (e.g. GFR < 25mls/min). For further information please refer to the latest edition of the RCPI National Immunisation Committee's Immunisation Guidelines for Ireland.⁷¹

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

Dose. Higher doses of vaccine (40mcg) should be used for adult patients with chronic renal failure.

There are several hepatitis B vaccine products currently licensed in Ireland. Clinicians should refer to relevant product license information for details of schedule and dosage.

Post-vaccination testing (Table 4). Anti-HBs should be checked 2 months after the course of vaccine has been completed:

Anti-HBs \geq 100 mIU/ml: This is considered a good response. Anti-HBs should be tested annually. If anti-HBs drops below 10 mIU/ml, a booster dose of vaccine should be given and annual testing continued. Retesting immediately after the booster dose is not necessary.

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

Anti-HBs $<$ 10 mIU/ml: This is considered non-response. Repeat a course of vaccination (a different brand of vaccine may be considered) and retest at 2 months post completion. If Anti-HBs $<$ 10 mIU/ml after repeat vaccination: the patient should be regarded as susceptible to HBV infection and tested for HBsAg on a monthly basis.

If the patient refuses vaccination, and has no markers of prior HBV infection, carry out monthly HBsAg testing.

Table 4: Post-hepatitis B vaccination anti-HBs testing

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

5.4 Infection control in a haemodialysis, CAPD and renal transplant setting

Environmental/design considerations

- Adequate layout and light is essential
- There should be adequate space between patients' stations. US and UK guidance is included below for illustrative purposes. The relevant professional and technical staff should consider the recommendations below in the design of these units.
 - The American Institute of Architects recommends 7.5m² (80ft²) per patient treatment station, with a minimum of 1200mm (4ft) between each patient/chair, excluding all other furniture, equipment and cabinets. They also recommend no more than four stations per room and at least one isolation room with negative pressure ventilation per unit.⁸¹
 - NHS recommends that 10.5m² per station with 900 mm (3ft) minimum between stations, and 1-2 isolation rooms (negative pressure ventilation) per 12 station units.⁸²
- There should be one hand basin between three dialysis stations, with one for each isolated or segregated area.
- Each unit should have a dedicated clean area or room away from patient treatment areas where medications are stored and prepared, and clean and sterile stores are stored. Any article brought to a patient's station must not be returned, used or unused, to the clean area or used on another patient without cleaning and/or disinfection.
- No handling or storing of unclean supplies, equipment, or blood samples should occur in the dedicated clean area.
- Multi-dose vials must only be used for single patient use or discarded after every use.
- Haemodialysis, CAPD and transplant units are classified as high risk areas for environmental cleaning specification, and cleaning frequencies should reflect this.⁸³
- Domestic staff should wear aprons and gloves when working in the unit.

Standard precautions

Standard precautions should be applied by all staff to all patients at all times. Each unit should, in conjunction with the local infection control team, develop and update annually

guidelines/protocols on all points of Standard Precautions (see table below).

Table 1: STANDARD PRECAUTIONS

- Observe good hand hygiene practices – see NDSC guidelines 2004.⁶⁶
- Wear gloves if contact possible with blood, body fluids, non-intact skin or mucous membranes.
- Prevent puncture wounds, cuts and abrasions in the presence of blood and body fluids.
- Use safety devices where appropriate and avoid use of or exposure to sharp instruments (needles, glass, metal, etc.) when possible but, if unavoidable, take particular care in handling and disposal.
- Protect all breaks in exposed skin by means of waterproof dressings and/or gloves.
- Protect the eyes and mouth by means of a visor or goggles/safety spectacles and a waterproof mask when splashing is a possibility. (This will also protect the eyes and mouth against bone fragments in orthopaedic surgery and post-mortem examinations).
- Avoid contamination of the person or clothing by use of waterproof/water-resistant protective clothing, plastic aprons, etc.
- Wear rubber boots when the floor or ground is likely to be contaminated.
- Footwear/rubber boots should be decontaminated by a washer-disinfector.
- Health care workers should be aware of the first aid and follow up procedures to follow in the event a percutaneous or mucotaneous exposure to blood or body fluids.
- Avoid mouth-to-mouth resuscitation by using mouth pieces or resuscitation bags.
- Control surface contamination by blood and body fluids by containment and appropriate decontamination of spillages.
- Ensure that all single use items are disposed of after every use.
- Ensure appropriate decontamination of reusable medical devices by following manufacturer's instructions. The NDSC CJD guidelines provide additional advice for best practice on decontamination.⁶⁷
- Dispose of all contaminated waste and sharps safely.⁶⁸
- Ensure linen contaminated with blood or body fluids is bagged appropriately at the bedside.
- The infection control committee should develop and update annually all relevant protocols as new information becomes available on best practice.

Haemodialysis machine and treatment area

- Venous and arterial transducers should be protected with a filter for every treatment.
- If the transducer filters are blood stained during a treatment, check for breakthrough (blood visible at the back of the filter) and replace the filter. If breakthrough occurs the transducer should be replaced after treatment and before the machine is used again.
- The dialysis fluid pathway should be disinfected after each patient.
- Each treatment couch/bed, locker, bed table etc should be washed with soap and water after each treatment, and a hypochlorite solution (1,000ppm) used if visible blood is present.
- The surface of each dialysis machine should be cleaned and disinfected as appropriate after each treatment according to the manufacturer's instructions.
- Clamps should be washed and disinfected (chemical or heat) after each treatment.
- Items brought to the treatment area which are difficult to clean thoroughly such as blood pressure cuffs, adhesive tape, ear phones etc should be single use items or dedicated as single patient use only.

CAPD fluid waste

Used CAPD fluids should be disposed of directly into a drain or sluice. Where CAPD bags are known to be contaminated by BBVs, they should be treated as clinical health-care risk waste. Local arrangements may need to be put in place to facilitate this.

Surveillance and record keeping

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

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

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

Audits

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

5.5 Management of BBV infected patients

HBsAg positive patients

- The patients should be dialysed in a separate isolation room on dedicated machines with dedicated HBV immune staff. While physically separate facilities may not be readily available in all institutions providing dialysis, hospitals should take steps to ensure that these facilities are provided as a priority service development.
- Staff should not care for HBV positive patients and HBV negative patients on the same shift.
- There is a significant risk of HBV being transmitted via environmental surfaces and therefore a separate machine should be used for infected patients.
- The surface of the machine should be cleaned with soap and water and disinfected with a disinfectant advised by the manufacturers.
- Fluid pathways should be disinfected after each treatment (heat and/or chemical, as per manufacturer's instructions).
- There should be no sharing whatever of items used for blood pressure monitoring, trays, stethoscopes or other utensils with any other patients or staff in the unit.
- Patients should be educated on prevention of transmission of infection in the home and in other settings.
- Family members should be tested for HBsAg and anti-HBc and offered vaccination if negative.

HBsAg negative, anti-HBc positive patients

- No isolation is necessary if the patient remains HBsAg negative.

HCV/HIV positive patients

- HCV or HIV infected patients should be dialysed in separate shifts, in a segregated area or isolation room and on dedicated machines.
- Patients should be educated on prevention of transmission of infection in the home and in other settings.

Dedicated machines

Dialysis machines dedicated for use by patients with BBVs should be stored in a segregated area which is separate to the storage area of other dialysis machines. It is not recommended

that such dedicated machines be returned to general use.

Patients having more than one BBV

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.

Patients treated by CAPD

Before starting CAPD patients should be screened for BBVs and should also be encouraged to be immunised against HBV, if appropriate, and tested for BBVs annually thereafter. Patients on CAPD who are infected with BBVs do not need isolation. Standard precautions should be sufficient to avoid cross-contamination.

BBVs and patients in CRF not yet on dialysis

Precautions should be observed for patients in CRF not yet on dialysis in exactly the same way as those on dialysis. Immunisation for HBV is best carried out in the CRF clinic.

5.6 Management of a previously unidentified case of BBV infection in a haemodialysis patient

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

1 Consultant microbiologist/laboratory director to inform the consultant nephrologist and notify the Director of Public Health immediately. (*Notification to the DPH should be made anonymously for HIV.*)

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

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

The infected patient should be dialysed in a separate isolation room, using a dedicated machine, with dedicated HBV immune (*not for HCV or HIV*) staff. Staff should not care for HBV positive and negative patients on the same shift.

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

Serum from the infected patient should be sent to the local virology laboratory or the NVRL for molecular testing, e.g. genotyping. The consultant virologist will advise on the need for and timing of additional testing.

Notification to the Director of Public Health

HBsAg positive hepatitis B (*also HCV, not HIV*) virus infection is notifiable under the Infectious Diseases Regulations. Details regarding the infected patient should be sent to the Director of Public Health by both the Laboratory Director and the clinician.

3 Identification of the exposed cohort

The exposed cohort is defined as all patients who have shared a dialysis machine or dialysis session with the infected patient since that patient was last HBsAg negative or (*last tested negative for HCV/HIV*).

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

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

4 Management of the exposed cohort

Patients belonging to the exposed cohort should be informed of the incident and counselled as appropriate.

HBsAg and anti-HBs testing should be carried out immediately on all patients in the exposed cohort. The need for anti-HBc testing should be discussed with a consultant virologist. Details of hepatitis B virus (HBV) vaccination history for the exposed cohort should be reviewed and documented. (*For HCV and HIV – PCR testing for infection should be carried out and specialist advice should be obtained from a virologist about the need for further testing*).

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

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

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

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

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

(c) No history of HBV vaccination.

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

5 **Communication**

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

- Relevant staff in the dialysis unit
- If the infected patient was dialysed in another unit in the past 3 months, the Consultant Nephrologist in this unit should be informed
- The Consultant Nephrologists in other dialysis units, to which members of the exposed cohort have been transferred
- Consultant Microbiologist
- Consultant Occupational Health Physician
- Hospital infection control team
- Hospital Chief Executive or Deputy
- Hospital Director of Nursing
- Director of Public Health, who will inform the Health Protection Surveillance Centre and the Director of Population Health

6 **Incident Control Teams**

A local incident team should be set up in the hospital, to manage the incident within that hospital. The team should include the Director of Public Health and at least one expert in infectious diseases external to the situation concerned.

A national incident team should be set up by the Director of Population Health and led by the HPSC to coordinate the incident nationally. National coordination is essential as incidents in dialysis units generally have national implications. The national team should include the Director of Public Health of the local incident team.

7 Identification of exposed staff

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

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

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

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

(HCV/HIV – The testing of staff members who have had contact with the infected patient should be guided by risk assessment).

5.7 Staff and BBVs

Staff working in dialysis units in contact with patients, machines or materials used in dialysis should be immunised against HBV and their response to vaccine checked. Non-responders or poor responders should be tested annually for HBsAg. Guidelines for EPPs should be followed.

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

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

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

1. That the infected health-care worker fully understands Standard Precautions and the implications for patients (and others) should they be breached at any time.
2. That the definition of exposure-prone procedures is understood.

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

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

Carers

Carers who assist in the dialysis treatment of patients should be tested for HBsAg and, if found to be negative, should be offered immunisation against HBV.

5.8 Infection control training and education

Staff members

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

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

Training and education of patients

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

- Personal hygiene and hand-washing techniques
- The patient's responsibility for proper care of access and recognition of signs of infection, which should be reviewed each time the patient has a change of access type
- Recommendations for vaccination.

Table 5: KEY ACTION POINTS

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

- Strict implementation of infection control procedures
- Use of HBV vaccine for susceptible patients and staff
- Segregation of infected patients and their equipment
- Routine serological testing for HBV and HCV infections, and molecular testing where appropriate
- Infection control training and education.

Before commencing dialysis:

- **Laboratory Screening**
All patients should be screened for HBsAg, anti-HBc, anti-HBs, anti-HCV, HCV PCR and ALT. Testing for anti-HIV should be based on risk assessment
- **HBV Vaccination**
All susceptible patients should be offered HBV vaccination before dialysis
The higher dose of vaccine (40mcg) should be used and an accelerated schedule
- **Vaccination follow-up**
Anti-HBs should be checked 2 months after the course of vaccine has been completed.

On dialysis:

- **Laboratory Screening**
HBV:
HBsAg negative/anti-HBc positive: HBsAg to be tested **monthly**
Unvaccinated and vaccine non-responders: HBsAg to be tested **monthly**
Vaccinated with good response (anti-HBs \geq 100 mIU/ml): Anti-HBs to be tested annually
Vaccinated, with low level response (anti-HBs 10-99 mIU/ml): HBsAg to be tested 3 monthly and anti-HBs to be tested annually
HCV: Monthly ALT, 3 monthly anti-HCV and annual HCV PCR
HIV: Annual anti-HIV, based on risk assessment.
- **Infection Control**
HBsAg positive/anti-HBc positive: The patient should be dialysed in a separate isolation room on dedicated machines, with dedicated HBV immune staff
HBsAg negative/anti-HBc positive: No isolation is necessary if HBsAg remains negative
- **HCV/HIV infected:** The patient should be dialysed in separate shifts, in a segregated area and on dedicated machines.

CHAPTER 6: PROCEDURES TO IDENTIFY SOURCES OF BBVs IN THE HEALTH-CARE SETTING AND TO MINIMISE THE RISK TO PATIENTS AND STAFF

6.1 Procedures

It is recognised that the implementation of risk management, infection control and occupational health policies will require extra resources. This should be considered in the resource allocation process at national and regional levels.

Employing authorities should ensure that the resources required to implement and monitor infection control and risk management policies, and to provide adequate training in infection control, are made available at local level. Employers should take all necessary steps to establish that the HCWs in their employment provide a safe service to patients in accordance with the recommended actions in this document. For example, employers should do more than passively reacting to situations where HCWs disclose their infection, and instead put in place active, effective and confidential systems that will identify and minimize risk in the setting of a supportive environment.

On commencement of employment, all employees must be made aware of the risk factors for acquiring blood-borne diseases and of their ethical duty to disclose any blood-borne infections to the Occupational Health Physician or another appropriate person. The employing authority should ensure the health-care workers understand their ethical and medical duty to inform their physician, if they might be infected.

On commencement of employment or during the course of their employment, where an employee or prospective employee knows or suspects that he/she may be infected with a blood-borne pathogen, he/she must inform their employer or Occupational Health Physician who in turn should consult with the Director of Public Health. Depending on the nature of the risk, an incident team in the institution concerned should be established (see following pages). The HCW must cease carrying out any exposure-prone procedures pending instruction/advice from their employer/occupational health physician.

The physician should then inform the Director of Public Health about the work circumstances of the health-care worker. If there is clearly no risk to patients, then no further action is taken. If there is any possibility of risk to patients, currently or in the past, the Director of Public Health should convene a Local Expert Group, composed of not less than 3 relevant experts, drawn from disciplines such as Occupational Health, Clinical Microbiology, Infectious Diseases and Public Health, to anonymously assess the case. If there is no current or past risk to patients, no further action is taken. If there is current risk to patients, a restriction in work practices will be recommended to the referring physician. The referring physician should tell the infected health-care worker of the need for this restriction, and also inform the Chief Executive Officer (CEO) of the hospital or institution concerned of this requirement. (For the purposes of this chapter, the term CEO will be taken to refer to the Chief Executive Officer or Manager of the affected hospital or institution.) The referring physician should ensure that the restriction is adhered to and inform the CEO to this effect. If there was a risk to patients in

the past, the Local Expert Group will assess the need for a look-back exercise. Other experts may be called in to help in the decision. No decision will be taken to carry out a look-back exercise without first informing the national Standing Advisory Committee. (See Figure 2).

This algorithm and responses contained in the following pages apply to incidents involving potential transmission of BBVs from HCWs to patients. They may be adapted for analogous situations, for example incidents involving potential transmission of BBVs from equipment or outbreaks of BBV infections in the health-care setting. This may also be used in situations involving potential transmission between patients.

6.2 Protocol for infected health-care workers

- An infected health-care worker has an ethical and legal duty to inform his/her physician of his/her status immediately after he/she becomes aware of his/her status.
- An infected health-care worker, on identification of his/her status, must stop performing exposure-prone procedures.
- If any restriction of work practices is necessary, the referring physician will inform the health-care worker's employer (usually the CEO) in confidence of this requirement for restriction.
- The infected health-care worker must abide by any restrictions of work practices.
- An infected health-care worker must agree to undergo regular medical evaluation by a physician.
- An infected health-care worker must demonstrate a thorough knowledge and application of standard precautions.
- An infected health-care worker must provide accurate information on the nature of all previous employment to the Local Expert Group, to allow an accurate assessment of involvement in exposure-prone procedures in the past.

6.3 Actions to be taken by the physician once informed by an infected health-care worker of his/her status

- Once notified by an infected health-care worker of his/her status, the physician must inform the Director of Public Health on an anonymous basis in the first instance.
- The physician must assess the infected health-care worker's knowledge and application of standard precautions where appropriate and evaluate work practice.
- The physician should arrange for a regular occupational health/infectious disease review of the health-care worker.

- If restriction of work practice is required, the physician must inform the infected health-care worker and the CEO of the hospital or institution in confidence of this requirement.
- The physician must ensure confidentiality for the health-care worker, as far as possible.

6.4 Actions to be taken by the Director of Public Health once informed that a health-care worker is infected

- The Director of Public Health in his/her role as Medical Officer of Health has a statutory function in relation to the surveillance and control of infectious diseases.
- All occurrences of notifiable infectious diseases, e.g. hepatitis viruses, must be notified to the Director of Public Health. The Director should also be advised of other serious infections, e.g. HIV, and other incidences where patients are put at potential risk as a result of infections in the health-care setting.
- The Director of Public Health will ascertain, as a result of communication with the Occupational Health Physician, whether an infected health-care worker may have been involved in exposure-prone procedures.
- If exposure-prone procedures are involved, the Director will establish a Local Expert Group whose role includes an evaluation of the necessity or otherwise to perform a look-back exercise.
- If the Local Expert Group advises that a look-back exercise is necessary, then the Director should inform the Chairperson of the National Standing Advisory Committee on the Prevention of Blood-Borne Diseases in the Health-Care Setting.
- The Director of Public Health is responsible for leading the look-back exercise.
- Where an incident occurs and it is deemed necessary to have a look-back exercise, the Director of Public Health should get regular updates from the Institution concerned in support of the look-back process.
- If more than one institution is involved in the same region, the Director of Public Health is responsible for establishing a Co-ordinating Committee to lead and co-ordinate the look-back exercises in all of the institutions involved.
- If two or more administrative regions are involved, there should be co-ordination between the differing regions in relation to the look-back exercise. The lead and coordinating role in such incidences should be carried out by the Director of Population Health, through the HPSC.

6.5 Actions for the CEO of a hospital or institution once informed that a health-care worker is infected

- The CEO should ensure that the Director of Public Health has been informed.
- The CEO should ensure adequate access for the health-care worker to a specialist Occupational Health Physician and/or to a specialist in infectious diseases.
- The CEO should maintain confidentiality as far as possible for the health-care worker.
- The CEO should determine the infected health-care worker's previous employment record.
- The CEO should ensure that prompt access to medical records is facilitated.
- All occurrences of notifiable infectious diseases, e.g. hepatitis viruses, must be notified to the Director of Public Health. The Director should also be advised of other serious infections, e.g. HIV, and other incidences where patients are put at potential risk as a result of infections in health-care workers.

6.6 Actions for the CEO of a hospital or institution where patients are put at risk of infection as a result of a procedure (other than those involving an infected health-care worker)

- The CEO should ensure that the Director of Public Health has been informed.
- An Incident Team should be established in the institution concerned and follow the advice of the Local Expert Group.

6.7 Actions to be taken by medical staff where patients are at risk of infection as a result of contaminated equipment or other reasons

- The Chief Executive Officer of the hospital or institution involved should be informed immediately.
- The Director of Public Health should be notified.
- The CEO will establish an Incident Team in the institution concerned, which should include the Director of Public Health or a nominee and at least one other expert in infectious diseases external to the institution concerned, e.g. a Consultant in Infectious Diseases or a Microbiologist. Medical staff should comply with the actions considered necessary to deal with the incident.

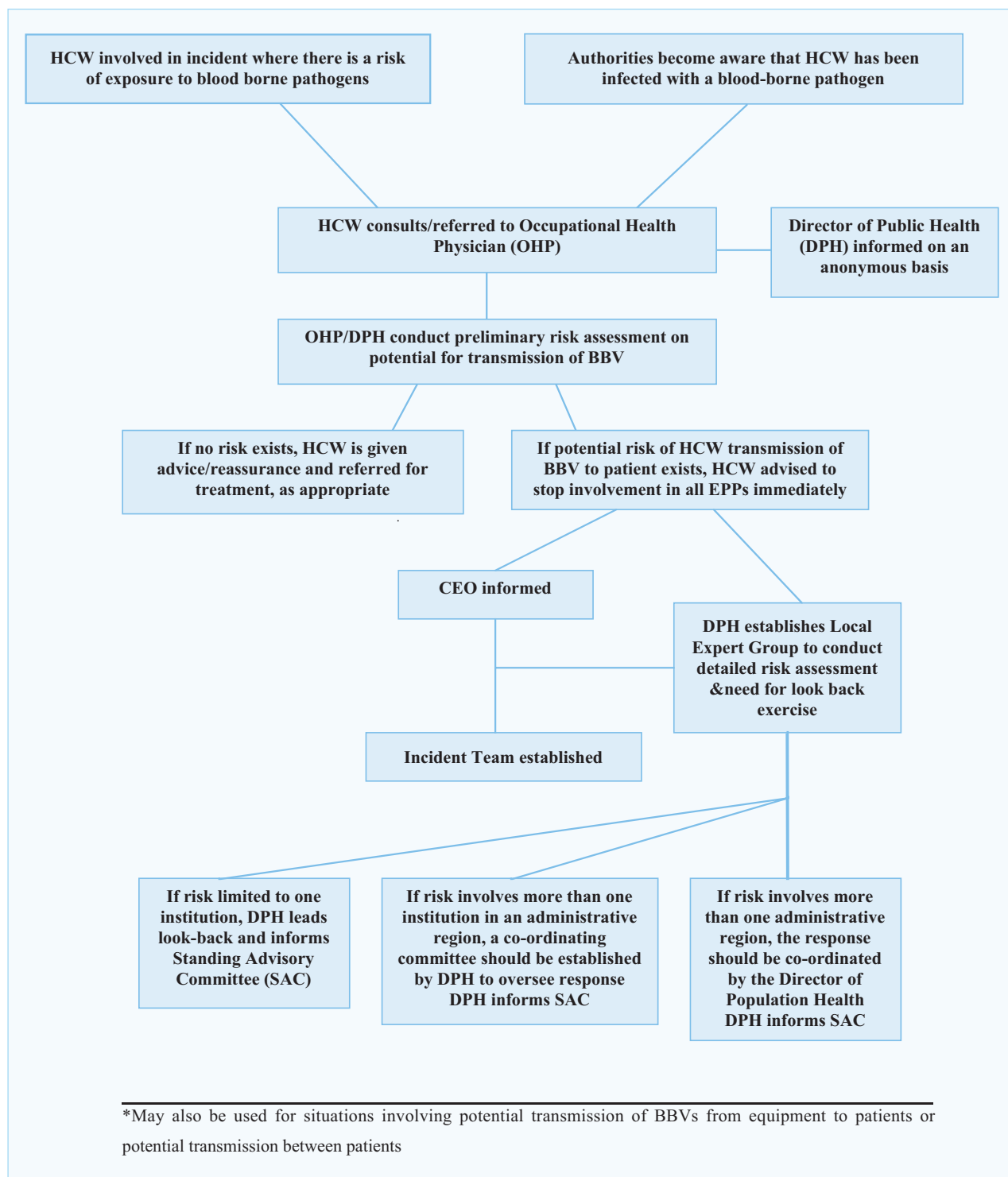
6.8 Actions for the CEO of a hospital or institution once it is determined that a look-back exercise is required

- The CEO or nominee should participate in the look-back exercise if such is required.
- The CEO should facilitate redeployment of administrative staff, if required, for the look-back exercise.
- The CEO should arrange that a spokesperson will handle public relations.

6.9 Look-back exercises

- A look-back exercise, i.e. one where patients are notified that they may have been exposed to a risk of infection from an infected health-care worker, should be considered by the Local Expert Group where patients have undergone exposure-prone procedures, which were performed by an infected health-care worker. The risk of infection following an exposure-prone procedure is remote, but follow-up of such patients may be recommended until the level of this low risk is better quantified. Counselling should be provided, where appropriate.
- No decision to undertake a look-back exercise should be taken without informing, on an anonymous basis, the national Standing Advisory Committee on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting. The expert advice of the Standing Advisory Committee should be made available to the local Expert Group, if required. Once the decision to undertake a look-back exercise is taken, this may result in a public announcement. The infected health-care worker should be informed and, along with his/her family, will need practical and psychological support. If at all possible, case finding should be complete before any public announcement is made, so as to reduce unwarranted public anxiety.
- If a look-back exercise is required, as assessed by the Local Expert Group, a dedicated group or team should be set up to manage the look-back. This should be led by the Director of Public Health or a nominee and include senior management, an Occupational Health Physician, an Infectious Diseases Consultant, a Microbiologist, a Consultant Virologist, an Infection Control Nurse and the health-care worker's Head of Department. Either the microbiologist or infectious disease consultant should be external to the institution concerned.
- Hospitals, dental practices and medical practices should ensure that charts, log books, theatre lists, operating notes, etc are maintained in a form that facilitates retrieval of information in the event of a look-back exercise being necessary.

Figure 2: Algorithm for management of incidents involving Health-Care Workers found to be infected with a blood-borne pathogen*



CHAPTER 7: RETRAINING, REDEPLOYMENT AND/OR SUPPORT PACKAGE

It is recognised that health-care workers who have become infected with blood-borne pathogens may need retraining, redeployment and/or a support package, whichever is most appropriate for the individual. Retraining, redeployment and/or a support package will be facilitated, subject to confirmation of occupational exposure in the Irish health service, but cases should be assessed on their merits on an individual basis.

There may be difficulties in facilitating the retraining of infected health-care workers. These difficulties relate to the level of seniority of the health-care worker at the time when infection is identified and the practicalities of retraining a person who may be considerably older than the average person in training. For a younger health-care worker at the beginning of his/her career, retraining is generally feasible. For the health-care worker who is further on in his/her career, retraining is more difficult. For the individual concerned, such a change in career direction might publicise the fact that the person has become infected with a blood-borne pathogen. There is also the difficulty caused by a shortage of training posts and intense competition for them. In such a situation, it is recommended that some training posts are protected specifically for health-care workers who acquire blood-borne infections occupationally. The group recommends that the training bodies be cognisant of the difficulties posed by identification of an infected health-care worker who requires retraining and that they take these into consideration when organising training positions. For some professions, there are very limited possibilities for retraining or redeployment. The presence of a comprehensive support package should facilitate self-disclosure.

Employing authorities should make every effort to re-deploy an infected health-care worker within the organisation where this is the most appropriate course of action for the employee. Where redeployment of an infected health-care worker within a hospital or health-care setting alters the job description of a consultant post, this may have to be discussed with bodies such as the National Hospitals Office of the Health Service Executive.

To facilitate disclosure of their status by infected health-care workers, appropriate support arrangements should be in place. These arrangements should include ongoing counselling, treatment and provision for all health-care needs. Consideration should be given to the introduction of a benefits package aimed at ensuring the maintenance of employees' basic income and pension rights for the period of retraining. In the very remote event that an infected health-care worker's spouse and/or dependants also became infected, their health-care needs should also be met within the public health service system. Consideration should be given as to whether an employer's contribution to private insurance would be sufficient to protect people who became infected.

The financial, medical and career consequences for an infected health-care worker need to be discussed with the individual concerned. A mentoring system that would provide support and information on all these aspects would be of benefit to an infected health-care worker. This could be instituted under the auspices of the specialist faculties in such a way that the infected health-care worker could avail of it if he/she so wished.

The recommendations in this chapter are applicable to occupationally acquired infections in health-care workers who acquire an infection working in the Irish public health sector. The broader issues concerning adherence to best practice, standard precautions, etc. should apply throughout the Irish health service, in both the public and private sectors.

CHAPTER 8: OTHER POTENTIAL RISKS FOR THE TRANSMISSION OF BLOOD-BORNE PATHOGENS IN THE HEALTH-CARE SETTING

While the emphasis in this Code of Practice is on the prevention of person-to-person transmission of blood-borne diseases, there are many other circumstances within health-care settings where transmission can occur. In particular, this can apply to transmission from contaminated equipment. It is important to recognise that the general protocols described here can be adapted for use in relation to the circumstances identified above.

All hospitals should have in place a comprehensive infection control programme covering a range of procedures appropriate to that institution. Such a programme should include the following:

- Infection control practices, specifically designed for various settings and procedures
- Surveillance
- Training and education.

Within the institution, guidelines should be in place in relation to infection control in respect of a range of appropriate procedures, e.g. critical care machines such as dialysis machines and endoscopy equipment. These guidelines should conform to international best practice and be reviewed regularly by the Infection Control Committee of the institution.

In rare circumstances, where a breakdown in procedure occurs which potentially puts patients at risk, the procedures outlined in Chapter 6 should be followed.

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APPENDIX A

SAMPLE OCCUPATIONAL HEALTH FORM TO ASSESS RISK OF BLOOD-BORNE VIRAL INFECTION

Name (in confidence):

Post (to be) held:

Will you practice exposure-prone invasive procedures? Yes No

(e.g. surgical, dental, obstetric procedures where fingertips may be invisible whilst operating or performing other procedures)

Will you be working in the renal unit? Yes No

Please give examples of procedures in which you will be involved and state whether you will perform or assist:

.....
.....
.....

You are reminded of your ethical obligation to seek diagnostic testing if you think that you may be infected with a serious contagious disease, i.e. any blood-borne virus, hepatitis B, C or HIV. Risk factors for these infections are detailed below. Any concerns you may have in this regard may be discussed with the Occupational Health Advisor/Occupational Health Physician where they will of course be dealt with in strict confidence.

Risk factors for blood-borne viral infections:

1. Homosexual activity
2. Bisexual activity
3. Sexual contact with either of the above or other high risk partner
4. IV drug use
5. Jaundice/hepatitis

6. Haemophilia
7. Blood transfusions
8. Blood product transfusions (e.g. Anti “D”)
9. Occupational blood exposures (i.e. needle-stick injuries/blood splashes)
10. Have you ever been treated with Human Pituitary Growth Hormone or other Human Pituitary extracts?
11. Have you worked or lived (other than holiday) in areas where hepatitis B, C or HIV are endemic?
12. Household contact with a BBV, infected person
13. Renal dialysis.

Do any of the above risk factors apply to you?

Yes

No

Signature: _____

Date: _____

Please provide details/dates of hepatitis B vaccinations and titres post hepatitis B vaccinations with this form. Please validate this form with your current Occupational Health Department stamp below in the box provided.

APPENDIX B

Glossary of abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine aminotransferase
AntiHBc	Antibody to hepatitis B core antigen
AntiHBe	Antibody to hepatitis B e antigen
AntiHBs	Antibody to hepatitis B surface antigen
AntiHCV	Antibody to hepatitis C virus
AntiHIV	Antibody to human immunodeficiency virus
ARF	Acute Renal Failure
BBV	Blood-Borne Virus
CAPD	Continuous Ambulatory Peritoneal Dialysis
CDC	Centers for Disease Control (Atlanta, USA)
CEO	Chief Executive Officer
CRF	Chronic Renal Failure
DNA	De-oxyribonucleic Acid
DPH	Director of Population Health
EIA	Enzyme-linked immunoassay
EPP	Exposure-Prone Procedure
ESRF	End-Stage Renal Failure
HBcAg	Hepatitis B core antigen
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBIG	Hepatitis B immune globulin

HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCW	Health-Care Worker
HIV	Human Immunodeficiency Virus
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
ICN	Infection Control Nurse
IMO	Irish Medical Organisation
INO	Irish Nurses Organisation
IV	Intravenous
NCHDs	Non-Consultant Hospital Doctors
NDSC	National Disease Surveillance Centre
NIH	National Institutes of Health
NVRL	National Virus Reference Laboratory
OH	Occupational Health
OHD	Occupational Health Department
OHP	Occupational Health Physician
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PHLS	Public Health Laboratory Service (Colindale, UK)
PPE	Personal Protective Equipment
RNA	Ribo-Nucleic Acid
RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction



