Infection control guidelines
for the prevention of transmission of infectious diseases in the health care setting

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This document is also included in PARADIGM'S annotated index of healthcare epidemiology and infection control literature at http://bookstore.phf.org/prod125.htm

How to use this document

Overview

IMPORTANT NOTE: Part 1 of this document (Principles of Infection Control) provides recommendations that form the foundation for all work practices and procedures detailed in the remainder of the document. Reading and applying these principles is the key to understanding the issues involved that affect infection control. Please read Part 1 first, then the table of contents where all the information is listed in a logical sequence.

These guidelines should be considered in association with the State and/or Territory legislative requirements that affect work practices of the health care establishment and/or health care worker. If the recommendations in this document conflict with State or Territory guidelines, the statutory requirements of the state or territory should take precedence.

This document outlines the principles involved, and the procedures necessary for the prevention of transmission of infectious diseases in the health care setting, hereafter in this document referred to as ***infection control*** or ***infection control procedures.***

Successful infection control is based on good hygiene around a range of practices that arise from identifying hazards and implementing risk management for the hazards.

This involves understanding –

- the infectious agents;
- the work practices that prevent the transmission of infection in different settings; and
- management systems that support effective work practices.

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To address these issues, this document has been prepared in five main parts. Part 6 details the references associated with the document.

Part 1 Principles of Infection Control provides the foundation for all work practices and procedures detailed in the remainder of the document. Reading and applying these principles is the key to understanding the issues involved.

Parts 2 to 5 may be read in their entirety or used as a ready reference to obtain specific information about the many different aspects of an effective infection control program. For example, to find information on a specific disease, refer to **Part 4 (Infectious diseases in the health care setting).**

Part 1 Principles of infection control	Introduces the concepts necessary for an effective infection control strategy and outlines the basic principles that are applied throughout the remainder of the guidelines.
Part 2 Quality Management	This section describes administrative arrangements for effective infection control and quality management. The ethical and legal considerations that affect quality management are also discussed.
Part 3 Effective Work practices and procedures	This section is about personal and environmental hygiene, support services, equipment and instruments including reprocessing, surveillance, HCW protection, blood and blood products and transplants.
Part 4 Managing Infectious diseases in the health care setting	This section identifies the major risk factors and recommends management procedures for patients, HCWs, instruments and the health care environment. A short description is also included of the viral, bacterial, anti-biotic resistant and other infectious diseases that are important in the health care setting.
Part 5 Infection control in specific health care settings	This section identifies the major risk factors and management procedures for specialised health care settings. These include operating rooms, office practice including dental practice, midwifery and obstetrics, home and community, and residential aged care.
Part 6 Appendices	Appendix 1 – Consensus numerator definitions Appendix 2 – Notifiable Diseases in Australia Appendix 3 – Australian/New Zealand Standards Appendix 4 – Sample questionnaire from ARCBS Appendix 5 – Reviewers of previous edition of ICG Appendix 6 – Respondents to public consultation ICG Appendix 7 – National contact information Appendix 8 – ANCHARD Bulletin No 16 Appendix 9 - Expanded version of Chapter 31 (CJD) Appendix 10 - State and Territory Chief Health and Medical Officer Contacts Appendix 11 – Glossary Appendix 12 - Acronyms Appendix 13 - References

The table of contents provides a detailed breakdown of all the sections, subsections tables and figures included in the ICG. A subject index is also included for easy reference to particular subject areas.

Many sections of the document refer to Australian Standards (AS) or Australian and New Zealand Standards (AS/NZS). A full list of all the standards referred to in this document is given in Appendix 3 on page ###. Other references are listed in the References section on page ###.

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Preface

The intention of this document — *Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting* (ICG) is to provide national best practice guidelines for infection control procedures in Australian health care settings. The scope of ICG is broad and applies to a wide range of health care establishments including hospitals, office practices (medical and dental), long-term residential care establishments, community nursing, emergency and first aid services. This document is also intended to be used as a resource to guide or implement infection control policy for health care establishments and individual health care workers (HCWs).

The aim of this process has been to:

- develop infection control guidelines that are substantiated by advice from experts and evidence from published scientific and medical literature.
- provide accurate and up-to-date technical information or 'best practice guidelines' for infection control management; and
- address ethical issues pertaining to infection control where a national approach is appropriate.

These guidelines have been prepared under the auspices of the Communicable Diseases Network Australia (CDNA), which is a subcommittee of the National Public Health Partnership (NPHP). CDNA is comprised of public health experts drawn from Commonwealth, State and Territory public health departments and agencies, and recognises that the information needs to be reviewed continuously because of technical developments, new instrumentation, regulatory changes and microbial evolution. Regular updates will be made to this document in light of these developments. Amendments to the text will be posted on the Commonwealth Department of Health and Ageing's web site

http://www.health.gov.au/pubhlth/publicat/document/icg_guide/index.htm

An Infection Control Guidelines Steering Committee (ICGSC) was formed to oversee the project and to provide expert medical and scientific advice. The ICGSC was supported by a project team drawn from the Communicable Diseases and Health Protection Branch of the Department of Health and Ageing. The Department's project team provided scientific advice, and administrative and secretariat support.

Recognised experts and organisations drafted various sections of the document to reflect current scientific evidence and best practice. The draft was posted on the

Department's website in July 2000 and public comment invited. All submissions were considered by ICGSC, and in August 2001 further public comment was sought on the revised draft. The draft was further amended by the ICGSC in light of the public consultation, before consideration and endorsement by the CDNA.

Disclaimer

The members of the Infection Control Guidelines Steering Committee, the members of the Communicable Diseases Network Australia, the National Public Health Partnership, and the commonwealth give no warranty that the information contained in the *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting* (*ICG*) is correct or complete. *ICG* are necessarily general and are not intended to be a substitute for a health professional's judgement in each case. The members of the Infection Control Guidelines Steering Committee, the members of the Communicable Diseases Network Australia, the National Public Health Partnership, and the Commonwealth shall not be liable for any loss whatsoever whether due to negligence or otherwise arising from the use of or reliance on (*ICG*).

Special thanks and acknowledgment to the ICG Review Steering Committee (honorary) members for their generous donation of time, their technical advice and cheerful cooperation that contributed to the success of the project.

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Terms of reference

The terms of reference for the Infection Control Steering Committee were as follows.

1. Review the documents:

   A. *Infection Control in the Health Care Setting: Guidelines for the Prevention of Transmission of Infectious Diseases* (NHMRC/ANCA 1996)

   B. *Creutzfeldt–Jakob Disease and Other Human Transmissible Spongiform Encephalopathies: Guidelines on Patient Management and Infection Control* (NHMRC 1995); and

   Provide a revised document on infection control in health care settings, by March 2000, to the Communicable Diseases Network Australia New Zealand (CDNANZ) for endorsement.

2. As part of the review process:

   - consult with key stakeholders;
   - consider the available scientific evidence and current best practice methods, both in Australia and internationally that may impact on the ICG revision; and
   - take legal advice about current and emerging trends, both ethical and practical, influencing infection control practice in the health care setting.

3. Incorporate appropriate recommendations based on current scientific, medical and legal advice into a revised document for publication and distribution to health care providers.

4. Advise CDNANZ on mechanisms for the ongoing:

   - review of infection control issues;
   - implementation of the guidelines into infection control practice;
   - evaluation of the guidelines; and
   - incorporation of new or emerging issues into future revisions of ICG.

5. Report progress of the review to the CDNANZ, through the National Centre for Disease Control (NCDC), at least once every six months during the current revision process.

6. Disband the current committee.

Committee membership

Department of Health and Ageing - Infection Control Guidelines Review Steering Committee (ICGSC)

Professor Peter McDonald (Chair)	Flinders University of South Australia, Department of Microbiology and Infectious Diseases, Adelaide
Dr John Carnie	Department of Human Services, Infectious Diseases Unit, Melbourne
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Mrs Sandra Thorman (November 2000 to March 2002)	Steering Committee Secretariat and editor
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Ms Anne Marie Nielson (From February 1999 to October 2000	Project officer
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Part 1

Principles of infection control

1 Infection control strategy

Key points

- Because many infectious agents are present in health care environments, patients may be infected while receiving health care, health care workers may be infected during the course of their duties and other people may be infected when working or interacting with patients in a health care establishment.
- These *health care associated infections* could occur in any health care setting eg, hospitals, general practice, day surgery centres, domiciliary nursing services, residential aged care, community services or office practices (dentistry, podiatry, etc).
- Adopting quality control measures (based on identifying hazards and assessing risks) may minimise health care associated infections.
- Successful infection control involves five elements, which form the basis for parts 1 – 5 of these guidelines:
  – Applying basic infection control strategies (Part 1);
  – Quality management practices (Part 2);
  – Effective work practices that prevent transmitting infectious agents (Part 3);
  – Managing specific infectious agents (Part 4); and
  – Identifying infection control strategies in specialised health care settings (such as operating rooms, dentistry, residential aged care facilities) (Part 5).

1.1 Introduction

A fundamental activity in Australian health care establishments is to continually improve the quality of care and provide a safe working environment. Central to this activity is an effective infection control strategy preventing the transmission of infections from person to person within the health care environment.

Infectious agents evolve and continually present new challenges in the health care setting. Continually modifying and improving procedures is important to meet the challenges in the health care environment.

Many infectious agents are present in health care settings. Patients could become infected while they are receiving health care and HCWs are also at risk while they are doing their work. Other people may also be at risk visiting and working in the health care establishment. In some cases, these health care associated infections are extremely

serious or even life threatening. HCW should adopt the guidelines in this document to minimise these infections.

1.1.1 Scope

The scope of this document is intentionally broad and aims to establish a nationally accepted minimum standard for infection control. These guidelines provide a basis for HCWs and health care establishments to develop detailed protocols and systems for infection control that apply to their specific health care setting.

The guidelines in this document apply to a wide range of health care establishments including hospitals, office practice (medical and dental), nursing homes, extended care establishments, community nursing, emergency and first aid services.

The following general definitions are used throughout these guidelines.

Health care associated infections (HAI)— refers to infections acquired in health care establishments ('nosocomial' infections) and infections that occur as a result of health care interventions ('iatrogenic' infections) which may manifest after leaving the health care establishment.

Health care establishments — refers to any facility that delivers health care services. They could be hospitals, general practice, dentistry, other community-based office practices, day surgery centres, domiciliary nursing services, residential aged care, alternative health providers and other community services such as needle exchanges.

Health care workers (HCWs) — refers to all people delivering health care services, including students, trainees and mortuary attendants who have contact with patients or with blood or body substances.

Definitions of other terms used in these guidelines are given in the Glossary.

1.2 Successful infection control

Maintaining a safe environment for people, patients and HCWs in a health care environment is a complex matter. Identifying hazards and classifying the associated risks is the key to successful infection control management. This task requires unselfish cooperation between management, HCWs and support staff.

- Health care establishments should develop detailed protocols and policies that cover the five elements of successful infection control discussed in the *Key point* box at the beginning of this section.

These five elements are addressed in ICG and organised in five main parts.

Part 1. Principles of infection control:

- overall strategy;
- basic measures for infection control (standard and additional precautions);
- identifying hazards and minimising risks;
- identifying who is at risk and from what;
- responsibilities of health care establishments, HCWs, patients, carers and other people; and
- routine practices essential to effective infection control such as aseptic technique, handling of sharps, use of single-use equipment, reprocessing of instruments, antibiotic use and the appropriate use of antiseptics and disinfectants .

Part 2. Quality management:

- administrative arrangements for effective infection control, including
  - implementing an infection control program,
  - appointing an infection control committee and infection control practitioner,
  - compliance and accreditation standards,
  - quality improvement program maintenance,
  - continuum of care responsibilities, and
  - employee health policies;
- educating and training HCWs, to improve their awareness and to encourage their compliance with national infection control standards; and
- ethical and legal issues that affect health care service delivery.

Part 3. Effective work practices and procedures:

- design and maintenance of premises;
- handwashing and personal hygiene;
- use of personal protective equipment;
- handling and disposal of sharps;
- management of clinical and related wastes;
- reprocessing of instruments and equipment (including instruments requiring special reprocessing);
- environmental cleaning and spills management;
- health care establishment support services (linen, laundry and food services);
- use of therapeutic devices;

- surveillance;
- protection for HCWs, including health status records, immunisation and testing of immune status;
- management of incidents involving blood or body fluid exposure;
- handling and use of blood and blood products; and
- organ transplants.

***Part 4. Managing infectious diseases in the health care setting**:*

- this section identifies the major risk factors and recommends management procedures for patients, HCWs, instruments and the health care environment. A short description is also included of the viral, bacterial, antibiotic resistant and other diseases that are important in the health care setting.

***Part 5. Infection control in specific health care settings**:*

- this section identifies the major risk factors and management procedures for specialised health care settings:
  - operating rooms;
  - office practice (general);
  - dental practice;
  - midwifery and obstetrics;
  - home and community; and
  - long-term care.

HCWs should recognise that although specific settings may have their own requirements, the principles outlined in these guidelines form the basis for infection control procedures in all health care settings.

Overall, successful infection control depends on:

- the health care establishment ensuring that policies and practices are guided by an infection control professional;
- adequate resources (people, equipment and space) to do the work of infection control, which are consistent with both the establishment's infection control strategic plan and its business plan;
- applying the infection control program across all components in the organisation including support services as well as direct clinical care;
- integrating a system of quality management into the infection control program;
- appropriate training and management of all staff that fosters commitment to the infection control program;

- ongoing assessment, including incident monitoring of the infection control program that encourages adjustment to work practices when required; and
- regularly evaluating the infection control program with feedback to management and HCW on the program's effectiveness with provision for adjustment as required.

2 Basic infection control measures

Key points

- *Standard precautions* are standard operating procedures that apply to the care and treatment of all patients, regardless of their perceived infectious risk. These precautions include aseptic technique, handwashing, use of personal protective equipment, appropriate reprocessing of instruments and equipment and implementing environmental controls. Standard precautions should incorporate safe systems for handling blood (including dried blood), other body fluids, secretions and excretions (excluding sweat), non-intact skin and mucous membranes.

- *Additional precautions* are required when standard precautions may not be sufficient to prevent the transmission of infectious agents eg, tuberculosis, measles , Creutzfeldt–Jakob disease (CJD). Additional precautions are tailored to the specific infectious agent concerned and may include measures to prevent airborne, droplet or contact transmission and health care associated transmission agents.

2.1 Background

The strategies for infection control described in these guidelines are based upon current understanding of the aetiology of the infections involved and the most effective ways to control them. Before the advent of human immunodeficiency virus (HIV) in the early 1980s, and the increase in high throughput, short-stay surgical and medical treatments, the majority of recognised health care associated infections occurred in hospitals.

Prior to the 1980s, infection control systems were based on identifying at risk patients in hospitals and applying isolation systems or special treatments. The isolation approach failed to take account of the possibility of transmitting infection from asymptomatic individuals, particularly those with bloodborne viruses and antibiotic-resistant bacteria.

By the mid-1980s the HIV/AIDS epidemic created an urgent need for new strategies to protect HCWs from bloodborne infections in their working environment. In 1985, universal blood and body fluid precautions (*universal precautions*) were proposed by the United States Centers for Disease Control and Prevention (CDC 1987). This new approach emphasised the universal use of blood and body fluid precautions regardless of a patient's presumed infectious status.

As initially defined by the CDC *universal precautions* applies to blood and body fluids that had been implicated in transmitting bloodborne infections. CDC *Universal precautions* do not apply to faeces, nasal secretions, sputum, sweat, tears, urine or vomit, unless they contain visible blood (CDC 1994a).

State and Territory health departments in Australia adopted a broader approach to *universal precautions*. They agreed that all blood and body substances should be considered as potentially infectious and introduced the term *standard precautions*. This principle was applied to all people, regardless of their perceived or confirmed infectious status, as a strategy for minimising heath care associated infections, from both asymptomatic and symptomatic people. In 1996, the National Health and Medical Research Council (NHMRC)/Australian National Council on AIDS (ANCA) Infection Control Working Party adopted the terms 'standard precautions' and 'additional precautions' (based on modes of transmission of infectious agents), to define appropriate work practices.

- *Standard precautions* are work practices required to achieve a basic level of infection control and are recommended for the treatment and care of all patients.
- *Additional precautions* are recommended for patients known, or suspected to be, infected or colonised with disease agents that cause infections in health care settings and may not be contained by standard precautions alone.

This two-tiered approach should provide high-level protection to patients, HCWs and other people in health care establishments (see **Sections 2.2 and 2.3**).

2.2 Standard precautions

Standard precautions are work practices required to achieve a basic level of infection control. A directory of these work practices, that are pivotal to infection control in the health care environment, is shown in **Table 2.1.**

Table 2.1 Standard precautions for infection control in health care settings

Work practice	Relevant section(s)
Aseptic technique, including appropriate use of skin disinfectants	6.1, 7
Personal hygiene practices, particularly handwashing before and after all significant patient contacts	12
Use of personal protective equipment, which may include gloves, impermeable gowns, plastic aprons, masks/face shields and eye protection	13
Appropriate handling and disposal of sharps and other clinical waste	14, 15
Appropriate reprocessing of reusable equipment and instruments, including appropriate use of disinfectants	7, 16, 17
Environmental controls, including design and maintenance of premises, cleaning and spills management	11, 18
Appropriate provision of support services such as laundry and food services	19

Standard precautions are recommended for the care and treatment of all patients, regardless of their perceived or confirmed infectious status and in the handling of:

- blood (including dried blood);
- all other body fluids, secretions and excretions (excluding sweat), regardless of whether they contain visible blood;
- nonintact skin; and
- mucous membranes

The use of standard precautions is essential as the primary strategy for the successful minimisation of transmission of health care associated infection because:

- infectious patients may not show any signs or symptoms of infection that may be detected in a routine history and medical assessment;
- a patient's infectious status is often determined by laboratory tests that may not be completed in time to provide emergency care;
- patients may be infectious before laboratory tests are positive or symptoms of disease are recognised (the window period of disease); or
- people may be placed at risk of infection from those who are asymptomatic but infectious.

The work practices outlined in Table 2.1 should be considered minimum requirements for infection control. Implementing standard precautions minimises the risk of transmission of infection from person to person even in high-risk situations. Standard precautions should be implemented at all times particularly when patients are undergoing invasive procedures, including catheterisation, cannulation or intubation. Health care establishments that offer these procedures should provide detailed protocols for patient management in their infection control procedures manuals.

DISCUSSION POINT

Routine practices questioned

Over years, many 'routine' practices intended to reduce infection risk have been adopted in the workplace. Examples include wearing of masks in operating theatres by all personnel, the use of overshoes, requirements to wear fresh uniforms on a daily basis, exclusion of nasal staphylococcal carriers from designated duties.

Often the evidence base to support many of these practices is lacking in terms of scientific trials. Nevertheless, some activities, such as washing hands between administering care to successive patients have a credible history to support their routine application in preventing cross infection. Other practices, such as some uniform and clothing requirements, are more to do with the ethos of quality care and workplace culture than with a proven reduction of cross-infection.

Today, 'routine' practices, such as wearing protective masks for routine procedures, are being questioned, which may be appropriate. However, the absence of evidence to support routine practice should not be considered to be a basis for abandoning these practices. Rather, 'routine' practices should continue until there is sufficient evidence to support alternative procedures.

2.3 Additional precautions

Additional precautions should be applied in a health care setting for patients known or suspected to be infected or colonised with infectious agents that may not be contained with standard precautions alone and that could transmit infection by the following means:

- by airborne transmission of respiratory secretions (eg pulmonary tuberculosis, chickenpox, measles);
- by droplet transmission of respiratory secretions (eg rubella, pertussis, influenza);
- by contact with patients who may be disseminators of infectious agents of special concern, for example from
  –

  - faecal contamination from carriers of vancomycin-resistant enterococci;

- by inherent resistance to standard sterilisation procedures or other disease-specific means of transmission where standard precautions are not sufficient (eg patients with known or suspected CJD — see **Section 31**). [1]

Additional precautions should be tailored to the particular infectious agent involved and the mode of transmission, and may include one or any combination of the following:

- allocation of a single room with ensuite facilities;
- a dedicated toilet (to prevent transmission of infections that are transmitted primarily by contact with faecal material, such as for patients with infectious diarrhoea or gastroenteritis caused by enteric bacteria or viruses);
- cohorting (room sharing by people with the same infection) may be an alternative if single rooms are not available;
- special ventilation requirements (eg monitored negative air pressure in relation to surrounding areas);
- additional use of personal protective equipment (eg HCWs attending to patients in respiratory isolation should wear a well-fitting mask: a 0.3-µm particulate filter mask[2] is recommended for tuberculosis);
- rostering of immune HCWs to care for certain classes of infectious patients (eg chickenpox);
- dedicated patient equipment; and
- restricted movement of both patients and HCWs.

An outline of the application of additional precautions for infections with respiratory (airborne or droplet) transmission or contact transmission is shown in **Table 2.2**. Further information about the diseases in these categories are detailed in **Part 4 (Infectious diseases in the health care setting)**.

Additional precautions are not required for patients with bloodborne viruses, such as HIV, hepatitis B virus or hepatitis C virus, unless there are complicating infections, such as pulmonary tuberculosis.

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[1] Unless otherwise specified, in this document, the term 'Creutzfeldt–Jakob disease (CJD)' is used as a general term to cover the classical forms of CJD (including related human transmissible spongiform encephalopathies) and variant CJD. For further details of this group of diseases, see Section 31.1.

[2] See Section 13.4 for definition and description of appropriate masks and personal respiratory protection.

To minimise the exposure time of other people in office practices or hospital waiting rooms, people identified as at risk of transmitting droplet or airborne diseases (eg a child with suspected chicken pox) should be subject to additional precautions and also be attended to before other people waiting for treatment.

Table 2.2 Outline of requirements for specified categories of additional precautions

Requirement	Additional precautions type		
	Airborne transmission	**Droplet transmission**	**Contact transmission**
Gloves	Nil	Nil	For all manual contact with patient, associated devices and immediate environmental surfaces
Impermeable Apron/gown	Nil	Nil	When HCWs clothing is in substantial contact with the patient, items in contact with the patient, and their immediate environment
Respirator or mask.	P2 particulate respirator for tuberculosis only. all others, surgical mask [a]	Yes — surgical mask [a]	Protect face if splash likely
Goggles/face-shields	Protect face if splash likely	Protect face if splash likely	Protect face if splash likely
Special handling of equipment	As per standard precautions	As per standard precautions	Single use or reprocess before reuse on next patient (includes all equipment in contact with patient)
Single room	Yes Or Cohort patients with same infection. Door closed.	Yes Or Cohort patients with same infection. Door closed.	If possible, or cohort with patient with the same infection (eg methicillin-resistant *Staphylococcus aureus*)
Negative pressure	Essential for pulmonary TB	No	No
Transport of patients	Surgical mask [a] for patient Notify area receiving patient	Surgical mask [a] for patient Notify area receiving patient	Notify area receiving patient
Other	Encourage patients to cover nose and mouth when coughing or sneezing and wash their hands after blowing nose. Provide one metre of separation between patients in ward accommodation	Provide one metre of separation between patients in ward accommodation	Remove gloves and gown, and wash hands before leaving patient's room

[a] Surgical mask refers to a fluid repellent, paper filter mask used in surgical procedures (see **Section 13.4** and AS 4381).

2.4 Triage policy

Specific triage policies should be developed to minimise transmitting diseases to other patients in outpatient/emergency units or health care waiting rooms. This applies particularly where there is a high risk of transmission (eg respiratory viruses such as respiratory syncytial virus, influenza and chickenpox). Triage staff and clinicians have a pivotal role in instigating an outbreak management plan.

Prior to hospital admission a detailed medical history should be collected from an individual or their carer to identify conditions that may require additional precautions when individuals are being admitted to hospital or presenting at an emergency unit. Triage staff should use a 'checklist' to assess patients for conditions that require additional precautions, as well as prioritising those who may require urgent attention, isolation or immediate treatment.

When referring patients (for surgery, dental treatments or hospital admission) the treating doctor should advise the clinician in charge of admission of any known infectious conditions that are relevant to the purpose of the referral. The patient's consent should be sought before the release of any sensitive information (for further information see **Section 10 Ethical and Legal Issues)**.

2.5 Quarantine

The Commonwealth Government has legislative responsibility for human quarantine. Under the Human Quarantine Program, the Commonwealth Government develops policy on diseases of quarantine importance, and in collaboration with chief quarantine officers of each State and Territory health department, coordinates the national response to outbreaks of quarantinable diseases.

Certain diseases are listed as quarantinable under the *Quarantine Act 1908* (Commonwealth) and its proclamations. These include yellow fever, cholera, plague, rabies, Japanese encephalitis and four viral haemorrhagic fevers (Crimean–Congo, Ebola, Lassa and Marburg). The Chief Quarantine Officer (CQO) of the relevant State/Territory should be notified immediately, by phone or fax, of any suspected or confirmed case of a quarantinable disease as required by local legislation. Contact may be made through the State/Territory health department.

2.6 Handling and transport of deceased patients

All bodies of deceased patients should be handled using standard precautions as bloodborne pathogens may remain infective for some time. Any exposures to blood or body fluids should be reported and managed as outlined in **Section 23**. If additional precautions were required before death, those handling the body after death should continue these precautions.

Viewing of the body by relatives should not be prohibited on infection control grounds. Unless contact with blood or other body fluids of the deceased is likely, relatives should not be discouraged from superficial contact, such as touching or kissing.

When deceased patients need to be transported, appropriate arrangements should be made to contain any potential spillage of blood or body fluids. Generally, an

impervious plastic wrap should be used to encase the deceased patient before transport. The Australian Funeral Directors Association (AFDA 1992) suggest the use of polyethylene sheeting of suitable strength and size folded into an 'envelope' and sealed with 40-mm wide waterproof adhesive tape.

HCWs involved in transport and handling of deceased patients should also be aware of the dangers from sharps that may still be with or in the body. Appropriate personal protective clothing should be worn when handling deceased patients.

3 Identifying hazards and minimising the risks of infection

Key points

- To successfully control transmission of infectious agents in health care settings it is necessary to:
  – identify hazards;
  – assess, classify and manage risks; and
  – develop risk management protocols and communication strategies to effectively minimise the risks.

3.1 Identifying hazards

A hazard in a health care setting is defined as an agent (biological, chemical or physical) that has the potential to cause harm to people or the environment. In infection control a hazard is either an infectious agent or a mechanism that allows the transmission of an infectious agent (eg invasive device).

Identifying a hazard involves:

- Identifying and documenting the activities and tasks that put patients and HCWs at risk of infection (eg sharps injury);
- Identifying and documenting the infectious agent involved;
- Identifying and documenting the route of infection; and
- Obtaining evidence to confirm that the infection may be spread using this route (observational or experimental studies plus expert knowledge).

3.2 Assessment of risks

Risk assessment for the transfer of infectious diseases includes:

- ***hazard identification*** — see **Section 3.1**;
- ***hazard characterisation*** involves evaluating the infective dose of the infectious agent and a relationship between the dose received and the frequency/severity of the infection (dose-response relationship), and;
  – knowledge of infectious agents, epidemiology etc;

  - assessment of the health care establishment physical environment (layout, facilities and practices);
  - assessment of current infection control procedures;
  - analysis of records of infection; and
  - level of knowledge and/or training of patients and HCWs.

- ***exposure assessment*** involves evaluating factors relating to hazard exposure to determine the dose of infectious agent received, which may be quantitative, or qualitative. (For example for a sharps injury this would be the source of infection and the level of contamination); and assessing -
  - patient categories;
  - HCW categories;
  - procedures (critical, semicritical, noncritical); and
  - frequency of exposure.

- ***risk characterisation*** involves integrating hazard and exposure information to give a qualitative estimate of risk (eg low risk) or, if data are available, a quantitative population-based estimate (eg 1 in 1000).

3.3 Risk management

The purpose of risk management/control is to minimise exposing people to sources of infection, including blood or body fluids, in the health care setting. Depending on the nature of specific risks, risk management may be achieved by:

- eliminating the risk factors;
- modifying procedures, protocols and work practices;
- engineering controls;
- implementing safe work practices;
- monitoring HCW and patient compliance with infection control procedures;
- providing HCW with information about personal health conditions that may place them or patients at risk;
- providing information/education and training to patients and HCWs; and
- using personal protective equipment appropriately.

In addition to AS/NZS 4360:1995 a 'hazards analysis critical control points' (HACCP) approach (ANZFA 1996, Mortimore and Wallace 1998) provides a framework for identifying hazards, assessing the risks and implementing risk management using the following principles:

- determining critical control point plans required to control identified hazards;

- specifying critical limits that determine whether a procedure is under control at a particular control point;
- establishing a monitoring system for critical limits;
- implementing corrective action if critical limits are not met; and
- verifying the system is operating according to specification.

These principles form a framework to link identifying specific hazards with critical control points. Implementing suitable procedures within this framework should provide effective control over the transmission of infectious agents in the health care environment.

For example, the critical points for ensuring reprocessed instruments are sterile may include cleaning the instruments before sterilisation, packing the sterilized unit and validating of the steam sterilisation process. Routine procedures are then required to ensure that each of these identified critical control points are adequately monitored (for example, see AS4185[3]).

Using this approach, critical control pathways may be mapped for all activities where hazards have been identified. The higher the risk associated with the identified hazard, the more critical control points and/or the more rigorous monitoring procedures may be required.

Details of the application of HACCP principles for food preparation are given in **Section 19.2**.

Health care establishments have a legal and ethical responsibility to provide HCWs with:

- risk assessment guidelines;
- a safe working environment;
- effective workplace instruction and ongoing education about infection control procedures;
- appropriate facilities and equipment, including occupational health services; and
- health screening programs.

Ongoing monitoring and evaluation of infection control procedures is also required.

[3] AS/NZS 4815 (2001) *Office-based health care facilities not involved in complex patient procedures and processes — Cleaning, disinfecting and sterilising reusable and surgical instruments and equipment*

3.4 Risk communication

Risk communication is the process of interactive exchange of information and opinion among risk assessors, risk managers and other interested parties. For this to occur, infection control objectives should be established and evaluated regularly. Feedback on the effectiveness of infection control programs should be provided to all the stakeholders of the establishment.

3.4.1 Health care establishment communication strategies

An empowering infrastructure and environment are important factors for increasing the level of compliance with infection control programs. Hence, management should:

- provide direction (eg nominate issues for attention that are relevant to the establishment, such as rotavirus in paediatrics or urinary catheter sepsis in paraplegic care);
- establish goals (ie nominate benchmark rates for performance improvement);
- provide resources; and
- provide information to individuals, self-directed work groups, patients and other stakeholders, with an emphasis on continually improving performance.

Health care establishments should incorporate a communication plan and process that:

- provides timely information necessary to accomplish their objectives;
- facilitates feedback; and
- increases awareness of the infection control program.

3.4.2 Health care worker communication strategies

Strategies for communicating infection control issues among HCWs include:

- developing a set of shared values, behavioural guidelines and quality principles in support of the establishment's infection control strategy that are reflected in job descriptions and duty statements;
- communicating annual infection control objectives to HCWs in simple and measurable terms to form the basis for HCW work plans;
- ensuring that HCWs understand the establishment's infection control objectives and may articulate their contribution as part of regular HCWs performance reviews;

- ensuring all HCWs understand the link between the establishment's infection control program objectives and their personal work objectives;

- regular reviews to ensure that HCW objectives are translated into work plans that act as
  - a mechanism for ongoing formal feedback on individual and collective behaviours, and
  - a system to build feedback into the process of continuous personal improvement;

- multidisciplinary workshops to
  - devise individual infection control codes of conduct,
  - communicate the interdependent mechanisms of infection control, and
  - build infection control codes into career development.

3.4.3 Patient communication strategies

Health care establishments are responsible for communicating to patients their reasons for infection control policies and procedures. This should encourage patient cooperation that is required to minimise cross infection.

Education

Patient cooperation is vital to an effective infection control program. Health care establishments should inform patients about the risks associated with medical and surgical treatment.

Educational material should be provided in all health care settings, including the home/community setting using a variety of mediums including posters, printed material, educational videos etc. Patients should be familiarised with the infection control strategies that are employed in health care establishments to protect them, the people caring for them and the health care environment. Information should also be provided about procedures for dealing with infection control breaches.

Risk disclosure

Health care establishments should inform patients about the risks associated with their medical care and the protocols for protecting their privacy and confidentiality. Patients should be encouraged to disclose their health or risk status and/or any lifestyle choices that make them a potential risk or source of infection to HCWs and/or other people within the health care establishment. Informing the patient of the protocols for protecting their privacy and confidentiality should form part of this discussion.

Patients should informed about, and encouraged to use, feedback procedures to staff/management about any concerns they have about infection control procedures.

3.4.4 Communication with the health care industry

HCWs should liaise with the health care industry and interest groups to improve infection control procedures by providing feedback about equipment design. Risk prevention and optimal maintenance/cleaning by health care establishments should be considered, in conjunction with evidence-based infection control data, to ensure that high standards of design may be achieved.

3.5 Tracking and traceability

For surveillance purposes and in the event of a lookback investigation, health care establishments should implement an effective system to track and trace surgical instruments and devices that have been associated with health care associated infections.

3.5.1 Devices and instruments

Health care establishments should have systems in place that allow key items (for high risk procedures - See Table 4.1) of equipment to be tracked. Those hard to clean instruments classified as semi-critical items (see Table 4.2) that have been known to transmit infectious agents, (eg flexible endoscopes) should also be tracked (see Section 17 Instruments and equipment requiring special processing). The system should show individual devices/instruments, details of patient use, details of reprocessing steps, and process validation proof (see **Section 17.1.2** for further information).

Health care establishments should be able to identify the patients on whom individual instruments have been used so that these patients may be traced if potential exposures have occurred (eg after use on patients with CJD or pulmonary tuberculosis).

3.5.2 Prostheses

Due to the potential dangers in the use of prostheses, health care establishments that are involved in the implantation or insertion of prostheses must maintain adequate records. These records must cross-reference patients with the batch and manufacturer code details of all implanted prostheses to allow identification of individual patients in the event of a recall or other event (eg health risk).

3.5.3 Contact tracing

When there are cases of specific infectious diseases (eg tuberculosis, measles), the health care establishment involved may be required to provide details of patients, HCWs and others who have been potentially exposed to the disease to public health

officials responsible for tracing and informing potentially exposed persons. Health care establishments should maintain appropriate systems to enable such tracing.

4 Who is at risk and from what?

Key points

Risk of contracting a health care associated infection

- Patients may contract infections from themselves (endogenous infection) or from other patients, health care workers (HCWs), instruments and equipment or the environment (exogenous infection). The level of risk relates to the health care setting (presence or absence of infectious agents), the type of health care procedures performed and the susceptibility of the patient to infection.

- HCWs may contract infections from infected patients, instruments and equipment, or the environment. The level of risk relates to the type of clinical contact HCWs have with potentially infected patient groups, instruments or environments, and the health status of the HCW (eg immunised/previously exposed).

Risk of transmitting a health care associated infection

- Patients may transmit infections to other patients, HCWs, instruments and equipment, or the environment. The level of risk relates to the transmissibility of the infectious agent, the availability of a route of transmission, the susceptibility of exposed persons, and the success of applied control measures (ie standard and additional precautions).

- HCWs may transmit infections to patients during clinical contact, or to other HCWs, instruments and equipment or the environment. The level of risk relates to the procedures undertaken (interviews and noninvasive procedures being lowest risk and exposure-prone invasive procedures the highest risk) and the efficacy of the aseptic techniques used.

- Instruments and equipment may transmit infections to patients during clinical procedures. The level of risk relates to the site where the instrument is used — instruments that contact sterile tissue (critical sites) are the highest risk, and instruments that contact only intact skin (noncritical sites) are the lowest risk.

- Infections may be transmitted from the environment when infectious agents are provided with a route of entry into susceptible patients or HCWs (eg airborne bacterial contamination of open wounds). The level of risk relates to the susceptibility of the patient/HCW, the availability of a route of entry from the environment and the level of contamination of the environment.

4.1 Spreading infection

Spreading infection involves three elements:

- a source of infecting micro-organisms or other infectious agents (at a sufficient level to cause infection);
- a susceptible host; and
- a path of transmission for infectious agent to susceptible host.

In a hospital, or other health care establishments, the patients and HCWs are both potential sources and potential hosts for infectious agents. Human hosts may be people who are acutely ill, people who have no symptoms but who are in the incubation or window period of a disease (ie the time after infection has occurred but before a diagnosis is possible), or people who are chronic carriers of an infectious agent. Other sources of infectious agents are the normal endogenous microbial flora of patients or HCWs, or environmental sources, such as air, water, medications or medical equipment and devices that have become contaminated.

People have variable resistance to infection depending on their age, underlying disease, and other factors that may compromise their immune status, such as medical treatment with immunosuppressive drugs or irradiation. The risk of transmission of infection is higher for patients undergoing invasive procedures, and for patients who stay in hospital for a long time. 'Indwelling' devices, for example catheters, may also increase the risk of infection, particularly when used over long periods. These risk factors are discussed further in this section by considering four main elements:

- patients;
- health care workers;
- instruments and equipment; and
- the health care environment.

Infections may pass between any of these elements in either direction, as shown in **Figure 4.1**. The risks associated with specific routes of infection are described in more detail in **Part 4 (Infectious diseases in the health care setting)**.

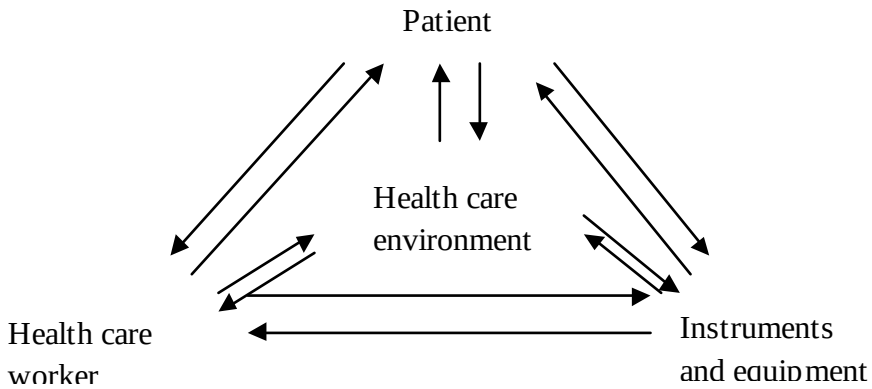


Figure 4.1 Spread of infection in health care settings

4.2 Patients

4.2.1 Risk of contracting a health care associated infection

Patients may contract infection from:

- their own (endogenous) flora;
- exogenous sources, including:
  - contact with other patients or with health care workers (HCWs);
  - cross-contamination of equipment by either infected patients or HCWs;
  - procedures (eg inadequately reprocessed instruments); and/or
  - the health care environment (eg ventilation, food).

DISCUSSION POINT

Infection from within

The most common source of health care associated infection is the patient's own flora. Some of these types of infections may even be considered 'inevitable' (eg fungal infections in immunocompromised patients). Infection control practices should minimise the risk from the patient's own normal (endogenous) flora (eg the use of skin antisepsis before invasive procedures), as well as from exogenous sources (eg appropriate reprocessing of instruments).

The risk of a patient contracting a health care associated infection is related to the presence or absence and burden of infectious agents (either endogenous or exogenous), the susceptibility of the individual patient to infection and the type and quantity of health care procedures performed on the patient.

The burden of infectious agents is related to:

- virulence (the ability to cause disease); and
- the number of infectious agents present (dose).

Susceptibility to infection is related to:

- disease immunity and/or immunisation status;
- systemic immune deficiency (inherent or acquired, including treatment-mediated);
- physical breaches of body defence mechanisms (eg invasive devices, surgical wounds);
- skin/mucosal conditions (eg psoriasis, excoriation);

- other physical/health factors (eg age, pregnancy).

Immunocompromised patients are generally at increased risk from both endogenous and exogenous sources of infection. They may vary in their susceptibility to health care associated infections, depending on the severity and duration of immunosuppression. These patients may be particularly susceptible to environmental contaminants, such as *Legionella* spp or *Aspergillus* spp.

Children and confused adults who have not learnt or are unable to control their personal hygiene pose an additional challenge to maintaining infection control standards in health care establishments because they may be incontinent and use their hands and mouth to explore the environment. Very young children or babies may also be at increased risk of health care associated infection, due to their general lack of exposure to common diseases in the community, and perhaps due to their current immune status.

The type and quantity of procedures relates to factors such as:

- whether the procedure is invasive or exposure-prone;
- appropriate reprocessing of instruments;
- length of procedure or length of device use; and
- number of procedures performed (eg multiple procedures on one patient).

4.2.2 Risk of transmitting a health care associated infection

Patients may transmit infection to other patients, HCWs or visitors when:

- they have an active symptomatic infection;
- they are infectious with detectable markers for a particular disease but asymptomatic (ie asymptomatic carriers); and/or
- they are infectious but have no detectable markers (ie 'window period').

DISCUSSION POINT

Infected or not?

The chances of patients being infectious but asymptomatic may vary in different population groups and this may be used to determine risk status; for example, intravenous drug users demonstrate a higher prevalence of, and a higher risk of contracting, bloodborne viral diseases (eg hepatitis C) than nonusers.

However, such 'lifestyle' information may not be volunteered by the patient, and the right to privacy must be respected. All patients should therefore be considered a potential infectious risk.

The risk of transmission of infection to others is also related to factors such as the susceptibility of others to infection and the availability of a route of transmission (see **Section 4.2.1**).

4.3 Health care workers

4.3.1 Risk of contracting a health care associated infection

The main risk to HCWs is that they may contract an infection from contact with patients, instruments or from the health care environment. The risk of a HCW contracting a health care associated infection is related to the presence or absence and burden of infectious agents (number and virulence), the susceptibility of the individual HCW to infection and the type of infectious hazard encountered (see **Section 4.2.1**).

The infectious hazards encountered by particular types of workers vary between and within health care establishments. For example, clerical staff in a paediatric outpatient clinic may encounter viral infections more frequently than clerical staff in a pay office.

Three main categories of HCWs in relation to infectious hazards are given below. These are useful for targeting education programs and establishing immunisation protocols. These categories are not comprehensive, however, and do not necessarily represent the category that should be assigned to HCWs in similar positions in all health care establishments.

Clinical contact

This category includes all HCWs who have clinical contact with patients. Some of the HCWs in this category have physical contact with, or potential exposure to, blood and body substances. For example:

- dentists, medical practitioners, nurses, student HCWs and allied health practitioners;
- emergency HCWs (fire, police, ambulance and volunteer first aid workers);
- maintenance personnel who service clinical equipment;
- sterilisation services personnel;
- mortuary technicians; and
- cleaning staff responsible and waste management personnel.

This category also includes HCWs in patient areas who have less direct contact with patients or with blood or body substances. These HCWs may be exposed to infections spread by droplet, such as rubella, but are unlikely to be at risk from bloodborne diseases. Examples include:

- catering staff
- primary care reception staff and ward clerks

- maintenance personnel

Nonclinical contact

In many health care establishments, clerical staff, gardening staff and many other occupational groups have no greater exposure to infectious diseases than does the general public. These employees do not need to be included in vaccination programs or other programs aimed at protecting clinical contact staff.

Laboratory and mortuary staff

Laboratories contain special risk factors because of the equipment used (eg centrifuges) and the possibility of exposure to high concentrations of infectious agents generated by culture procedures. The major risk to laboratory staff occurs in the handling of blood and blood products.

The strategies for controlling infectious hazards in laboratories to create a safe working environment should be covered in laboratory manuals prepared inhouse in individual establishments to address the specific disease agents likely to be encountered based on AS/NZS 2243.3.[4]

Mortuary staff may be at risk of exposure to infectious agents through contact with body substances, or through certain procedures such as autopsies or embalming. These risks may be minimised by appropriate handling of deceased bodies (see **Section 2.6**) and the use of standard precautions. Further information about safe work practices in mortuaries may be found in AFDA (1992, 1995).

4.3.2 Risk of transmitting a health care associated infection

The risks of a HCW transmitting an infection to a patient in their care, another HCW or visitor are the same as those described in **Section 4.2.2** for patients.

Transmission from HCW to patient

The risk of an infected HCW transmitting an infection to patients is of particular concern. The possibility of this happening is related to the types of procedures the HCW is involved in, their infection status and the types of patients they provide care for. **Table 4.1** shows the level of risk to patients from HCWs infected with bloodborne viruses associated with various clinical procedures, from low-risk procedures (such as an interview or noninvasive examination), to high-risk, exposure-prone procedures (see below).

Invasive procedures carry a risk of infection and include any situation where a HCW enters the tissue, body cavity or organs of a patient, or surgically repairs traumatic

[4] AS/NZS 2243.3 (2002*Safety in laboratories - Part 3: Microbiological aspects and containment facilities.*

injury to a patient. Operator factors may also increase the likelihood of transmission. These include technical competency (that may relate to skills-training/education) and infectious status (eg HBV DNA high titre).

Exposure-prone procedures are those invasive procedures where there is potential for direct contact between the skin (usually finger or thumb) of the HCW and sharp surgical instruments, needles, or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites, including the mouth (NSW Health 1995b) of a patient. An exposure-prone procedure is any situation is where there is potentially a high risk of transmitting a blood borne disease between a HCW and a patient during a medical or dental procedure.

Table 4.1 Level of risk to patients from HCWs infected with bloodborne viruses, associated with particular procedures

Risk category	Procedures
High risk **(exposure-prone procedures NSW Health 1995b)**	Any submucosal invasion with sharp, hand-held instruments, or procedure dealing with sharp pathology/bone spicules, usually in a poorly visualised or confined space (eg orthopaedic surgery, trauma, internal cavity surgery, oral surgery)
Variable risk[a,b]	Minor dental procedures (excluding examination), routine dental extractions Internal/instrument examination/biopsy (eg endoscopy, vaginal examination, laparoscopy) Minor skin surgery
Low risk	Interview consultation, dental examination Noninvasive examinations or procedures (aural testing, electrocardiograph, abdominal ultrasound) Intact skin palpation (gloves not required, no pathology) Injections/venepuncture (gloves required)

[a]'Variable risk' refers to procedures where the risk may be dependent upon operator factors such as training, experience, competence or other operator-specific factors related to status of infection (eg HbeAg, high levels of HBV DNA).

[b]Where the risk to patients from HCWs infected with bloodborne viruses during specific procedures is unclear, consult with State/Territory and/or professional advisory boards for further advice.

Risk assessment for transmission from infected HCWs

For high-risk procedures (See **Table 4.1**), the incidence of exposures is sufficiently high to recommend that HCWs who perform these procedures should ascertain their status with respect to bloodborne viral diseases. HCWs who are infected, should not perform high-risk procedures. In the case of hepatitis B virus (HBV), hepatitis C virus (HCV) and possibly HIV infection, treatments may alter the infectious status. Thus, the determination about whether or not to participate in high-risk exposure-prone

procedures requires consultation with State/Territory and/or professional advisory boards. This issue is discussed **Section 24**.

Variable-risk procedures (see **Table 4.1**) refer to procedures or interventions where there is usually a low incidence of exposures, and it is likely that the infected HCW may safely perform such procedures provided that strategies are used to minimise risk (see below). However, if the HCW is more prone to exposures (eg HCW in training, or those with a previous history of exposures during procedures) or if the assessment of the infected HCW indicates a highly infectious status (eg high HBV DNA), then the situation should be reviewed in consultation with State/Territory and/or professional advisory boards.

Low-risk procedures (see **Table 4.1**) may be safely performed by infected HCWs, provided that standard precautions are strictly observed.

Risk minimisation

Risk minimisation strategies may include alteration of clinical procedures (eg use of staple devices instead of handheld suture needles) or, if this is not possible, prevention of the infected HCW from carrying out the procedure (see above). Where there is uncertainty, either about whether certain procedures are classified as 'exposure-prone' or about the level of risk associated with those procedures, the matter should be referred to State/Territory and/or professional advisory boards for individual assessment.

HCWs who engage in exposure-prone procedures, and who have positive or indeterminate test results for potentially serious bloodborne viral infections, such as hepatitis B virus, hepatitis C virus or HIV, must be individually assessed by their State/Territory and/or professional advisory boards or in accordance with local legislation/regulations (see Section 24).

4.4 Instruments and equipment

The risk of transferring infections on instruments and equipment is related to the presence or absence and burden of infectious agents (number and virulence), the type of procedure (eg invasive versus noninvasive) and the body site where the instrument is used (eg submucosal invasion versus intact skin).

The risk of transmission of infection by instruments and equipment may be classified according to the site where they are to be used. The Spaulding classification (Spaulding 1968) system suggests that contact sites for instruments may be classified as critical, semicritical or noncritical as shown in **Table 4.2**, and that instruments be processed accordingly (see **Section 16**).

Table 4.2 Spaulding classification system for possible contact sites of instruments

Application	Classification	Examples
Entry or penetration into sterile tissue cavity or bloodstream	Critical	Surgical procedure with entry into sterile tissue, intravascular cannulation
Contact with intact nonsterile mucosa (or nonintact skin)	Semicritical	Respiratory therapy, gastrointestinal endoscopy
Contact with intact skin	Noncritical	Noninvasive procedures (eg palpation, abdominal ultrasound)

All instruments and equipment contaminated with blood or body substances must be cleaned as soon as practicable. Reusable instruments and equipment should be reprocessed in the way described in **Sections 16 and 17**. Instruments that come into contact with sterile tissue must be sterile (see **Section 16.2.2**).

Instruments and equipment should be designed to minimise the potential for injury in routine use. Wherever possible, instruments or equipment that incorporate sharps should be minimised or guarded to reduce the likelihood of sharps injury.

4.5 Environment

Most environmental microorganisms are nonpathogenic (ie they do not cause disease in humans) but a small number are capable of causing disease in certain situations (eg *Legionella* spp). Some infectious agents may be shed by patients and/or HCW's into the environment (eg *Staphylococcus aureus*).

The risk of contracting an infection via the environment is related to the presence or absence and burden (number and virulence) of infectious agents in the environment and their ability to gain entry to a susceptible host.

Only a small proportion of all health care associated infections are transmitted from the environment. Although the environment is usually contaminated with bacteria, unless there is an opportunity for these bacteria to access open wounds or other potential sites of entry in sufficient numbers, they are not likely to cause infection.

Reducing the number of infectious agents in the environment — for instance by appropriate management of blood spills (see **Section 18.2**), use of aseptic technique (see **Section 6.1**) and effective engineering maintenance programs (see **Section 11.8**) — will minimise the likelihood of contracting an infection from the environment.

The major environmental infection risk occurs with invasive procedures and devices. HCWs must use procedures to reduce the likelihood of environmental contamination during invasive procedures or in the use of invasive devices. Such procedures may

include use of aseptic technique (see **Section 6.1**), specific ventilation requirements (eg during orthopaedic implant procedures; see **Section 11.5**) or procedures for handling/use of invasive devices (eg keeping drainage bags off the floor; see **Section 20.1.3**). Contaminated environmental surfaces may also be a potential source of infection for more than one patient. Effective environmental cleaning is essential to minimising these risks.

There may also be a risk of infection from the environment to specific patient groups, such as the potential for fungal infections in immunocompromised patients. Environmental or engineering controls may be required to reduce these risks (eg minimising dust that may contain *Aspergillus* spores, controlling legionellae in water supplies). Further information on environmental controls is given in **Section 11**.

5 Responsibilities

Key points

- The management of each health care establishment has a number of responsibilities in relation to infection control. These include:
  - use of appropriate measures to prevent transmission of infection between health care workers (HCWs) and patients;
  - development and/or maintenance of surveillance procedures, equipment and facilities, and education and training programs;
  - the provision of options for the protection of HCWs;
  - communication and protection of patients' rights; and
  - prevention of discrimination against patients or HCWs with infections.
- HCWs who undertake exposure-prone procedures have a responsibility to know their infection status with regard to bloodborne viruses. Infected HCWs should seek appropriate medical care and advice.
- Patients have a responsibility to declare their infectious status to the health care establishment. Patients should be informed of their rights to privacy and records as well as their responsibilities. Health care establishments should encourage a spirit of cooperation.

5.1 Health care establishments

The management of each health care establishment has a responsibility to prevent transmission of infections in the clinical environment. This requires coordination of clinical and nonclinical services to identify the hazards and to minimise the risk of the spread of infection. Specific aspects of this general responsibility are as follows.

General

- Use recommended measures to prevent the transmission of infection between health care workers (HCWs) and patients.
- Maintain surveillance for infections that may spread amongst patients and HCWs.
- Establish and practise infection control procedures that take account of the relevant pathogens for the particular clinical situation and pay due regard to the psychosocial welfare of the patient, thus enlisting their support and cooperation.

- Take good medical histories, which explore known risk factors for infectious diseases (eg tuberculosis, immunodeficiency) of all patients entering the establishment.

Equipment and facilities

- Maintain adequate physical facilities to control the spread of infectious agents.
- Ensure that all equipment is maintained in sound working order and is subject to regular quality checks.

Education and training

- Provide education in hygiene, including specific advice about handwashing and special requirements for specific areas where HCWs are working.
- Inform and educate HCWs about the infectious hazards they will face during their employment. This information should be provided when they are first appointed and before rostering to hazardous areas. If patients present special or unusual hazards (eg tuberculosis in a general medical ward), HCWs at risk in the area should be informed and appropriate control measures should be taken.

Protection of health care workers

- Maintain awareness of new vaccines becoming available to protect HCWs and initiate procedures to ensure that those at risk are fully immunised. An appropriate immunisastion strategy is one that identifies the infectious agents likely to be encountered by HCWs at risk and offers immunisation programs that encourage compliance by providing full information about the vaccines (NHMRC 2000. See also **Section 22**).
- Take positive measures (eg immunisation) to implement appropriate infection control. Health care establishments should then advise HCWs of the potential consequences if they refuse reasonable requests for immunisation. Such advice and refusal to comply should be documented. Should such HCWs subsequently develop work-related infections, it is most likely that the health care establishment would not be found to be in breach of its duty of care. Nevertheless, HCWs may be entitled to workers' compensation under present legislation.
- Testing should be offered following occupational exposure to blood or body substances, for example, by needlestick injury (see **Section 23**).
- Ensure that there is access to appropriately experienced counselling services for HCWs who may become anxious about their health as a result of exposure to a potential hazard, whether actual or perceived.

Awareness of patients' rights

- Ensure that HCWs are adequately informed of the rights and responsibilities of patients.
- Maintain procedures to ensure that knowledge of patient risk status may be handled in a calm and confidential fashion.

5.2 Health care workers

- HCWs have an obligation to follow specific establishment infection control policies as part of their contract of employment. This includes reporting of any known potential exposures to blood and/or body substances. Failure to follow infection control policies and procedures may be grounds for disciplinary action. Some States and Territories have statutory infection control requirements for HCWs.
- All HCWs should be aware of their requirements for immunisation against infectious diseases and maintain personal immunisation records.
- HCWs who undertake exposure-prone procedures have a responsibility to know their infectious status with regard to bloodborne viruses such as hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV), and should be given relevant information about the tests available and encouraged to have voluntary testing.
- HCWs with infections should seek appropriate medical care from a doctor qualified to manage infectious diseases. Where there is a risk of a HCW transmitting infection to a patient or other HCW (ie if the HCW is infected with a bloodborne virus, other transmissible infection or predisposing skin condition), then the HCW should be counselled about their work options and either rostered appropriately or provided with information and facilities to enable them to continue to provide safe care.

Section 24 provides further discussion on management of HCWs, including students, who may be infected with a bloodborne virus.

5.3 Patients

Although there is no legal requirement for people who know they are infectious to declare their infectious status to health care establishments, there is an ethical responsibility for patients to declare their infectious status if there is a known risk to others associated with their treatment. In addition, as is the case with any other members of the community, patients who know or have reason to believe that they

are infectious may be exposed to both civil and criminal liability if they knowingly transmit infections.

If a situation arises where there is a need to know the infectious status of a patient (such as a sharps/blood accident), the patient has a responsibility to provide information or consent for testing that enables the health care establishment or responsible health professional to ensure the safe management of the injured HCW. When obtaining consent, the patient should be offered pretest counselling to advise them of the types of tests that may be needed and to outline the consequences to the patient of doing such tests. Post-test counselling may also be required, particularly if the test is positive.

Patients should have their responsibilities in this respect explained and be encouraged to acknowledge that responsibility. When a patient is admitted to hospital or arrives at an accident and emergency unit, they should be encouraged to provide all relevant information about their infectious status to assist in triage management (see **Section 2.4**). Admission forms should be designed to ensure that this information is collected.

Patients are more likely to provide the relevant information if the risk of transmission of infection is explained in simple terms. They are also more likely to provide information if confidentiality is assured and if they are informed about the establishment's policy and procedures for maintaining confidentiality. Health care establishments should promote a spirit of cooperation and participation among affected communities and seek to identify procedures or practices that encourage this spirit of cooperation.

5.4 Responsibilities relating to specific diseases

Health care establishments should fulfil their legal responsibilities in relation to infection control by adopting standard and additional precautions for specific infections as directed in these guidelines.

There are particular responsibilities relating to bloodborne viruses which are described in more detail in **Sections 23 and 24**

Infections that require additional precautions (eg tuberculosis, CJD, antibiotic-resistant bacteria) and other infections requiring special consideration are described in their respective sections in **Part 4 (Infectious diseases in the health care setting**).

6 Other key issues for infection control

Key points

- All health care workers should be aware of the concepts of aseptic technique, handling of sharps, the use of single-use equipment and reprocessing procedures.
- Restraint in prescribing and adherence to the principles of prudent antibiotic use is essential to avoid the danger of emerging antibiotic resistance.

6.1 Aseptic technique

Asepsis is defined as the absence of infectious agents that may produce disease. Aseptic technique refers to practices used by health care workers (HCWs) to:

- reduce the number of infectious agents;
- prevent or reduce the likelihood of transmission of infectious agents from one person or place to another; or
- render and maintain objects and areas as free as possible from infectious agents.

Techniques to maintain asepsis may be categorised into 'clean' and 'sterile' techniques.

6.1.1 Clean technique

Clean technique refers to practices that reduce the numbers of infectious agents. Routine practices include:

- personal hygiene, particularly handwashing, to reduce the numbers of infectious agents on the skin;
- use of barriers to reduce transmission of infectious agents;
- use of environmental controls to reduce transmission of infectious agents; and
- reprocessing of instruments and equipment between patient use.

These routine work practices include most of the same elements as standard precautions. However, clean technique was conventionally seen as primarily providing protection for patients from infections carried by HCWs or by the health care environment. With the advent of human immunodeficiency virus (HIV)/acquired

immunodeficiency syndrome (AIDS) and other bloodborne diseases, this concept was expanded to include protection for HCWs and patients from bloodborne (mainly) and other infections, through standard precautions (see **Section 2.2**).

Basic work practices associated with standard precautions and clean technique are described in more detail in **Part 3 (Work practices and procedures).**

6.1.2 Sterile technique

Sterile technique refers to practices designed to render and maintain objects and areas as free from microorganisms as possible.

The concept of the 'sterile operative field', which has been practised for many years by operating room personnel, should be adopted by all practitioners undertaking invasive medical procedures. Everything within a defined radius must be clean and sterile (or as a minimum high-level chemical or thermal disinfection). HCWs who come into contact with the sterile operative field must be appropriately trained and prepared (see **Section 33.2**).

In dental practice, the operative field includes anywhere that the patient's blood (or other body substances, including saliva) may transfer to during a procedure (see **Section 35**).

Provision needs to be made for a sterile operating field in the design of buildings, particularly with regard to ventilation systems and working surfaces (see **Section 11**).

6.2 Handling of sharps

Sharps represent the major cause of incidents involving potential exposure to bloodborne diseases. Sharps must be handled with care at all times. Methods of handling sharps during medical or dental procedures should be devised and discussed, so as to minimise the risk of injury.

Sharp instruments must not be passed by hand between HCWs. Specified puncture-resistant sharps trays should be used for transfer of all sharp items (RACS 1998). Where possible, alternatives should be considered, including needleless intravenous systems, use of blunt needles for drawing up sterile solutions from ampoules, or retractable needle and syringe systems.

Details on the disposal of sharps are given in **Section 14.2**.

6.3 Single-use medications, injectables and instruments

To avoid cross-contamination between patients, single-use equipment should be used wherever this is practical.

6.3.1 Medications, solutions and injectables

Single-dose vials

Medications or solutions that comes into contact with normally sterile tissue should be sterile. The most effective way to avoid cross infection via injection of medication is through the use of single-dose vials or ampoules and single-use sterile injecting equipment. Single-dose vials or ampoules, or prefilled syringes, should be used wherever these are available.

Multidose vials and multiuse products

As advised by the Australian Drug Evaluation Committee (ADEC), injectable products packaged in multidose vials should not be used except where products such as insulin are intended solely for the exclusive use of an individual patient.[5,6] In these particular cases, specific protocols should be in place to ensure that the products are used for those individuals only. Every precaution should be taken to ensure that the unused portion of the vial is not contaminated, including using a clean needle and syringe to draw up the remaining contents of the vial on every occasion.

Medical and dental practitioners and paramedical HCWs should be aware of situations where cross-contamination from products may occur during routine medical or dental procedures. Protocols to prevent multiple-patient use in these circumstances should be developed. Examples include the use of topical lubricants in proctoscopy and/or vaginal examination, and local anaesthetics in throat procedures.When single-dose vials or ampoules are not available then the risk of cross-contamination is high if injectable products are used on multiple patients. The risk may be controlled by:

- drawing up all of the contents of the container into individual syringes before commencing to administer the contents into patients;
- establishing a separate area designated for the placement of these medications away from any work area;
- covering the medications to prevent environmental contamination;
- having only the current patient's medication in the immediate working environment;

[5] ADEC 1995 *Resolution No 5914*
[6] ADEC 2001 *Resolution No 7813*

- using a clean needle and syringe to draw up the remaining contents of the vial or ampoule on every occasion; and
- discarding any open ampoule(s) at the end of each procedure.

6.3.2 Instruments and equipment

Instruments or equipment intended for single use and labelled as "single-use" by the manufacturer should be disposed of after use.

The Therapeutic Goods Administration's (TGA) advice about reprocessing "single use" instruments is as follows –

Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use", should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.

This option only applies to instruments and equipment that are capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods as detailed in Table 31.14.1,without compromising product safety and integrity.

There is further discussion on single use instruments and equipment in **Section 16.2.4**

6.3.3 Implantable items

Devices or items intended for implantation must not be reprocessed or reused after use. Implantables that have had their sterile packaging opened but have not had contact with human tissue may be reprocessed and repackaged according to methods outlined by the manufacturer and approved by the Therapeutic Goods Administration (TGA).

See **Section 16.2.4** for further information on implantable items.

6.4 Reprocessing procedures

Any infectious agents introduced into sterile body sites may establish infection or colonise mucosal surfaces. Infectious agents are always present on skin and are likely to be carried through the air on dust particles. Infectious agents may contaminate instruments, medications and solutions that are intended to be sterile. Instruments and equipment used in critical sites must be sterile; instruments and equipment used in semicritical sites should be sterile or a minimum of high-level disinfected (see **Table 4.2** for definitions of critical and semicritical sites).

In order to achieve sterile conditions during procedures, all potential sources of contamination should be identified and minimised. Effective reprocessing involves:

- cleaning to remove organic residue and chemicals immediately after use;
- disinfection by
  - heat and water (thermal) or
  - chemical disinfectants; and/or
- sterilisation.

Reprocessing procedures are described in more detail in **Section 16**. **Section 17** gives further information on reprocessing of special instruments and equipment. General information on chemical disinfectants is given in **Section 7**.

Special reprocessing requirements apply to Creutzfeldt–Jacob disease (CJD) (see **Section 31.9**).

6.5 Antibiotic use

Adherence to the principles of prudent antibiotic use is essential to avoid the danger of emerging drug resistance and provide best practice and quality care for patients.

The acquisition and spread of resistance to antimicrobial agents is more common in hospitals than in the community. This is due to:

- the selective pressure exerted by high-levels of drug use, which allows the amplification of resistant infectious agents; and
- increased opportunities for transfer of infectious agents between HCWs and patients.

However, the same principles apply for both hospital and communtiy or office practice settings. In all settings, antibiotics should be used according to the principles outlines in the Australian *Therapeutic Guidelines: Antibiotic* (Therapeutic Guidelines Ltd 2000). In addition, all prescribers of antibiotics should adopt the 'prudent use principles' shown below.

Prudent use principles for antibiotics*

General

- Antibiotics should only be used where the benefits are scientifically demonstrable and substantial.
- In general, the antibiotic spectrum of the drug selected should be the narrowest to cover the known or likely pathogen(s).
- Single agents should be used unless it is proven that combination therapy is required to ensure efficacy or reduce the selection of clinically significant resistance.
- The dosage should be high enough to ensure efficacy and minimise the risk of resistance selection, and low enough to minimise the risk of dose-related toxicity.

Therapy

- Choice should be based on either culture and susceptibility test results (directed therapy) or known common pathogens in the condition and their current resistance patterns (empirical therapy)
- Duration should be as short as possible, and should never exceed seven (7) days unless there is proof that this duration is inadequate.

Prophylaxis

- Choice should be based on known or likely target pathogen(s).
- Duration should be as short as possible .A single dose delivered in a timely fashion to achieve adequate levels at the time of surgery is recommended. Longer-term prophylaxis should be administered only when it has been demonstrated that the benefits outweigh the risk of resistance selection or propagation.

*Modified from the National Health and Medical Research Council's publication *The Use of Antibiotics in Food-Producing Animals*

Successful implementation of antibiotic policies requires that the clinical administrations of health care establishments:

- Formulate prescribing strategies appropriate for their establishment or practice;
- Audit antibiotic use;
- Participate in appropriate educational measures; and
- Recognise the forces influencing doctors' prescribing habits/practices.

Particular attention should be given to effective prescribing of antibiotics that are considered critical to human medicine (ie where there are no or few alternative antibiotics available for treatment of infections); for example third-generation cephalosporins (eg cefotaxime, ceftriaxone, ceftazidime, cefpirome and cefepime) and glycopeptides (eg teicoplanin, vancomycin). Important antibiotic-resistant pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), multiresistant gram-negative bacilli and multidrug-resistant tuberculosis (MDR-TB) are discussed further in **Part 4 (Infectious diseases in the health care setting)**, Section 30.

7 Disinfectants and sterilants

Key points

Surface disinfectants/sterilants

- Surface disinfectants and sterilants are regulated by the Therapeutic Goods Administration under *Therapeutic Goods Order No. 54* (TGO54) as sterilants, instrument grade disinfectants, hospital grade disinfectants or household/commercial grade disinfectants.
- Sterilants are chemical agents that may be used to sterilise instruments or devices for use in critical sites (entry or penetration into sterile tissue cavity or bloodstream).
- Instrument-grade disinfectants are further classified as high, low or intermediate level, where the level of activity is defined by the risk associated with specific in-use situations (see **Section 16.4.1**).
- High-level instrument grade disinfectants provide the minimum level of processing for instruments used in semicritical sites (contact with nonsterile mucosa or nonintact skin).
- The performance of chemical disinfectants and sterilants is affected by temperature, contact time, concentration, pH, presence of organic and inorganic material, and numbers and resistance of microorganisms present.
- Chemical disinfectants and sterilants should always be used with care according to the manufacturer's instructions and material safety data sheets.

Skin disinfectants (antiseptics)

- Skin disinfectants, or antiseptics, are substances used for dermal or mucous membrane application to kill or prevent the growth of microorganisms. They are regulated by the Therapeutic Goods Administration as either registered medicines (AUST R), or listable medicines or medical devices (AUST L). Label claims must be followed.

7.1 Introduction

Chemical disinfectants and sterilants act by damaging the structure or impairing the metabolism of infectious agents. The biocidal (inactivation) range of a disinfectant or sterilant varies according to its active chemical structure and the general properties of

the group to which it belongs (see **Table 7.1**). All solutions labelled as disinfectants inactivate a range of vegetative bacteria, such as gram-positive and gram-negative bacteria, but may not inactivate more resistant bacteria, bacterial endospores, viruses or other microorganisms such as fungi (eg *Candida* spp) or protozoa (eg *Giardia* spp).

Sterilants and higher-level disinfectants also inactivate bacterial endospores, mycobacteria, viruses (both the more sensitive lipid-coated viruses, such as human immunodeficiency virus (HIV), and relatively resistant viruses, such as polio virus) and other micro-organisms (see **Section 7.2.1**). However, the sporicidal activity during the usual shorter exposure time for high-level disinfection may not be optimal. Most chemical disinfectants and sterilants are only partially effective against the agents of Creutzfeldt–Jakob disease (CJD). See **Table 7.1 and Section 31.8** for details of inactivation methods for these agents.

Chemical substances may be formulated for use on inanimate surfaces (ie surface disinfectants) or for use on skin (ie skin disinfectants, or antiseptics).

Table 7.1 identifies the categories of active chemical substances used to formulate disinfectants/sterilants and antiseptics, and their ranges of activity. Classification of a product using any of these active ingredients as household, hospital, instrument grade, sterilant or antiseptic depends on the formulation used.

7.2 Chemical disinfectants and sterilants

Disinfectants and sterilants intended for use in the health care setting are regulated by the Therapeutic Goods Administration (TGA) under *Therapeutic Goods Order No. 54* (TGO 54) and are classified in the following broad categories:

- sterilants
- instrument grade disinfectants (3 sub classes)
  - low grade
  - intermediate grade
  - high-level grades
- hospital grade disinfectants (2 sub classes)
  - dirty conditions
  - clean conditions
- household/commercial grade disinfectants

Critical factors that may affect the performance of disinfectants or sterilants include temperature, contact time, concentration, pH, presence of residual organic and inorganic soils, and numbers and resistance of the initial bioburden on a surface.

It is essential that disinfectants and sterilants are always used in accordance with the manufacturer's directions to ensure that the product meets its label claims for efficacy in accordance with the requirements of TGO 54.

Disinfectants and sterilants should not harm instruments or equipment and the compatibility of instruments/equipment and should be a consideration when choosing products. Products should not be mixed and 'use-by' dates should be checked for currency. Products should be used at the recommended strength for soaking or exposure times. The required amount of product should be decanted as required to avoid contamination of the stock solution. Unused product should be discarded after use.7.2.1

Sterilants and instrument grade disinfectants

The TGA assesses products as instrument grade (high, intermediate or low level) disinfectants or sterilants on the basis of stringent conditions outlined in TGO 54. The manufacturer is required to provide data to the TGA that demonstrates in-use efficacy and compatibility with a range of instruments. Those chemical disinfectants intended for use in automated washer–disinfectors should perform effectively as claimed on the label. Any disinfectant or sterilant used to reprocess medical instruments must be registered on the Australian Register of Therapeutic Goods (ARTG).

Sterilants

A sterilant is a liquid chemical agent that may be used to sterilise critical medical devices that will not withstand steam sterilisation (see **Section 16.5**). Sterilants inactivate all microorganisms, giving a sterility assurance level of less than 10^{-6} (see Glossary), which is the sterility level required for medical equipment that will contact critical body sites.

All chemical sterilants should be used in accordance with the manufacturer's approved label conditions for sterilisation. That is, for products that may be both sterilant or high-level disinfectant (multiuse), the sterilisation time is the longer of the two times that appear on the label).

Automated chemical processing systems based on peracetic acid or high concentration hydrogen peroxide (plasma) sterilants achieve sterilisation within a reasonable period of time (between 30 and 80 minutes, depending on the model and the system purchased).

There are TGA-approved sterilant products for both manual and automated systems. If users of sterilants and/or high-level disinfectants are unsure of the TGA-approved status of a product, they should ask the manufacturer initially to supply the product's AUST R code number.

Instrument grade disinfectants

Instrument grade disinfectants are classified as high, intermediate or low level. Careful selection of an appropriate level of disinfectant is required to achieve the desired level of disinfection. The definitions given in TGO 54 state that, when used as recommended by the manufacturer:

- high level chemical disinfectants inactivate all microbial pathogens, except large numbers of bacterial endospores;
- intermediate level disinfectants inactivate all microbial pathogens except bacterial endospores; they are bactericidal (including mycobacteridal), fungicidal against asexual spores (but not necessarily dried chlamydospores or sexual spores) and virucidal; and
- low level disinfectants rapidly inactivate most vegetative bacteria as well as medium sized lipid-containing viruses; they may not be relied upon to destroy, within a practical length of time, bacterial endospores, mycobacteria, fungi or all small nonlipid viruses.

The level of activity (high, or intermediate, or low) is defined by the risk associated with a specific in-use situation (see **Section 16.4.1**). The minimum level of processing required for specific items in use is shown in **Table 16.1**.

Halogens (such as chlorine and iodine) may perform as high-level disinfectants at high concentrations but none are currently registered in Australia. Quaternary ammonium compounds usually perform as low-level disinfectants, which are ineffective against many microorganisms (eg bacterial spores, mycobacteria and many viruses). However, when coformulated with other active chemical substances, the final formulation may deliver the increased activity required of an intermediate or high-level disinfectant. Depending on the formulation, alcohols may be good intermediate-level disinfectants (see **Table 7.1**).

7.2.2 Hospital grade disinfectants

Hospital grade disinfectants are regulated by the TGA. These disinfectants must not be used to disinfect medical instruments. This should be stated on the product label.

The use of hospital grade disinfectants is not necessary in health care establishments. The recommended procedure is the manual removal of visible soil/dirt followed by cleaning with water and detergent (see **Section 18.1.1**). However, hospital grade disinfectants may be used on environmental surfaces such as walls, floors, furniture and equipment that do not come into direct contact with the patient.

The activity of hospital grade disinfectants is usually restricted to a range of vegetative bacteria of the type usually encountered in a health care setting, unless the

TGA approves additional specific label claims, such as tuberculocidal or virucidal activities.

IMPORTANT NOTE

Do not use hospital grade disinfectants to reprocess medical instruments and equipment

The term *hospital grade* in the Therapeutic Goods Act may be misleading as it implies that it is the correct disinfectant for all purposes in health care establishments. This is not true. *Hospital grade* should be regarded as general-purpose (non-instrument grade) disinfectant and is only so labelled to distinguish these from other commercial and household disinfectants.

Disinfectants labelled *hospital grade* should not be used to disinfect medical instruments and equipment. *Instrument grade* disinfectants or sterilants are the only compounds that are suitable for use with medical instruments and equipment.

7.2.3 Household/commercial grade disinfectants

Household/commercial grade disinfectants are also regulated by the TGA. These disinfectants have limited use as their efficacy has not been tested under conditions likely to be encountered in health care settings.

7.3 Skin disinfectants (antiseptics)

An antiseptic is a substance that is recommended by its manufacturer for dermal application or application to the mucous membrane of a person or animal to de-activate microorganisms, or to prevent the growth of microorganisms to a level that may cause clinical infection. An antiseptic is not represented to be suitable for internal use (TGO54).

Skin disinfectants/antiseptics are regulated by the TGA. Most antiseptic products marketed in Australia are either registered medicines or listable medicines (eg tea tree oil) on the ARTG and therefore require an AUST R or AUST L number, respectively, on the label. Other products contained in sachets are currently classified as listable medical devices for which the display of an AUST L number is optional. The label claims of such products are important and should be followed.

Skin disinfectants/antiseptics should always be used according to the manufacturer's directions, which are designed to ensure that a product, when used as directed, meets its label claims for efficacy in accordance with TGA requirements.

Hygienic handwash/scrub products are formulated to reduce transient bacteria on the hands. Surgical scrubs reduce the level of both transient and resident bacterial flora. Handwashing disinfectants chosen for HCWs should demonstrate residual as well as immediate activity.

HCWs should use skin disinfectants on their hands before participating in any surgical procedures including, cannulation, catheterisation or intubation. Skin disinfection prior to surgery should reduce the number of resident bacteria and thus the infectivity of skin or mucosal tissue in the patient and on the hands of the HCW. Each skin disinfectant should be labelled with the date when first opened and discarded after its designated 'use by' date as indicated on the manufacturer's label.

Before use, sufficient skin disinfectant for an individual patient's use should be decanted into a sterile container. Any fluid remaining in this container should be discarded at the end of each procedure (see **Section 6.3**).

HCWs should check the label for the specific contact time of each antiseptic used and use strictly in accordance with the manufacturer's instructions. There is a wide range of antiseptics available. The formulations and concentrations chosen should be appropriate to the tissues to which it is applied. Particular note should be taken of the flammability of the product in relation to the setting in which it is to be used.

The following preparations may be used but the choice should be appropriate for the nature and site of the procedure:

- 70–80% w/w ethanol;
- 60–70% v/v isopropanol;
- chlorhexidine in aqueous formulations (0.5 to 4% w/v) or in alcoholic formulations with chlorhexidine (0.5 to 1% w/v) in 60-70% isopropanol or ethanol
- 10% w/v aqueous or alcoholic povidone–iodine (1% w/v available iodine); and
- solutions containing 1% w/v diphenyl ether (triclosan) (Gardner and Peel 1998).

It should be noted that particular preparations are contraindicated for use at particular sites. For example, 4% w/v chlorhexidine is widely used as a bacterial skin cleaner for hygienic and surgical handwashing (Gardner and Peel 1998). An aqueous solution of 0.5% w/v chlorhexidine is recommended for use on facial skin. Weaker solutions (0.02–0.05% w/v) may be used for application to mucous membranes — for example during bladder irrigation (Gardner and Peel 1998). Where disinfectant is used during dental procedures, oral membranes should be dried/isolated to prevent dilution of the disinfectant with saliva.

Studies have indicated that 2% aqueous chlorhexidine is more effective than 10% povidone-iodine or 70% alcohol for cutaneous disinfection before insertion of an

intravascular device and for post-insertion care, and may substantially reduce the incidence of device-related transmission of infection (Maki et al 1991, cited in Gardner and Peel 1998). However, 2% aqueous chlorhexidine is not currently marketed in Australia.

Chlorhexidine should never be used in surgery on the middle ear because it may cause sensorineural deafness (Bicknell 1971). Corneal toxicity — including transient epithelial defects, chronic corneal ulceration and corneal oedema — has been observed following ocular exposure to a proprietary product in which chlorhexidine was the active ingredient (Tabor et al 1989, Varley et al 1990).

An alcohol wipe (70% w/w ethanol or 60% v/v isopropanol) may be used before venous blood collection, injection or insertion of acupuncture needles to reduce the bacterial load on the skin, and thus lessen the risk of infection. Currently, there is no evidence to suggest a minimum drying time to effect skin disinfection before venous blood collection, injection, or acupuncture. However, the alcohol should be allowed to dry before proceeding to reduce discomfort in the patient. Alcohols are flammable and should be used with caution. Therefore, they should not be used for skin disinfection before electric cautery or laser. Alcoholic solutions are inappropriate for use on mucous membranes.

7.4 Occupational health and safety issues for using chemical disinfectants

Chemical disinfectants should be used with caution and in accordance with the manufacturer's instructions. Information on the safe handling of chemicals in laboratories is also given in AS/NZS 2243.1[7] and AS/NZS 2243.2.[8] Health care establishments should provide comprehensive induction and training programs for HCWs about the safe handling of chemicals.

Material safety data sheets (MSDS) for disinfectants should be consulted before use. Personal protective equipment (PPE) must be worn when working with disinfectant/sterilant solutions. Ventilation should be adequate when using concentrated or volatile chemicals as defined by the National Occupational Health and Safety Commission (NOHSC 1994). Fume extraction systems should comply with AS 1668.2.[9]

[7] AS/ANZ 2243.1 (1997) and Amendment 1 (2000) *Safety in laboratories — General*
[8] AS/ANZ 2243.2 (1997) *Safety in laboratories — Chemical aspects*
[9] AS 1668.2 (1991) and Supplement 1 (1991) *The use of mechanical ventilation and air-conditioning in buildings – Mechanical ventilation for acceptable indoor air quality*

The use of hazardous substances is regulated under workplace health and safety legislation in each state and territory. All chemical disinfectants should be discarded in accordance with State/Territory and local government regulations (see AS/ANZ 3816[10]).

[10] AS 3816 (1998) *Management of clinical and related wastes*

Table 7.1 Categories and ranges of activity of the active chemical substances used to formulate disinfectants and antiseptics[a]

Activity range	Other properties/comments
Alcohols • Effective: bactericidal fungicidal mycobactericidal • Variable: virucidal • Poor: not sporicidal • Ineffective: CJD	Ethanol: • 70% w/w ethanol is rapid acting and dries quickly • 90% w/w ethanol useful as a virucide • 100% ethanol is not an effective disinfectant • less effective against nonenveloped viruses (eg HAV) than against enveloped viruses (eg HIV) Isopropanol: • Most effective at 60–70% v/v • Variable mycobactericidal activity • Not an effective virucide General properties of alcohols: • Do not penetrate organic matter well, this means prior cleaning is required as alcohol acts as fixative • Flammable • May be combined with other bactericidal compounds for skin disinfection • May only be used as an instrument-grade disinfectant if labelled accordingly by manufacturer
Aldehydes • Effective: bactericidal fungicidal virucidal sporicidal (slow) • Variable: mycobactericidal • Ineffective: CJD	• Highly irritant • Act as fixatives: prior cleaning required • Penetrate organic material slowly and usually not inactivated by inorganic materials • Usually noncorrosive to metals • Buffered alkaline solutions must be activated immediately before use and have a limited shelf life • Acidic solutions are more stable but are slower acting; glycolated (mildly acidic) solutions have shorter inactivation times • Instrument grade disinfectant when used for a short period (usually <60 minutes) according to label: specific to each formulation • Instrument sterilant when used for a prolonged period (usually >5 hours) depending on formulation/labelling • Slow acting against atypical mycobacteria
Chlorhexidine and biguanide polymers • Effective: gram-positive organisms less active against gram-negative organisms • Variable: virucidal fungicidal (subject to species variation) • Poor: not mycobactericidal not sporicidal • Ineffective: CJD	• Low toxicity and irritancy • Inactivated by organic matter, soap and anionic detergents • Useful for skin and mucous membrane disinfection but are neurotoxic (must not contact middle ear) and may cause corneal damage • Chlorhexidine activity range increased when combined with other agents (eg alcohol) • Polyhexamethylene biguanide (PHMB) hydrochloride may be combined with quarternary ammonium compounds for increased activity • May only be used on instruments if labelled as an instrument grade disinfectant

Activity range	Other properties/comments
Hypochlorites • Effective: bactericidal fungicidal virucidal • Variable: sporicidal (pH 7.6 buffer) mycobactericidal (5000 ppm available chlorine) May be used at 20,000 ppm available chlorine against CJD if more stringent procedures are not suitable (Table 31.14.14)	• Fast acting • Inactivated in presence of organic matter at low concentrations • Incompatible with cationic detergents • High concentrations corrosive to some metals (some compounds may contain corrosion inhibitors) • Diluted form unstable with short shelf life • Decomposed by light, heat, heavy metals • Chlorine gas released when mixed with strong acids • Carcinogenic reaction product when mixed with formaldehyde • Useful in food preparation areas and virology laboratories higher-risk CJD spills/contamination: 20,000 ppm for 1 hour (see **Table 31.14.1**) Activity may be increased by combining with methanol May only be used on instruments if labelled as an instrument grade disinfectant There are available chlorine requirements for: Blood spills: 10000 ppm (1%) Laboratory discard jars: 2500 ppm (0.25%) Clean environmental disinfection: 1000 ppm (0.1%) (ie environment that has been precleaned of all soil and other organic and inorganic material or has not been exposed to soiling with body fluids) Disinfection of clean compatible items: 500–1000 ppm (0.05-0.1%)
Iodine preparations • Effective: bactericidal mycobactericidal fungicidal virucidal • Variable: sporicidal • Variable/partially effective: CJD	• May be inactivated by organic matter • May corrode metals (eg aluminium) • Useful as a skin disinfectant but some preparations may cause skin reactions (povidone–iodine is much less irritant than iodine itself) • Antiseptic strength iodophores are not usually sporicidal • May only be used on instruments if labelled as an instrument grade disinfectant
Peracetic acid and other peroxygen compounds • Effective: bactericidal fungicidal virucidal sporicidal mycobactericidal • Variable/poor: mycobactericidal (peroxygen compounds) • Ineffective: sporicidal (peroxygen compounds) CJD	• Peracetic acid is highly irritant • Corrosive to some metals/instruments • Reduced activity in presence of organic matter • Usually contain detergent • Useful for small spills • May be used as an instrument grade disinfectant or sterilant under specified conditions, if compatible • Hydrogen peroxide and potassium monoperoxygen sulfates have low toxicity and irritancy

Activity range	Other properties/comments
Phenolics • Effective: bactericidal mycobactericidal fungicidal • Variable: virucidal • Poor: nonenveloped viruses • Ineffective: CJD	• Avoid contact with skin/mucous membranes • Stable in presence of organic matter • Incompatible with cationic detergents • Not for use on food preparation surfaces/equipment • Detergent usually included • Absorbed by rubber and plastics • Diluted form unstable • Useful for mycobacteria on surfaces
Sodium dichloroisocyanurate (SDIC) granules Similar to hypochlorites Ineffective: CJD	• Less corrosive than hypochlorite • More resistant to inactivation in presence of organic matter • Stable in dried form; unstable in solution
Acids (formic) and alkalis (sodium hydroxide) Restricted use for CJD	• Corrosive/caustic • Use only with special care

CJD = Creutzfeldt-Jakob disease; HAV = hepatitis A virus; HIV = human immunodeficiency virus

[a] Classification of a product using any of these active ingredients as household, hospital, instrument, sterilant grade or as an antiseptic depends on the formulation used.

Note: Instruments contaminated with the agent of CJD should either be destroyed or reprocessed according to the guidelines in **Table 31.14.1**.

Sources: Ascenzi (1996), Ayliffe et al (1993 1999), Block (1991), Gardner and Peel (1998), Russel et al (1999), Rutala (1995, 1998), (WHO 2000).

Part 2

Quality Management

Part 2 – Table of Contents

8 Quality administrative arrangements

Key points

- The details outlined in this Section are primarily written for the hospital setting. However, the principles of quality management and infection control apply to all health care settings.
- In order to implement a coordinated approach to infection control, public and licensed private health care establishments should have a strategic plan for infection control.
- Health care establishments should develop a comprehensive infection control procedures manual that specifies performance standards for routine work practices and procedures.
- Policies and procedures for infection control should be consistent with national minimum standards and generally accepted infection control principles, as outlined in these and other relevant national and State/Territory guidelines.
- Health care establishments should have a system of infection control management (such as a committee) with input from across the spectrum of clinical services and management. The committee should meet regularly to consider and resolve current infection control issues that affect their working environment.
- Health care establishments should employ an infection control practitioner (ICP) with an appropriate education to practice in that setting. The ICP should be primarily responsible for implementing the establishment's infection control policies including compliance with the respective State/Territory and/or national accreditation, licensing, policy or regulatory requirements. In Hospital the recommended staffing level is 1.5 ICPs to 200 acute care beds.
- Health care establishments have a legal responsibility to provide a safe work environment and safe systems of work and a safe environment for patients and visitors in their care.

Some studies have shown that hospitals with effective infection control programs could effectively reduce infection rates by up to one-third compared to those with no infection control programs (Haley et al, 1985).

In Australia, a recent survey found that the majority of Australian hospitals have infection control programs in place (Murphy and McLaws, 1999). However **all health care establishments** should implement infection control programs to prevent the transmission of infectious diseases. An integral part of the program should be a system to monitor and document any incident of health care associated infections (iatrogenic or noscomial).

8.1 Implementing an infection control program

To implement a coordinated approach to infection control, health care establishments should have an infection control program in place that includes:

- development of an annual strategic business plan for infection control;
- preparation of a comprehensive procedures manual that specifies performance standards for routine work practices and procedures as outlined in these guidelines (see **Section 1.2**), and including the following -
  - strategies to modify procedures and equipment associated with increased risk of occupational exposure to blood and/or body substances, and to ensure their appropriate management;
  - strategies to monitor the effectiveness of the infection control program and ongoing compliance with regulatory and licensing requirements;
  - strategies to monitor antibiotic resistance;
  - strategies to monitor and manage critical incidents;
  - contingency plans to manage outbreaks of heath care associated infections and breakdowns in infection control practices; and
- coordination by a suitably qualified health care worker (HCW), for example a registered nurse, clinical/medical microbiologist or infectious diseases physician (in smaller establishments this function may be combined with other tasks).

Policies and procedures should be consistent with national minimum standards and infection control principles outlined in these and other relevant national and State/Territory guidelines.

To promote ownership and compliance, policies and procedures should be developed in collaboration with all clinicians involved. They should also be practical, workable, necessary and sufficiently flexible to ensure their implementation.

8.2 Infection control management

Each health care establishment or region/district should have a committee or system of management that is responsible for the development, oversight and evaluation of the infection control program. Infection control management should reflect the spectrum

of clinical services and administrative arrangements of the health care establishment so that policy decisions take account of implementation issues. The spectrum of advice should include:

- executive management;
- responsible clinical expertise (eg surgeons, physicians, nurses);
- microbiology;
- infection control practitioners;
- support services (eg catering, cleaning, sterilising services); and
- Occupational Health & Safety (OH&S).

Infection control management should regularly evaluate -

- routine surveillance reports from the infection control practitioner (ICP) as based on the strategic plan, eg clinical indicators such as:
  - device-related infections (eg catheter infections),
  - procedure-related infections (eg surgical wound infections),
  - blood and body substance exposures;
- HCWs vaccination and education;
- outbreaks of health care associated infection;
- purchasing and equipment issues;
- building and refurbishment issues;
- clinical practice standards/guidelines/policies;
- advice from the National Health and Medical Research Council (NHMRC), the Communicable Diseases Network Australia (CDNA), State/Territory and Commonwealth health departments, professional colleges and other advisory groups about infection control issues and their implications for the establishment; and
- issues referred by the clinical service units or individuals within the establishment.

Infection control management should have the capacity to initiate a rapid response when specific needs arise.

The evaluations of the surveillance data and a report of the activities of the infection control program, should be made available to all relevant staff. Consideration should also be given to allowing access by patients and the public to these reports.

8.3 Infection control practitioner

A recent study of Australian ICPs has demonstrated that there is a clear move away from any single focus of the role of the ICP, towards more strategic management and clinical monitoring (Jones et al 2000). The role now comprises:

- management, including change management;
- clinical practice;
- consultancy;
- research;
- surveillance; and
- education.

Furthermore, each of these areas covers issues of:

- strategic planning;
- resource management, including staffing, and access to computers and appropriate software;
- staff health;
- policy development and implementation;
- risk management;
- data collection and analysis (epidemiology); and
- professional development.

The scope of the ICP's role will be influenced by the context of practice (eg acute care, long-term care). The complexity and scope of the role of the ICP have made it necessary for ICPs to be formally qualified and specialist courses are available in Australian tertiary institutions. These tertiary courses are encouraged to seek infection control credentialling by the Australian Infection Control Association (AICA) Credentialling Board (established in 2000). The ICP is most often a registered nurse (Murphy and McLaws 1999) although medical microbiologists or other HCWs with additional training in hospital epidemiology and surveillance have also been appointed.

Staffing for infection control remains a controversial topic. There are currently no methods to precisely determine the required level of infection control staffing in Australian health care establishments (Murphy and McLaws 1999). Research into this area should be encouraged.

The number of hours dedicated to infection control within any health care establishment should be commensurate with the size, acuity, and level of infectious risks encountered (Sheckler et al 1998, Friedman and Chenoweth 1998, Friedman et al 1999).

In the Australian setting, in recognition of the expanded role of the ICP as described by Jones et al (2000), the AICA and the Australian Council on Healthcare Standards

(ACHS) have recommended a ratio of 1.5 ICPs to 200 acute health care beds (ACHS, 2001). The equivalent ratio for long-term care establishments is discussed in **Section 38.1**.

8.4 Compliance standards and accreditation

This document contains minimum infection control standards that apply to health care establishments. Demonstrated compliance with these infection control standards should be a minimum requirement for accreditation or licensing.

Professional organisations should be consulted on accreditation requirements relating to infection control. The contact details of national organisations are given in **Appendix 7**.

8.5 Quality improvement program maintenance

To be effective, infection control should be a part of an establishment-wide quality improvement program. Continuous quality improvement involves an organised and methodical range of activities and processes to implement practice guidelines and/or standards of care. Key performance indicators should be developed that can identify any breaches of practice guidelines, indicate when corrective interventions are required, and/or evaluate such interventions for effectiveness. Key performance indicators should be monitored and appropriately communicated.

8.6 Continuum of care responsibilities

To ensure a continuum of care across different health care settings, service agreements or contracts can be developed between providers (eg acute care hospitals, long-stay residential establishments, community health centres) outlining roles and responsibilities, including those for infection control. The aim should be to provide safe effective care across the whole spectrum of health care delivery, with mechanisms in place to monitor outcomes appropriately, including infection control outcomes. Multidisciplinary pathways that include infection control principles, and process indicators/incident monitoring of health care associated infections across different health care settings, would also improve coordination.

8.7 Employee health policies

Both employers and employees have a responsibility in relation to occupational health and safety (see **Section 5**).

As part of their infection control program (see **Section 8.1**), each health care establishment should develop, implement and document effective policies and risk reduction procedures, including strategies to:

- minimise occupational exposure to infection hazards;
- minimise occupational risks from chemicals or processes used for recommended infection control activities; and
- implement HCW immunisation programs for infectious agents likely to be encountered by HCWs in the course of their duties (see **Section 22.3.2**).

Further details the handling of chemical disinfectants are given in **Section 7.4**. Protection for HCWs; needlestick, blood and other incidents; and issues for HCWs relating to infection with bloodborne viruses are discussed in **Sections 22, 23 and 24**, respectively. Details relating to the management of HCW exposure to specific diseases are given in **Part 4 (Infectious diseases in the health care setting)**.

9 Education and training

Key points

- Universities and training institutions that offer courses in health-related areas should ensure that the curriculum includes current information on infection control policy, procedures, incident monitoring and quality assurance. This applies to courses in medicine, nursing, allied health care, health services management, public health and natural therapies.
- Health care establishments should provide a program of education and training on infection control principles for all health care workers and students that also emphasises the importance of on-going education and training.

9.1 Universities and training colleges

Universities and training colleges that offer undergraduate and postgraduate courses in health-related areas should ensure that the curriculum includes up-to-date information on infection control policy, procedures, quality assurance and incident monitoring.

Tertiary institutions have an obligation to inform prospective students of the impact that particular infections may have on their ability to complete the course and engage in the full spectrum of clinical practice after graduation (see Section 24.6). This information should include advice about specific measures, including immunisation, that reduce the risk of acquiring infection during a course of study.

9.2 Health care establishments

As part of their overall infection control program, health care establishments should provide a specific program of education and training for all HCWs and students about infection control principles, policies and procedures relevant to the establishment. Education and training programs should explain and emphasise the five basic areas of infection control, as outlined in these guidelines (see **Section 1.2**). Health care establishments should maintain records of HCW participation in education programs.

Managers should also emphasise the importance of continuing education and training (internal and/or external) for all HCWs. Orientation programs should include comprehensive information about the establishment's infection control policies and programs and the important role of the HCW. Education and training programs should be flexible in presentation and encourage all HCW participation including those HCWs from non-English speaking backgrounds or HCWs with disabilities.

Workplace education and training should use a variety of techniques, such as peer educators and group sessions, involving the active participation of employees. Organisations that provide support and care for people affected by diseases, such as human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), should be invited to speak to HCWs about the impact of these diseases. Professional organisations (**see Appendix 7**) may also provide educational aids (videos, publications etc).

10 Ethical and legal issues

Key points

- Health care establishments have duty of care to protect people working in, accommodated in, or visiting the establishment from exposure to infectious agents and also to protect the privacy and confidentiality of all people in their establishment.

- Health care ethics can be summarised by three basic principles:
  - *respect for persons* (respect for the autonomy and right of self-determination of people capable of making choices and the protection of persons with impaired or diminished autonomy);
  - *beneficence* (the obligation to maximise possible benefits and minimise possible harms); and
  - *justice* (fair distribution of the benefits and burdens of society to ensure that neither patients nor HCWs are denied appropriate health care or are discriminated against).

- These principles have important implications for procedures such as isolation of patients, provision of emergency care and referral to other practitioners.

- To encourage informed patient decision making and consent, all the relevant information should be provided to the patient, carer or guardian in a manner that ensures it is clearly understood.

- Commonwealth and State/Territory legislation prohibits discrimination on the grounds of physiological disability (which may include infectious disease). However, an individual's right to no discrimination should be balanced by the public health responsibility to prevent transmission of infectious diseases to other people.

10.1 Introduction

Major ethical and legal considerations arise in the implementation of guidelines for the prevention of transmission of infectious disease in health care settings. Broadly, ethical issues relate to consideration of the rights of infected individuals and the responsibilities of health care workers (HCWs) to do no harm to their patients. Legal issues arise in relation to the duty of care of health care establishments to protect both

patients and HCWs from infection and in relation to various State/Territory legislation concerning infectious diseases.

There is considerable overlap between the legal and ethical obligations of individual HCWs and establishments. Ethical imperatives are not always, nor necessarily, defined by law. HCWs need to be conversant with professional ethical codes as well as with the relevant laws.

The consideration of ethics in the health care setting can be summarised in three basic principles: respect for persons, beneficence and justice. These principles are described in the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999a).

Respect for persons has two fundamental aspects:

- respect for the autonomy of those individuals who are capable of making informed choices and respect for their capacity for self-determination; and
- protection of persons with impaired or diminished autonomy, that is, those individuals who are incompetent or whose voluntariness is compromised.

Beneficence is the obligation to maximise possible benefits and minimise possible harms. The obligation to do no harm is referred to separately as non-maleficence.

The application of *justice* requires a fair distribution of the benefits and burdens of society. Consideration of justice will ensure that infected patients and HCWs are not denied appropriate health care and are not discriminated against.

Due consideration should also be given to ethical decision-making concerning work and career choices for HCWs who may be infected with a bloodborne virus, so as to minimise emotional, psychological and financial harm for the infected HCW.

10.2 Developing and implementing policy and procedures

Health care establishments should implement policies and procedures that take account of their specific ethical and legal requirements. This is because the prevalence of disease will vary according to population groups and regions, and also because the risk to HCWs or patients will vary according to the prevalence of disease, the nature of treatment provided, the skills and experience of HCWs and other factors. Health care establishments should consider the potential risk of spread of infectious diseases and formulate clear guidelines for patients and HCWs in their own particular circumstances.

In developing and implementing policies, health care establishments should recognise the rights of, and the need for, individual HCWs to make judgments within their

professional competence and in accordance with clinical circumstances. It is important, however, that professionals making such decisions are aware of the health care establishment's policies in relation to legal and ethical obligations and the relationship which exists between the health care establishment and that professional.

HCWs should ensure that the standard of care they provide and the appropriate standards to minimise the risk of transmission they adopt are sufficient to prevent transmission of any health care associated infection or occupational acquisition of infection.

10.3 Isolation policies

Unnecessarily restrictive isolation procedures or screening programs may be unethical if they infringe individual rights and freedom. For example, the routine screening of patients for nasal carriage of methicillin-sensitive *Staphylococcus aureus* and the confinement of positive patients is unnecessary because implementation of standard and additional precautions will minimise the potential for transmission of infection. Effective antibiotics are available to treat the consequences of infection, although this should be in accordance with antibiotic guidelines to minimise potential for drug resistance (see **Section 6.5**). In the case of human immunodeficiency virus (HIV) and hepatitis viruses, implementation of standard precautions is the most appropriate means of preventing infection.

10.4 Duty of care — emergency care

Health care establishments and their HCWs generally have an ethical and, in some cases legal, responsibility to provide care to all patients seeking emergency treatment. Failure to provide appropriate care in an emergency may constitute a breach of duty of care for patients. In addition, a health care professional who fails to provide care to a patient in an emergency may be exposed to professional and/or institutional disciplinary action. Health care establishments must also provide HCWs with appropriate protective equipment and instructions for its use for safe emergency care. Failure to do so constitutes a breach of duty of care for HCWs.

Provision of emergency care may involve exposure to infectious risks, which may not be identified accurately at the time care is provided. These infectious risks to HCWs should be minimised by using standard and additional precautions and preventing direct contact with blood and body fluid secretions.

HCWs who think they are at risk and seek to withhold their services should be assessed by a medical practitioner with a sound knowledge of infection control to determine their actual level of risk. The results of the assessment should be explained to the HCW and they should be offered work in another area, if necessary. It is

important that HCWs are educated in the incidence of risk associated with the care of patients with particular infectious diseases.

10.5 Referral

Patients should only be referred to another practitioner with the patient's knowledge and consent. Referring practitioners have an ethical duty to provide relevant clinical information to the new practitioner. Depending upon the purpose of the referral, this may include information about the patient's infectious status as this may be relevant for the appropriate ongoing care of the patient and to minimising risk to other health care workers and other patients. If the infectious status of the patient needs to be revealed, the patient should be informed and consent obtained.

10.6 Patient decision making and consent

Important decisions that individuals make about their own lives, particularly medical decisions, should be both free (voluntary) and uncoerced. They should also be based on a sound understanding of what is at stake. Ensuring that this is so is part of what is implied in the fundamental principle of respect for the dignity of every human being and requires that great care be taken.

A voluntary decision is one made without undue pressure, without coercion, force or persuasion against one's will. A person's decision may not be voluntary if people who are powerful or influential have put too much pressure on him or her, or if he or she has not had the opportunity to consider all the relevant aspects of the situation. An informed decision is one based on information relevant to making the decision. Any information is relevant if it is important to the particular person making the decision.

Both the information provided and the way it is communicated will be influenced by patient characteristics, cultural background and understanding of spoken and written English. Informed decision making should take into account language and jargon barriers to ensure that a patient understands the nature of any risk that they may incur. Health care establishments should provide access to independent trained interpreters, ideally in person, or via a telephone interpreting service if this is not possible.

Whenever possible, the consent process should be planned ahead of time to ensure that the patient has enough time to absorb the information presented, to ask questions and to reflect on the decision to be made. Information provided orally should be backed up by written information in plain English or community languages to allow the patient an opportunity to go over the information several times.

Provision of information for the purpose of obtaining consent to testing should involve explanation of the reasons for the test and what the results may mean. It should also include pre-test counselling, as is required by law in some States/Territories, and often post-test counselling, regardless of the test result.

Informed and voluntary consent must be obtained before taking a blood sample to test for any purpose. For example, antenatal HIV testing on blood collected for routine blood-grouping without the patient's consent is unethical and unnecessary — specific consent should be obtained for each test. In addition, the patient must be provided with relevant information concerning the purpose of a blood test and any specific tests performed. Long- and short-term consequences of test results should also be discussed with the patient. In some jurisdictions, there are legislative requirements for pre and post-test counselling about the consequences of a positive result. The ethical indications for such counselling are likely to have broader applicability than existing legal requirements. This is especially so in the case of patients from non-English speaking backgrounds. It is not reasonable to assume a uniform level of comprehension when counselling patients about possible consequences of testing.

Individuals have a right to be informed when the results of tests have consequences beyond the particular disease being treated. Health care establishments and their HCWs have a duty to warn patients about foreseeable consequences. This applies especially to notifiable infectious diseases where one outcome of a test may be the compulsory notification of authorities, which could lead to subsequent restriction of the patient's freedom, or a change in the manner in which medical care is provided (that is, the patient may be subjected to isolation procedures).

Giving a patient all the relevant information about procedures involved in their care and treatment, including information about blood tests, may protect a HCW or health care establishment from liability for assault, damages for breach of contract, breach of confidentiality, discrimination and negligence. If a patient has a particular procedure, this only authorises action taken for the patient's benefit and does not justify action for the benefit of the health care establishment or its HCWs. For example, if a patient consents to a sample of blood being taken to test for the presence of meningococcal infection to determine appropriate treatment, the consent does not allow testing the sample for HIV or hepatitis B virus antibodies.

Patient competency

In obtaining consent for testing, treatment or other procedures, other than in an emergency, the treating medical practitioner must assure him/herself that the patient is an adult and has the cognitive capacity to understand what is being proposed. In general, the more complex or risky the procedure , the higher the level of understanding will be required.

Thus obtaining consent which is ethically acceptable and legally valid can be problematic when caring for a patient whose mental competence may be fluctuating or deteriorating.

The commonly accepted ethical goal of a consent process is to reach a decision that expresses and implements the patient's own choice, made for reasons that are most important for her or him. The expression "authentic" is sometimes used to describe a decision that so expresses an individual's well considered choice. It is implicit that the decision should not be influenced by other people's preferences or wishes.

Legally speaking, while it is customary to converse with and obtain informal consent from relatives for very minor aspects of medical and nursing care, health care workers need to be aware that a relative cannot legally give consent on behalf of a patient unless that person has been officially appointed as a decision maker, eg as guardian.

Health care workers therefore need to be conversant with the relevant guardianship or health decision legislation in their state or territory and if in doubt should not hesitate to contact the local Guardianship Board which in most jurisdictions provide a 24 hour advice service.

Preoperative testing

Preoperative testing of a patient for infectious agents should be on the basis of clinical assessment and with the patient’s full knowledge and decision to participate. However, medical practitioners should exercise their professional judgment in ordering any clinically relevant test.

Patients who are unable to make a decision or who refuse to undergo testing should be managed as if they are infectious, applying standard or additional precautions as required.

In both emergency and non-emergency situations, the emphasis at all times should be on maintaining high standards of infection control, regardless of whether or not a patient is known to be infectious. Standard and additional precautions should enable procedures to be performed on all patients with minimal risk of transmission of infection.

Decision to undergo testing for non-urgent/elective hospital admissions

Any decision by a patient to undergo testing before being admitted to hospital must be informed and voluntary and must not be subject to duress. For non-urgent admissions, and where testing is clinically relevant, patients should be considered infectious until the test results are known or if they refuse to be tested. If this is not practicable, and provided immediate care is not required, admission or treatment may be deferred until it becomes practicable or consent is given.

Decision to undergo testing for emergency/urgent hospital admissions

Where testing is clinically relevant, an attempt should be made to help the patient (or a legal guardian in the case of a patient who is not competent) make a decision in relation to testing. If it is not possible to obtain such a decision, or if there is a refusal to be tested, the patient should be considered infectious and managed according to standard and additional precautions.

10.7 Health care worker screening/testing

In establishing health screening policies and procedures, the relevant Commonwealth and State/Territory antidiscrimination legislation should be consulted to ensure that no illegal discrimination occurs. However, it should not be assumed that compliance with the legislation replaces any need to consider the ethical aspects of further screening.

Employers have a responsibility to protect HCWs (see **Section 5.2**), and should consider the need to offer appropriate HCW health screening/testing along with advice on immunisations to minimise the risks from infectious diseases.

HCW health screening is recommended in only a few situations (see **Section 22.3**). In each of these situations relevant information should be provided for specific screening activities and appropriate advice given and valid consent obtained. Education programs should emphasise the importance of regular routine screening for HCWs in high-risk situations, such as when caring for patients with infectious pulmonary tuberculosis.

Whenever screening/testing is offered to employees, it must be accompanied by appropriate information including:

- why the screen/test is being requested;
- who has access to/is notified of the results; and
- what consequences positive results may have.

HCWs who may present a specific risk to patients in the course of their duties should be offered voluntary screening/testing where applicable. An example may be those HCWs who perform exposure-prone procedures (see **Sections 24.2 and 24.3**).

Health care students should also be offered appropriate health screening before they have any clinical contact with patients and should be required to review their immune status and be immunised against diseases that are preventable by vaccination if they are not immune to them already (see **Section 22.3**).

Further information on HCW health issues is given in **Sections 22 and 24**.

10.8 Privacy and confidentiality

Privacy and confidentiality are important considerations in the relationship between a patient and the HCW. The Privacy Act 1988 regulates the way Commonwealth agencies, including ACT public sector agencies, and private sector organisations can collect, keep secure, use and disclose personal information. The Act obliges a private sector organisation to advise individuals why it is collecting their personal information, what information it holds about them, how it will use the information, who else will get the information, and it gives individuals the right to access their own records, as well as the right to correct the information if it is wrong.

Where it is necessary for a patient's personal information, including health information, to be used or disclosed for purposes other than purpose for which the information was originally collected, it will be necessary for establishments to take account of specific requirements under the Privacy Act and any other legislative or ethical guidelines.

Employers should provide induction and regular inservice training for all HCWs on confidentiality and privacy. Procedures for disciplinary action for breaches of confidentiality must be clearly formulated and adhered to.

HCWs involved in the treatment and care of patients for whom additional precautions are required should be informed of the infection control procedures needed. However, access to confidential medical information should be strictly limited to only those HCWs who need to access the information for the better clinical treatment of the patient.

10.9 Antidiscrimination

Specific legislation at both the Commonwealth and the State/Territory level prohibits discrimination on a number of grounds, including impairment (including physiological, psychological and intellectual disabilities). Precedents have been established which identify infectious diseases as a physiological disability. Although differential treatment of people with infectious disease or with particular susceptibility to infectious disease constitutes discrimination, the law recognises that discrimination may be necessary in some circumstances. This is because, at some point, the individual's right not to be discriminated against (because of their infectious status) must be overridden by the public health responsibility to prevent transmission to other parties. When developing protocols dealing with infectious diseases, relevant State/Territory and Commonwealth antidiscrimination legislation should be consulted to ensure that no illegal discrimination occurs.

HCWs can be either the victims or perpetrators of discrimination. However, they should be aware that sanctions may be taken against individuals who act in a discriminatory manner to others. Appropriate steps should be taken to allow all HCWs to work and to gain experience in the normal range of activities associated with the position to which they have been appointed, without being subject to discrimination.

Any HCW who believes that he or she cannot act in a nondiscriminatory manner should report the situation to the health care establishment's administration. Any patient management that could be construed as discriminatory should be properly documented. For example, the protocol for isolation of people suspected of having an infectious disease must be documented and the patient's infectious classification recorded in the clinical notes.

The health care establishment should inform HCWs of its antidiscrimination policy and require that it be followed. A monitoring program and protocol for handling complaints should be established and advertised to both HCWs and patients. There are independent health complaints units as statutory bodies in all States and Territories except in South Australia, where the Ombudsman's Office has responsibility for health complaints. Equivalent units also exist at departmental level.

10.10 Liability

In the context of these guidelines, civil liability for damages to a patient or HCW may arise where insufficient care has been taken to prevent transmission of infection or breach of confidentiality.

Currently, there is legislation in each State/Territory about the spread of infectious diseases under which liability for damages may arise (see the report of the Intergovernmental Committee on AIDS Legal Working Party, April 1992). Both the common law and the legislation will respond to meet changing needs in a changing environment and both reflect the minimum boundaries of acceptable social interaction.

Although in the past it has been uncommon for people who spread disease negligently to be charged with criminal offences, in most jurisdictions the present criminal law allows the more serious cases of the spread of infectious diseases to be brought to account. That is, if a person — HCW, patient or otherwise — infects another person negligently and causes serious illness, he or she can be charged with an offence of causing grievous bodily harm by negligent act.

If someone dies as a result of a negligent act, the person responsible can be charged with manslaughter. If the act of spreading the infection is deliberate, the appropriate charge is assault or murder. Liability would depend on the conduct amounting to criminal negligence as opposed to civil negligence. It is conceivable that medical

administrators could be charged with such offences if they were to permit the spread of infectious diseases in the health care establishments under their authority, either deliberately or negligently. In addition, under legislation in each jurisdiction, there are additional offences related to the specific transmission of disease. Such offences deal with those individuals who infect another person with a notifiable disease or, in some jurisdictions, merely engage in conduct such as to be likely to risk spreading a disease.

Part 3

Effective Work practices and procedures

11 Design and maintenance of health care premises

Key points

- New or renovated health care premises should be designed to minimise the risk of transmission of infection.
- Shared patient accommodation should have no more than four beds per room and include conveniently located toilets, baths and showers that are easy to clean.
- For acute care, there should be at least one single room for every five ward beds and one respiratory isolation room for every 100 beds.
- In waiting rooms, patients with infectious conditions should be identified using a triage system and separated from other patients.
- Dedicated work areas should be designed to minimise the transmission of infection. Procedural and cleaning areas should be separated.
- Workflow should be from clean to contaminated areas.
- Ventilation, airconditioning, cooling towers and water systems must meet Australian Standards.
- Handbasins with hot and cold water, nontouch taps, supplies of liquid handwash (preferably in nonrefillable disposable containers) and disposable paper towels or single-use, clean, cloth towels must be readily available in accordance with Australian standards.
- All aspects of the physical environment must be monitored and maintained to ensure that the establishment meets current standards, codes and regulations.

11.1 Introduction

The way health care premises are designed is fundamental to infection control and to the implementation of both standard and additional precautions. The design and layout of all new or renovated health care premises should take account of the movement of people and incorporate all necessary physical requirements to minimise the transmission of infection.

Advice on infection control issues should be sought at any time when changes are made to the design of health care establishments.

A new Australian Standards Handbook covering the design and maintenance of health care premises is currently being drafted. In this section, this document is referred to as HB 260 (Draft).

Further details of design features for specific health care settings are given in **Part 5 (Infection control in specific health care settings)**.

11.2 Surfaces

11.2.1 General

Functional design allows routine cleaning to be carried out efficiently. Unnecessary horizontal, textured and moisture-retaining surfaces, or inaccessible areas where moisture or soil can accumulate should not be used. Where possible, all surfaces should be smooth and impervious. All floors should have nonslip coverings.

Where there is likely to be direct contact with patients, or with blood and body fluids, the surface of floors and walls should be made of smooth, impermeable seamless materials, such as welded vinyl. In equipment-processing areas, work surfaces should be nonporous, smooth and easily cleaned.

Flooring should be able to be easily cleaned and in good repair. Treatment areas in office practice should not be carpeted. If the premises are carpeted and the procedure being undertaken is likely to result in spillage of blood or body fluids, plastic or rubber overlays can be used to prevent any spills soaking into the carpet.

11.2.2 Fixtures and fittings

All fixtures and fittings should be designed to allow easy cleaning and to discourage the accumulation of dust. Blinds that are easy to keep clean and do not allow the accumulation of dust are preferable to curtains.

11.3 Patient accommodation

11.3.1 General

To minimise the risk of transmission of infection, hospitals should, wherever possible, restrict room sizes and the number of beds per room (ideally not more than four beds per room). Shared patient accommodation should include facilities such as toilets, baths and showers that are easy to clean and conveniently located to the patient.

Clinical hand basins should also be located in patient areas as described in **Section 11.6**.

11.3.2 Acute care

In acute care situations (excluding psychiatry), it is essential that an adequate number of single rooms is available for infection control purposes (at least one single-patient room for every five ward beds). There should be at least one respiratory isolation room for every 100 beds, as described in the HB 260 (Draft).

A single room with self-contained toilet and washing facilities should be available for patients infected with pathogens that are of particular concern for transmission of infection — for example, methicillin-resistant *Staphylococcus aureus* (MRSA) or *Clostridium difficile* diarrhoea. Where this is not possible, and the likelihood of transmission of infection or reinfection is not significant, cohort placement may be considered, noting the difference between strains and origin (eg community, hospital) of infectious agents.

Emergency medicine departments should have provision for at least one respiratory isolation room as described in the HB 260 (Draft).

11.3.3 Patient waiting areas

Patient waiting areas in both hospital outpatient areas and office practice waiting rooms should have provision for separating patients who may be highly infectious (eg patients diagnosed with or suspected of having measles or pulmonary tuberculosis). A triage system should be used to identify such patients (see **Section 2.4**).

11.4 Work and treatment areas

11.4.1 General

Defined and dedicated work areas should be planned carefully. The areas should be well lit and well ventilated. There should be sufficient bench space in work areas to accommodate the necessary equipment (including a steam steriliser where applicable) and to ensure the separation of sterile, clean and soiled instruments and equipment. Equipment should be positioned and stored safely to minimise the risk of injury. Free access to work areas should be maintained at all times.

Work areas should also include provision for handling and storage of appropriate waste and should be designed to minimise the potential for injury or exposure of staff and others.

11.4.2 Work flow

Work flow should be from clean to contaminated areas, with care taken to avoid contaminated equipment re-entering clean work areas. Further information about workflow is given in AS 4187[1] and AS/NZS 4815.[2]

Staff eating and recreation areas must be separate from work areas and patient treatment areas.

11.5 Environmental considerations

11.5.1 General

Work areas and patient accommodation should be ventilated in accordance with AS 1668.2[3] or State/Territory guidelines, whichever is most appropriate for that situation. The work area and patient accommodation should also have adequate lighting. Work areas should have easy access to equipment and safe storage for equipment not in use.

The inflow of fresh air and the temperature, humidity and air purity (to minimise dust, infectious agents and gases) should be maintained within prescribed limits by ventilation equipment (AS 1668.2).

11.5.2 Airconditioning

Airconditioning systems in health care establishments should be monitored regularly and serviced by accredited service technicians; maintenance schedules should be documented.

Airconditioning or ventilation systems in critical areas, such as operating rooms, delivery suites, respiratory isolation rooms, burns and intensive care units, emergency treatment rooms, as well as special treatment or procedural areas, should be ventilated in accordance with the HB 260 (Draft).

Operating rooms must have high-efficiency particle arrest (HEPA) filtration of air supply with direction of airflow away from the operating room in accordance with HB 260 (Draft).

There is considerable debate about the use of laminar flow systems. However, there is some evidence to suggest that laminar flow systems could be useful in operating rooms where more than 100 arthroplasties are performed per year (see HB 260 [Draft]) for further discussion).

11.5.3 Cooling towers and water systems

Cooling towers and hot water systems are an important source of infection for *Legionella* spp (causing legionnaires' disease) and should comply and be maintained in accordance with State/Territory guidelines on cooling towers and hot and cold water services, and with other relevant Australian standards (eg AS SET 3500,[4] AS/NZS 3666 and Standards Australia Handbook HB32[5] and AS 3896[6]). Further details on transmission and management of *Legionella* spp are given in the National Environmental Health Forum *Guidance for the Control of Legionella* (NEHF 1996a) and in **Section 29.2** of these guidelines.

Cooling towers should be avoided, where possible, as they can be a source of legionellae. Health care establishments who care for patients at risk of legionella infection should consider alternatives to water-based cooling towers. Where this is not possible, outlets should be sited and directed as far as practicable from patient and public areas, particularly air inlets and openable windows. There is no minimum distance specified in the Australian standards, as they state that known outbreaks have occurred with transmission distances of 150 metres and suspected distances of up to 1.7 kilometres.

Spa pools, heated swimming pools and other water systems are also potential sources of infection with organisms such as pseudomonads, legionellae and cryptosporidia. Guidelines should be developed by individual health care establishments for the use of spas and therapeutic pools, based on State/Territory guidelines and other relevant Australian standards (AS 2610.1,[7] AS 2610.2,[8] AS 3979[9]). The risks and benefits of using these facilities should be assessed for individual patients (eg immunocompromised patients, patients with open wounds or diarrhoea).

Spa baths should be avoided in health care establishments because they are difficult to maintain in a clean condition. Ordinary bathtubs achieve a similar therapeutic effect and are more easily cleaned and maintained (see HB 260 [Draft]). Patients with infectious diarrhoea should not use spas for up to two weeks after resolution of symptoms (Carpenter et al 1999). Further information on the care of spas is given in the National Environmental Health Forum *Guidance on Water Quality for Heated Spas* (NEHF 1996b).

11.5.4 Respiratory isolation rooms

Accommodation and treatment rooms for patients with tuberculosis, or where there is a risk of airborne transmission of other infectious agents, should include a sufficient number of negative pressure single rooms (1 per 100 beds) with anterooms, in accordance with the HB 260 (Draft). Fresh air at 100% (that is no recirculating air) will achieve the most effective dilution of airborne microorganisms. If any recirculation

is contemplated, it is necessary to consider if available filters and controls will adequately deal with droplet nuclei, dust and odour.

11.5.5 Special purpose areas

Sterilising services

Where the sterilising services department is attached to operating rooms, ventilation should be provided by a treated air supply and airconditioning should comply with AS 1386[10]. Airconditioning in separate sterilisation services units should comply with AS 1668.2 and with the National Co-ordinating Committee on Therapeutic Goods *Standard for the Operation of Sterile Supply/Services in Health Care Facilities* (NCCTG 1995).

Bronchoscopy and other aerosol generating procedural and recovery rooms

The United States Centers for Disease Control and Prevention (CDC) recommends that bronchoscopy should not be performed on patients with active tuberculosis unless there is no alternative investigative approach (CDC 1994b). If bronchoscopy is necessary on a patient with known active pulmonary tuberculosis, procedural and recovery rooms where bronchoscopy is performed must have negative pressure ventilation with appropriate minimum air changes per hour in accordance with the HB 260 (Draft) on hospital acquired infection. The area used for bronchoscope cleaning must conform to appropriate workplace health and safety legislation in each State/Territory, with particular regard to ventilation and the control of hazardous aerosols.

Other procedures that are likely to generate aerosols or induce coughing (eg lung function testing) should only be performed on patients with active pulmonary tuberculosis in an area with negative pressure or local exhaust ventilation.

Operating rooms

Provision needs to be made for a sterile operating field (see **Sections 6.1 and 33**).

11.6 Handwashing basins

11.6.1 General

HCWs must wash their hands before and after every significant patient contact (see **Section 12**).

In all health care establishments, handbasins with hot and cold water supplies, nontouch taps, supplies of liquid handwash (preferably in nonrefillable disposable containers) and disposable paper towels or single-use, clean, cloth towels should be

readily available. The importance of regular handwashing must be emphasised in all situations where there is significant patient contact.

Taps should be fitted with an antisplash device, and should ideally be nontouch, as should liquid handwash dispensers (ie operated by elbow, knee or foot), in order to further reduce possible cross-contamination. Where filters or antisplash devices are fitted to taps, they should be cleaned in accordance with the manufacturer's recommendations, and with due regard to water quality.

IMPORTANT NOTE

Wash your hands!

Suitable handbasins and handwashing equipment is essential and should be available and easily accessible to encourage HCWs and patients to wash their hands appropriately.

Clinical handbasins must be provided for HCWs to wash their hands. Nonclinical (vanity) handbasins and sinks within patient rooms are not appropriate equipment for handwashing by HCWs for infection control purposes.

Handwashing is the single most effective hygiene practice for minimising health care associated infections.

Clinical handbasins should only be used for handwashing not for any other purpose such as for the disposal of liquid wastes. Liquid wastes should be disposed of in a separate disposal sink/sluice situated in a utility room.

See **Section 12** for further discussion of handwashing equipment.

11.6.2 Procedural areas

Each procedural room should contain at least one clinical handbasin or scrub sink/trough designated for handwashing only. Handbasins should comply with AS/NZS 1730.[11]

11.6.3 Hospitals

In hospitals, there should be one clinical handbasin within or in close proximity to each single patient room. The nonclinical (vanity) handbasin inside the room is not appropriate for handwashing by HCWs. If two single rooms are adjacent, a single clinical handbasin near the entrances to the rooms may be sufficient. However, it is preferable if they are placed inside each room. There should be at least one clinical handbasin for every four beds and these should be situated at the entrance to any

shared area and be easily visible and accessible. If the shared ward area is smaller than four beds, then this area will need its own easily visible and accessible clinical handbasin at or near the entrance to the room.

More detailed information concerning clinical handbasin requirements for hospitals can be found in the HB 260 (Draft) on hospital acquired infection.

11.6.4 Medical, dental and other office-based practices

Clinical handbasins should be provided in areas where patient treatments are performed in all medical and dental practices, but at a safe distance from patients to avoid inconvenience and or splashing patients during procedures.

In practices where minimal invasive procedures occur (eg physiotherapy, acupuncture clinics), clinical handbasins may be either installed in, or easily accessible from, areas where patient treatments are performed.

11.6.5 Long-term care establishments

In residential aged care and other long-term care establishments, clinical handbasins should be provided in all areas in which patient treatment may routinely occur. This will include each room for dependent patients and treatment areas for independent patients.

11.7 Cleaning and reprocessing areas

Health care establishments should have separate, dedicated procedural and reprocessing areas that should be cleaned and dried between patients. Both areas should have smooth impervious surfaces without crevices, adequate lighting, good ventilation (to reduce the risk of infection transmission from aerosols) and suitable receptacles for the disposal of clinical waste (AS 4031[12] and AS/NZS 4261[13]).

Health care establishments should have dedicated, defined areas for contaminated items and clean items with direct access for HCWs from the procedure room for cleaning and disinfection of endoscopic equipment (Cowen et al 1999).

All workflow should be from clean to contaminated areas(see **Section 11.4.2**).

11.7.1 Contaminated items

The area for decontaminating items should include:

- adequate bench space for dismantling and working on equipment;

- at least one stainless steel sink or trough deep enough to accommodate instruments and other equipment requiring cleaning (double sinks are preferred); and
- cleaning and reprocessing materials and equipment (including brushes and ultrasonic cleaners).

Cleaning sinks should be separate from clinical handbasins, to avoid risk of contamination, and should be used only for decontaminating of equipment and instruments. Where filters or antisplash devices are fitted to taps, they should be cleaned regularly.

11.7.2 Clean items

The section for storage of clean items should be carefully defined and protected from all vapours, splashing or aerosols produced during procedures, handwashing, equipment washing, ultrasonic cleaning and reprocessing. The area should have adequate storage space and be used only for the storage of effectively covered or packaged, cleaned, disinfected and/or sterilised instruments and equipment.

11.7.3 Special purpose areas

Some areas dedicated to cleaning of special purpose equipment have special requirements.

Endoscopy cleaning areas

Endoscopy units should have a separate area dedicated to the reprocessing of endoscopic equipment. The area should contain at least two large sinks plus appropriate disinfecting equipment. Instruments require immediate cleaning following use to prevent the drying of biological material within small channels. Adequate workflow patterns must ensure that there is no cross-contamination between dirty and clean areas. The area must conform to appropriate workplace health and safety legislation, with particular regard to ventilation and the control of hazardous aerosols. Space for, and availability of, appropriate cleaning utensils and accessory reprocessing devices such as ultrasonic cleaners must be available (see **Section 17.1** for further details).

The physical facilities necessary for reprocessing of endoscopic equipment are described in detail in *Infection Control in Endoscopy* (Cowen et al 1999).

11.8 Health care establishment building infrastructure maintenance and monitoring

11.8.1 General

The design, construction and renovation of health care establishments should take account of infection control and facilitate a monitoring and maintenance program for the physical environment.

The importance of monitoring and maintaining the physical environment of a health care establishment should not be underestimated. It is the primary responsibility of the engineering and building services department to maintain the services, equipment and fabric of the establishment in a safe and usable manner. Equally important is its role in ensuring that all facilities meet current standards, codes and regulations.

Before use, it is the responsibility of the departments to make available equipment and systems, whether purchased, contracted, loaned or on trial, to the engineering and building services department so that it may:

- undertake a safety and operational inspection;
- develop an appropriately scheduled preventive maintenance plan; and
-
- ensure that the equipment manufacturer's instructions, where appropriate, are available to users.

11.8.2 Education and training for users of equipment and systems

The engineering and building services department has a role in the education and training of potential users to ensure safe and competent use of equipment and systems, and to provide ongoing support to all departments within the establishment.

The level of communication between the engineering and building department and the infection control team can be improved by:

- formal involvement of the infection control team with renovations and new building works; and
- the involvement of representatives of engineering staff on infection control committees.
- making sure that infection control manuals are readily available;

11.9 Forensic and hospital mortuaries

Design of mortuaries within health care establishments should incorporate the principles contained within the Royal College of Pathologists of Australasia/Australian Forensic Mortuary Managers Association *Guidelines for Australian Forensic and Hospital Mortuaries* (drafted February 2001) and the Australian Funeral Director's Association *Infection Control Guidelines for the Funeral Industry* (AFDA 1992, AFDA 1995).

These include:

- refrigerated body storage facilities should be maintained at an internal temperature of 4°C, and must not be used for any purpose other than the storage of bodies;
- longer-term body storage (if necessary) should be in a freezer maintained at -20°C;
- all refrigerators/freezers should be monitored and fitted with alarms which operate 24 hours a day;
- mortuary design should minimises manual handling of bodies;
- where autopsies are performed, dedicated theatre(s) should be used with negative air pressure ventilation.

12 Handwashing and personal hygiene

Key points

- Handwashing is the most important hygiene measure in preventing the spread of infection.
- Gloves are not a substitute for handwashing.
- Hands should be washed before and after significant contact with any patient, after activities likely to cause contamination and after removing gloves.
- A mildliquid handwash should be used for routine handwashing. Skin disinfectants formulated for use without water may be used in certain limited circumstances.

12.1 Handwashing

Handwashing is generally considered to be the most important measure in preventing the spread of infection in health care establishments (Larson 1996).

Health care workers (HCWs) must wash their hands before and after significant contact with any patient and after activities likely to cause contamination. Significant patient contact may include:

- contact with, or physical examination of, a patient;
- emptying a drainage reservoir (catheter bag); and/or
- undertaking venipuncture or delivery of an injection.

Activities that can cause contamination include:

- handling equipment/instruments soiled with blood or other body substances;
- direct contact with body secretions or excretions; and/or
- going to the toilet.

Gloves are not a substitute for good handwashing (see **Section 13f.2**)

Table 12.1 summarises handwashing techniques for routine, aseptic (nonsurgical) and surgical procedures and includes examples for each level of handwashing.

A mild liquid handwash (with no added substances that may cause irritation or dryness) should be used for routine handwashing. Refillable containers are a potential

source of contamination as bacteria can multiply within many products. Liquid handwash dispensers with disposable cartridges, including a disposable dispensing nozzle, are recommended. Special attention should be taken to clean pump mechanisms as these have been implicated as sources of infection (Barry et al 1984, Archibald et al 1997, Sartor et al 2000). Scrub brushes should not be used because they can cause abrasion of the skin, and may be a source of infection (Kikuchi-Numagami et al 1999).

12.2 Other methods of hand cleaning

HCWs may clean their hands with antiseptic products formulated for use without water in the following situations:

- emergency situations where there may be insufficient time and/or facilities;
- when handwashing facilities are inadequate; and
- in circumstances where an alcohol-based preparation provides a more effective option for individuals such as those with a latex allergy.

Visible soil must be removed by some means (eg rinsing, mechanical rubbing or wipes) before use of the antiseptic product formulated for use without water (see **Section 7.3** on skin disinfectants). HCWs should wash their hands as soon as appropriate facilities become available.

DISCUSSION POINT

Is waterless hand cleaning with alcohol based hand rinse preparations better than hand washing?

It has been suggested that waterless hand cleaning with alcohol based preparations could be more effective in encouraging HCWs to ensure hands are clean between patient contacts (Voss and Widmer 1997). Although there is evidence to demonstrate that waterless hand cleaning may be less damaging to HCWs' hands than traditional hand washing (Winnefeld et al 2000), there is not yet enough evidence available to support adopting waterless hand cleaning in place of traditional hand washing with running water (CDC 1998).

Waterless hand cleaning may be used as an adjunct to traditional handwashing, for example during procedures where multiple handwashing episodes are usually required. Alcohol-based hand gels appear to be less microbiologically effective than alcohol-based liquid hand disinfectants. However, liquid alcohol preparations have a drying effect on the skin.

12.3 Hand care

Hand care is important because intact skin (with no cuts or abrasions) is a natural defence against infection. Any breaks or lesions of the skin are possible sources of entry for pathogens (Larson 1996).

- Rings should not be worn, nails should be short and clean, and artificial nails should not be worn as they contribute to increased bacterial counts (Larson 1996).
- Rings or artificial nails must not be worn when performing invasive procedures (ie were gloved hands are placed inside body cavities).
- Repeated handwashing and wearing of gloves can cause irritation or sensitivity, leading to dermatitis or allergic reactions. This can be minimised by early intervention, including assessment of handwashing technique and the use of suitable individual-use hand creams.
- To minimise 'chapping' of hands, use warm water and pat hands dry rather than rubbing them.
- Cuts and abrasions should be covered by water-resistant occlusive dressings that should be changed as necessary.
- HCWs who have skin problems such as exudative lesions or weeping dermatitis must seek medical advice and must be removed from direct patient care until the condition resolves.

Hand care products marketed in Australia that claim a therapeutic use are generally either listed (AUST L) or registered (AUST R) on the Australian Register of Therapeutic Goods (ARTG) and must display either the AUST L or AUST R number, respectively, on the label. Registered products are assessed for safety, quality and efficacy. Listed products are reviewed for safety and quality. Labelling is part of this regulatory system, and should be checked to determine the product's suitability, as some hand creams are not compatible with the use of chlorhexidine. Aqueous-based hand creams should be used before wearing gloves. Oil-based preparations should be avoided as these may cause latex gloves to deteriorate.

DISCUSSION POINT

Rings, jewellery and artificial (acrylic) nails

Jewellery and artificial nails provoke debate and contention. There is little hard evidence that jewellery constitutes an infection risk to staff or patients. Nevertheless, it is likely that poorly maintained (uncleaned) rings, nails and jewellery will harbour microorganisms that might contaminate operative fields and the like. Jewellery may also be a physical danger to either the patient or HCW during direct patient care (eg necklaces may be caught in equipment or bracelets cause injury during patient handling).

When gloved hands are placed in sterile or critical sites, it is possible that bacteria could be released into the sterile field, or that such items could attract patient bacteria, if the glove is punctured for any reason during the procedure. Also, rings with sharp surfaces (eg gemstones) and sharp fingernails may themselves puncture gloves. Thus, rings should be removed from hands that are likely to enter sterile sites or contact internal mucous membranes (eg mouth, vagina) in the course of procedures.

Artificial nails have been implicated in a number of outbreaks of health care associated infection and should be avoided by all HCWs with direct patient contact, particularly those who perform or assist in invasive procedures (Hedderwick et al 2000, Moolenaar et al 2000).

Each health care establishment should develop policies about the wearing of jewellery (including 'body piercings'), artificial nails or nail polish by HCWs that take into account the risks of transmission of infection to both patients and HCWs, rather than cultural preferences.

Table 12.1 Handwashing techniques

Level	Washing technique	Duration	Drying	When needed
Routine handwash	Remove jewellery Wet hands thoroughly and lather vigorously using neutral pH liquid handwash Rinse under running water Do not touch taps with clean hands – if elbow or foot controls are not available, use paper towel to turn taps off	10–15 seconds	Pat dry using paper towel, clean cloth towel, or a fresh portion of a roller towel	Before eating and/or smoking After going to the toilet Before significant contact with patients, eg physical examination, emptying a drainage reservoir (catheter bag) Before injection or venipuncture Before and after routine use of gloves After handling any instruments or equipment soiled with blood or body substances
Aseptic procedures	Remove jewellery Wash hands thoroughly using an antimicrobial skin cleaner Rinse carefully Do not touch taps with clean hands – if elbow or foot controls are not available, use paper towel to turn taps off	1 minute	Pat dry using paper towel	Before any procedures that require aseptic technique (such as inserting intravenous catheters)
Surgical wash[a]	Remove jewellery. Wash hands, nails and forearms thoroughly and apply an antimicrobial skin cleaner (containing 4% w/v chlorhexidine)[b] or detergent-based povidone–iodine containing 0.75% available iodine or an aqueous povidone–iodine solution containing 1% available iodine Rinse carefully, keeping hands above the elbows No-touch techniques apply	First wash for the day 5 minutes; subsequent washes 3 minutes	Dry with sterile towels	Before any invasive surgical procedure

[a]For further details, see **Section 33 (Operating rooms)**

[b]Gardner and Peel (1998)

13 Personal protective equipment

Key points

- All health care establishments should provide personal protective clothing and equipment that complies with relevant Australian standards and is appropriate for the intended use. All equipment should be readily available.
- Health care workers (HCWs) should wear gloves whenever there is a risk of exposure to blood or body substances. The type of gloves worn must be appropriate to the task. Wearing gloves must not replace handwashing. Gloves may have defects that are not immediately obvious or they may become damaged with use and become a hazard for HCWs.
- HCWs should wear protective eyewear or face-shields during procedures where there is potential for splashing, splattering or spraying of blood or body substances.
- HCWs should wear suitable masks during procedures where there is potential for splashing, splattering or spraying of blood or body substances, or where there is potential for airborne infection.
- HCWs should wear gowns and plastic aprons to protect their clothing and skin from contamination.

13.1 Protective clothing and equipment

The use of protective clothing (gowns or plastic aprons), worn over uniforms, protects HCWs from exposure to blood or body substances. Protective clothing and equipment that complies with relevant Australian standards should be readily available and accessible in each health care establishment. It may include:

- examination gloves (AS/NZS 4011[14]) and surgical gloves (AS/NZS 4179[15]);
- eye and/or facial protection (glasses, goggles or face-shields);
- surgical face masks (AS 4381[16]) and respirators (AS/NZS 1716[17]) designed for protection against respiratory pathogens (P2 particulate respirator – AS/NZS

[17] AS/NZS 1716 (1994, Amended 1996) *Respiratory Protective Devices*

1715[18]); *Note: Class P2 Respiratory Protection Devices are regarded as being equivalent to US Standard N95 Respiratory Protection Devices.*

- gowns and aprons (AS 3789.2[19] and AS 3789.3[20]); and
- footwear to protect from dropped sharps and other contaminated items.

The particular type of protective clothing required varies according to the nature of the procedure, the equipment used and the skill of the operator, and is a matter for individual professional judgment or establishment policies based on local occupational health and safety (OHS) legislation. Professional organisations may also provide advice on the level of protection required (see **Appendix 7**).

In determining the type of protective barriers to use for a given procedure, HCWs should consider the following factors:

- probability of exposure to blood and body substances;
- amount likely to be encountered;
- type of body substance involved; and
- probable route of transmission of infectious agents.

Full protective wear, including double gloves, protective eye/face shields, protective footwear and impermeable gowns or aprons, is recommended for operating room or mortuary procedures.

Appropriate respiratory protection should be worn by HCWs potentially exposed to *Mycobacterium tuberculosis*.

In order to ensure that effective personal hygiene and protection is practised, health care establishments must ensure that all the necessary materials and equipment are readily available (including appropriate size ranges of protective equipment), accessible and maintained in working order. Education/instructions about the correct use of personal protective clothing and equipment should also be provided to HCWs.

13.2 Gloves

HCWs should wear gloves when it is likely that their hands will be contaminated with blood or body fluid, or come into contact with mucous membranes. HCWs should

[18] AS/NZS 1715 (1994) *Selection, Use and Maintenance of Respiratory Protective Devices*
[19] AS 3789.2 (1991) and Amendment 1 (1992) *Textiles for health care facilities and institutions – Theatre linen and pre-packs*
[20] AS 3789.3 (1994) *Textiles for health care facilities and institutions – Apparel for operating theatre staff*

change their gloves and wash their hands after each patient procedure and also during multiple procedures on the same patient if there is a risk of cross-contamination.

HCWs should wash their hands both before and after using gloves (see **Table 12.1**). Wearing gloves must not replace handwashing, as gloves may have defects that are not immediately obvious, or may become damaged during use.

Gloves should comply with the standards for examination gloves (AS/NZS 4011) and surgical gloves (AS/NZS 4179). The types of gloves worn should be appropriate to the task:

- *sterile gloves* — for procedures requiring a sterile field, involving normally sterile areas of the body;
- *nonsterile gloves* — for procedures other than the above; and
- *general purpose utility gloves* — for housekeeping chores including cleaning.

Single-use (sterile) surgical gloves must comply with AS/NZS 4179, while examination and procedural gloves for general medical and dental use must comply with AS/NZS 4011.

HCWs should change and discard single-use gloves as follows:

- after contact with each patient, and when performing separate procedures on the same patient if there is a risk of cross contamination;
- as soon as they are damaged (torn or punctured);
- on completion of any task not involving patients but requiring the use of gloves; and
- before answering telephones or recording patient notes.

Sterile or procedural gloves should be removed carefully to avoid contamination of hands or other surfaces. They must not be washed or reused.

The use of gloves in dental practice is covered in Section 35.2.

In operating rooms, surgeons should wear double sterile gloves (RACS 1994). Further information about the requirements for surgeons is given in **Section 33.**

Some HCWs may develop allergy or sensitivity to latex gloves. This is likely to be due to contact with latex proteins that may not have been adequately removed during the manufacturing process. In the presence of sweat or moisture, these proteins may become adsorbed onto the lubricant powder used in the latex gloves (Swanson et al 1994, Heese et al 1997). Latex gloves that are powder-free or alternatives to latex (eg neoprene) can be used by HCWs who develop sensitivity or allergy to latex.

DISCUSSION POINT

Latex allergy and glove use

Although it has been suggested that latex allergy in HCWs is directly linked to the use of powdered latex gloves, and in particular aerosolisation of latex proteins in glove powder (Swanson et al 1994), it has not yet been clearly demonstrated that changing to nonpowdered gloves throughout a health care establishment will reduce development of latex allergy symptoms in HCWs (Trape et al 2000).

Utility gloves may be reused but should be washed in detergent after use, stored dry, and replaced if torn, cracked, peeling or showing signs of deterioration.

13.3 Protective eyewear and face-shields

HCWs must wear protective eyewear or face-shields during procedures where there is potential for splashing, splattering or spraying of blood or other body substances. This includes most dental procedures, most operating room procedures, dermabrasion and manual cleaning of instruments and equipment. Protective eyewear for HCWs should comply with AS/NZS 1336 and 1337[21], and must be optically clear, anti-fog and distortion free, close fitting and shielded at the side. Eyewear should be either reusable after cleaning or single-use. Dental patients should also be provided with protective eye equipment and a brief explanation about the potential for eye injury during some dental procedures.

13.4 Masks and Personal Respiratory Protection Devices

HCWs must wear masks whenever there is a possibility of splashing or splattering of blood or other body substances, or where airborne infection may occur. The type of mask best suited to a particular situation depends on the body substances likely to be encountered and the nature of the activity. There are two main types of masks used in health care:

- *surgical masks* — fluid-repellent paper filter masks worn during surgical and dental procedures (see **Sections 33 and 35**);
- *particulate filter personal respiratory protection devices (RPD)* — close fitting – (RPDs capable of filtering 0.3-µm particles and should be worn when attending patients with active pulmonary tuberculosis (see **Section 29.8**) In Australia, RPDs used in health care are generally made of paper, but other RPDs (eg purified air powered respirators) which are regarded as equivalent to United States N95

[21] AS/NZS 1336 *Recommended practices for occupational eye protection* and AS/NZS 1337 (1992), Amendment 1 (1994) *Eye protectors for industrial application*

standard are also suitable (see below – AS/NZS 1715 and 1716). These masks are also suitable for protection against laser plume.

Masks must:

- be fitted and worn according to the manufacturer's instructions;
- not be touched by hand while being worn;
- cover both mouth and nose while worn;
- be removed as soon as practicable after they become moist or visibly soiled;
- be removed by touching the strings and loops only; and
- not be worn loosely around the neck, but be removed and discarded as soon as practicable after use.

Generally, surgical masks worn during surgical procedures prevent HCWs' respiratory secretions from contaminating the operative site, and reduce the risk to HCWs from splashing and spraying of body substances. These masks are generally loose fitting without a tight air seal, and are not efficient in preventing the wearer from inhaling airborne particles. Detailed information about this type of mask is given in AS 4381[22]. Masks must be worn by all personnel within an operating room during an invasive procedure.

HCWs caring for patients with active pulmonary tuberculosis must wear a particulate filter personal respiratory protection device with a tight seal, capable of filtering out up to 95% of particles 0.3 µm or greater (see **Section 29.8.3**).

It is recommended that particulate filter personal respiratory protection devices conform with AS/NZS 1716 [23]

Dental procedures can generate large quantities of aerosols of 3 µm or less. Dental HCWs should therefore wear masks or facial barriers that conform to AS 4381[22] and block particles of this size (Christensen et al 1991). Dental HCWs should also change their masks after 20 minutes in the aerosol environment (Craig and Quale 1985).

13.5 Gowns and plastic aprons

HCWs should wear impermeable gowns and plastic aprons or covers to protect their clothing and skin from contamination with blood and body substances. Where there is a risk of large amounts of blood or body substances splashing their clothing, HCWs should wear impermeable or fluid-resistant gowns. Sterile prepacked gowns must be used in all aseptic procedures requiring a sterile field. Operating room attire should not

[22] AS 4381 (1996 – Amended 1997) *Surgical Face Masks*
[23] AS 1716 *Respiratory Protective Devices*

be worn outside the operating room environment. Further information on operating room gowns and other operating room attire is given in **Section 33**.

HCWs should remove protective clothing contaminated with blood or body substances as soon as possible, and bag it for laundering or disposal (see **Section 19.1**). If their skin has been contaminated with blood or body substances, HCWs should remove their protective clothing and wash their skin as soon as practicable.

13.6 Footwear

HCWs should wear enclosed footwear that can protect them from injury or contact with sharp objects (eg if sharps are accidentally dropped).

13.7 Uniforms

HCWs'uniforms should be clean and in good condition. HCWs long hair should be tied back or covered and beards covered when undertaking aseptic or sterile procedures.

Uniforms should be comfortable to wear and suitable for the type of work undertaken. Facilities for changing and disposal of soiled uniforms should be provided. The use of protective clothing (impermeable gowns or plastic aprons) worn over uniforms will avoid undue contamination where HCWs are exposed to blood or body substances.

14 Handling and disposal of sharps

Key points

- Inappropriate handling of sharps represents the major cause of incidents involving potential exposure to bloodborne infections.
- Health care workers must at all times handle sharps with care so as to minimise injury.
- The person who has used the sharp must be responsible for its immediate safe disposal following use.
- Needles should not be resheathed unless an approved recapping device is used. Needles should not be bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Sharps should be disposed of at the point of generation wherever possible.

14.1 Handling of sharps

Inappropriate handling of sharps represent the major cause of incidents involving potential exposure to bloodborne diseases. Sharps must be handled with care at all times. Methods of handling sharps during medical or dental procedures should be devised to minimise the risk of injury. These methods should be discussed between HCWs involved. Additional recommendations on the handling of sharps are to be found in AS/NZS 3825:1998 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles.

Sharp instruments must not be passed by hand between HCWs. Specified puncture-resistant sharps trays should be used for transfer of all sharp items (RACS 1998). Where possible, alternatives should be considered, including needleless intravenous systems, use of blunt needles for drawing up sterile solutions from ampoules, or retractable needle and syringe systems.

14.2 Disposal of sharps To prevent injury, needles should not be resheathed unless an approved recapping device is used. Needles should not be bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand.

The person who has used a sharp instrument must be responsible for its immediate safe disposal following its use. This must be at the point of use wherever possible. Disposable needle–syringe combinations, needles, scalpel blades, single-use razors and

other sharp items must be discarded in a clearly labelled, puncture-proof container which must conform with AS 4031 or AS/NZS 4261,[24] as appropriate.

Health care establishments should provide written protocols for safe handling of sharps, and ensure that HCWs are fully trained in the recommended handling techniques. Further information on the management of sharps injuries is given in **Section 23.**

[24] AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas*
AS/NSZ 4261 (1994) and Amendment 1 (1997) *Reusable containers for the collection of sharp medical items used in human and animal medical applications*

15 Management of clinical and related wastes

Key points

- Management of clinical and related waste must conform to relevant State/Territory regulations, Australian Standard AS/NZS 3816 (1998) and NHMRC National Guidelines for Waste Management in the Health Care Industry (NHMRC 1999).
- Waste should be segregated at the point of generation using appropriately colour-coded and labelled containers.
- Health care workers should wear gloves and protective clothing when handling clinical and related waste bags and containers. HCWs involved in the handling of such waste should be trained in the correct procedures.

15.1 Introduction

In 1999, the National Health and Medical Research Council (NHMRC) published new national guidelines for the management of waste in the health industry (NHMRC 1999b). The guidelines recommend that institutions generating such waste must ensure its safe identification, packaging, labelling, storage, transport, treatment and disposal, from the point of generation to the point of final disposal. Management of clinical and related wastes must also conform to relevant State/Territory legislation/regulations.

Health care establishments should also refer to AS/NZS 3816.[25]

15.2 Definition of health industry wastes

Providing a satisfactory and standard definition of clinical and related wastes has traditionally been a difficult issue for health care establishments. Terms such as hospital waste, clinical waste, infectious waste, medical or biomedical waste and biohazardous waste, have been used synonymously and often inappropriately in many situations. In the recent *National Guidelines for Waste Management in the Health Industry* (NHMRC 1999), health industry wastes are defined as all types of wastes (clinical, related and general) arising from medical, nursing, dental, veterinary, pharmaceutical or similar practices and wastes produced in hospitals or other establishments during the investigation or treatment of patients in research projects.

[25] AS/NZS 3816 (1998) *Management of clinical and related wastes*

Clinical waste includes the following categories:

- discarded sharps;
- laboratory and associated waste directly associated with specimen processing;
- human tissues, including material or solutions containing free-flowing blood; and
- animal tissue or carcases used in research.

Related waste includes:

- cytotoxic waste;
- pharmaceutical waste;
- chemical waste; and
- radioactive waste.

General waste includes other wastes that do not fall into the above categories. It forms the bulk of waste generated by health care establishments and is no more of a public health risk or concern than domestic or household waste.

15.3 Segregation of waste

Waste should be effectively segregated according to their category, at the point of generation, using appropriately colour-coded and labelled containers as per AS/NZS 3816:1998. The waste should be bagged, packaged or containerised and must be clearly marked with an adequate description of the contents. The three main categories are as follows:

- clinical waste must be placed in yellow containers bearing the international black biohazard symbol and clearly marked 'clinical waste'; (Table 15.1 delineates categories of clinical waste (eg sharps, non-sharps, liquids) and their appropriate disposal)

- cytotoxic waste must be placed in purple containers bearing the telophase symbol, and marked ‘Cytotoxic Waste’; and

- radioactive waste must be placed in red containers with the black international radiation symbol and marked ‘Radioactive Waste’.

Wastes that have not been segregated shall be treated as that portion of the waste representing the highest risk. Clinical and related wastes shall be segregated in line with licence requirements of the final disposal facility. The majority of clinical and related wastes is generally non-hazardous and can be disposed of in the general waste stream. Waste segregation allows for supervised landfill for the bulk of clinical and related wastes. See **Table** 15.1 for waste symbols and disposal methods.

15.4 Clinical waste

Any wastes can be classified as clinical by the relevant health care establishments or government authority. All clinical waste should be treated appropriately, contained and transported carefully.

Microbiological cultures should be rendered safe by a validated steam-sterilisation process monitored in accordance with AS 4187,[26] before they leave the control of laboratory HCWs. Clinical waste may be disposed of by incineration or landfill. Where landfill disposal of clinical and related wastes is intended, identifiable body parts, pharmaceuticals, cytotoxic and radioactive wastes should be excluded at source, and the landfill site must be confirmed as suitable.

Standard precautions should apply when handling clinical wastes. All waste should be handled with care to avoid injuries from concealed sharps (which may not have been placed in sharps containers). Gloves and protective clothing should be worn when handling clinical waste bags and containers. Staff involved in the handling of such waste should be properly trained, including training in the management of clinical waste spills (see **Section 18**). Where possible, manual handling of waste should be avoided.

Clinical waste must be placed in appropriate leak-resistant bags or containers. These should not be overfilled, and must not be compacted by hand.

Trolleys used for transport of infectious or other hazardous waste should be clearly labelled as such, and used only for waste transport. They should be cleaned daily, never overfilled, and fitted with drip trays to contain leaks or spills.

15.5 Collection and disposal of waste

Arrangements for collection and disposal of solid clinical waste depend on the location, size and existing infrastructure of health care establishments. In health care establishments, there should be clear access to waste disposal facilities, including sluices for disposal of large volumes of liquids (eg 24-hour urine collections). In office-based practice, small volumes of blood, urine or faeces can be disposed of via the sewerage system, but disposal of a large volume of clinical liquid waste must follow local regulations (NHMRC 1999b).

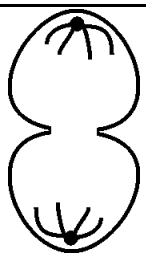
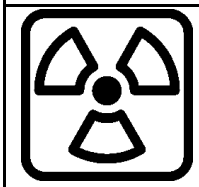
Protocols for waste disposal should follow national guidelines or codes of practice and must also comply with State/Territory and local regulations. Although current categories and terminology may vary between States and Territories, every effort

[26] AS 4187 (1998) *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*

should be made to comply with terminology and labelling of waste as specified in the NHMRC national guidelines for health industry waste management (NHMRC 1999b). AS/NZS 3816 should also be consulted.

Table 15.1 is a general guide only for recommended identification for containment and disposal of waste. Government authorities should be contacted for more detailed information.

Table 15.1 Categories of waste and recommended containment and disposal

Symbol	Waste	Container colour	Disposal
None	**General**	Black, buff, green, white	Landfill Consider recycling (Confidential waste to be shredded or incinerated)
	**Clinical waste** • sharps • nonsharps • liquid	 Yellow, rigid container Yellow bag	Licensed contractor (for disposal by approved technologies) Incineration Incineration or validated steam–sterilisation then supervised landfill Sewer: local regulations must to be followed
	**Cytotoxic**	Purple	Licensed contractor Incineration: 1100^{0}C (NHMRC 1999b)
	**Radioactive**	Red	Licensed contractor Monitor before disposal by incineration or supervised landfill Dilute isotopes may be disposed of via sewerage system in accordance with relevant guidelines

Note: Any waste, contaminated or stored with another waste requiring a higher level of destruction must be classified at the higher level.

16 Reprocessing of reusable instruments and equipment

Key points

- Reprocessing of instruments and equipment refers to the cleaning, disinfection (by heat and water, or chemical disinfectants) and/or sterilisation.
- All the steps outlined in Australian standards AS 4187 and AS/NZS 4815, or an equivalent protocol, must be followed, including process validation.
- The level of reprocessing required for instruments and equipment depends on the body sites where the instrument will be used (see **Section 4.4**).

  Critical site: **all items must be sterile**

  Semicritical site: items should be sterile (or **must be a *minimum* of high-level-disinfected** if other methods are not suitable or available).

  Noncritical site: items must be clean
- Generally, cleaning can be manual or automated. Enzymatic cleaners should not be used routinely. The cleaning area should not be used for any other purpose.
- Disinfection can be thermal or chemical. The level of chemical disinfection (high, intermediate or low) reached depends on the temperature, time and/or type of disinfectant used.
- Sterilisation should preferably be by steam under pressure. For instruments that will not withstand heat, other methods include ethylene oxide and automated low-temperature chemical sterilants
- Single-use sterile instruments and equipment should be used wherever the clinical situation dictates. Items intended for single use should not be reused (see Section 17.13).
- Special conditions apply for reprocessing instruments and equipment at risk of contamination with prions (Creutzfeldt–Jakob disease; see **Section 31**).

16.1 Introduction

Any infectious agents introduced into sterile body sites can establish infection. Infectious agents are always present on skin and are carried through the air on dust particles. They can therefore contaminate instruments, medications and solutions that are intended to be sterile. In order to achieve sterile conditions during procedures, attention must be given to all potential sources of contamination.

Effective reprocessing of reusable instruments involves:

- cleaning immediately after use to remove organic residue and chemicals, and either;
- disinfection (by heat and water or chemical disinfectants); or
- sterilisation

The procedures and process development necessary for cleaning, disinfection and sterilisation of reusable, medical and surgical instruments and equipment, and for the maintenance of associated environments in health care establishments, are given in AS 4187[27] and AS/NZS 4815.[28] For safe and effective reprocessing of instruments and equipment, it is essential that all steps outlined in these standards (or an equivalent protocol), including process validation, are followed.

Additional procedures are required for handling instruments and equipment contaminated with the Creutzfeldt–Jakob disease (CJD) agent. Details of these procedures are given in **Section 31.9**.

16.2 General principles

16.2.1 Training

Health care workers (HCWs) who clean instruments and equipment must be trained in all the necessary procedures. They should receive formal training in equipment cleaning and processing, disinfection and/or sterilisation at an appropriate level as recommended by professional bodies.

The importance of thorough cleaning before any disinfection or sterilisation regimen should be emphasised in infection control education programs. Failure to adequately

[27] AS 4187 (1998) *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*

[28] AS/NZS 4815 (2001) *Office-based health care facilities not involved in complex patient procedures and processes — Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment and maintenance of the associated environment*

clean items after use may result in lack of disinfection or sterilisation of the instruments or equipment (Deva et al 1998).

16.2.2 Level of reprocessing required

Routine reprocessing

Instruments and equipment must be reprocessed to a level appropriate for their intended use. The appropriate level depends on the body sites where the instrument will be used and the risk associated with a particular procedure. Three major categories of instrument use are described in **Section 4.4 and Table 4.2** (critical site, semicritical site and noncritical site).

The *minimum* levels of processing and storage requirements for reusable instruments and equipment, based on these three risk categories of use, are shown in **Table 16.1**. In brief, these minimum levels of reprocessing are:

- *critical site* — instruments should be sterile at the time of use. This means instruments should be single use or, steam sterilised (for instruments that are capable of withstanding heat), or low-temperature chemical sterilisation for heat-sensitive equipment;

- *semicritical site* — instruments should be single use or sterilised after each use. If this is not possible, high-level disinfection is the *minimum* level of reprocessing that is acceptable;

- *noncritical site* — cleaning alone is generally sufficient for all non critical items after every individual use, although either intermediate or low-level disinfection may be appropriate in specific circumstances.

These recommendations apply to office-based practice as well as to larger health care establishments.

Steam sterilisation is the best method to achieve sterility. If steam sterilisation is not suitable (eg heat-labile instruments, fibreoptic scopes), other sterilisation systems, such as ethylene oxide (EO) or automated low-temperature chemical sterilant systems may be used provided they are acceptable to the instrument manufacturer. Thermal disinfection does not kill all bacterial spores and therefore does not sterilise instruments but provides an acceptable level of disinfection when instruments are thermally treated under well-defined and controlled time and temperature parameters. Details of the procedures are given in **Section 16.4.2**.

Instruments used in operating rooms must be sterilised in accordance with AS 4187 and AS/NZS 4815 and with the National Co-ordinating Committee on Therapeutic

Goods *Standard for the Operation of Sterile Supply/Services in Health Care Facilities* (NCCTG 1995).

Under a new harmonised system with the European Union, all reusable medical device manufacturers will be obliged to provide reprocessing instructions. Manufacturers of existing devices will have five years to comply.

Details are given in **Section 31.9** for additional precautions that apply to instruments and surgical procedures for patients in risk categories for CJD.

Items to be serviced

Instruments and equipment should be reprocessed before being sent for servicing. If recommended reprocessing is not possible before repair, items should be sealed and labelled with the appropriate hazard warning before despatch (See Table 15.1 and 16.1).

Loan sets

Loan sets or instruments must be reprocessed on receipt at the health care establishment before use. After use, loan sets and instruments must reprocessed before being returned to the manufacturer or agent.

Special reprocessing

Information about instruments and equipment that need special reprocessing, eg. endoscopes, respiratory and anaesthetic apparatus and diagnostic ultrasonic transducers is provided in **Section 17**.

DISCUSSION POINT

Levels of reprocessing

According to the Spaulding classification system (see **Section 4.4**), it is not the item itself that defines the reprocessing required, but its intended use. Therefore the level of reprocessing required should be determined by the future use of the item.

This means an item that has been used on intact skin may require a higher level of reprocessing if it is to be used on sterile tissue in the future.

There are occasions when items cannot withstand the most suitable reprocessing requirements for the intended use. Some heat and/or moisture sensitive items cannot be steam sterilised (eg some fibreoptic endoscopic equipment and accessories) even though this is the recommended level of reprocessing for its intended use. This type of equipment should be reprocessed using a low-temperature chemical sterilisation system or high-level disinfection as the minimum level of reprocessing.

Health care establishments must also follow local State/Territory regulations that may mandate specific reprocessing requirements over and above those given in AS 4187 and AS/NZS 4815.

Table 16.1 Minimum level of reprocessing required for specific items in use

Level of risk	Application	Process	Storage	Example
Critical	Entry or penetration into sterile tissue, cavity or bloodstream	Sterilisation by steam under pressure, or a minimum of an automated low-temperature chemical sterilant system, other liquid chemical sterilant or ethylene oxide sterilisation (ie must be sterilised) *Special conditions apply to CJD (see **Sections 17 and 31**)*	Sterility must be maintained: – packaged items must be allowed to dry before removal from the steriliser – the integrity of the wrap must be maintained – wraps should act as an effective biobarrier during storage – store to protect from environmental contamination – unpackaged sterile items must be used immediately	Instruments, endoscopes and accessories used in invasive surgical and dental procedures,[a] including: – hysteroscopes – arthroscopes – laparoscopes – oral surgical instruments – ERCP equipment[b] and accessories – rigid bronchoscopes – flexible bronchoscopes[b] – cytoscopes[b] Podiatry instruments capable of penetrating or abrading the skin (scalpels, nail cutters, scalers, files), neurological testing sharps, forceps, etc used on nonintact tissue. Acupuncture needles (reusable)
Semicritical[c]	Contact with intact nonsterile mucosa (or nonintact skin)	**Heat-tolerant items** Preferably steam sterilisation where possible, or a minimum of thermal disinfection (see **Table 16.2**) *Special conditions apply to CJD (see **Sections 17 and 31**)*	Store to protect from environmental contamination	Breathing circuits Vaginal speculae -sterile Instruments for routine dental procedures Buffs used in dental laboratories
Semicritical[c]	Contact with intact nonsterile mucosa (or nonintact skin)	**Heat-sensitive items** If equipment will not tolerate heat, use low-temperature automated chemical sterilant systems or a minimum of high-level chemical disinfection *Special conditions apply to CJD (see **Sections 17 and 31**)*	Store to protect from environmental contamination	Flexible endoscopes: – fibreoptic scopes – sigmoidoscopes – gastroscopes – colonoscopes – bronchoscopes Invasive ultrasound probes
Noncritical	Contact with intact skin	Clean as necessary with detergent and water If decontamination is required, disinfect with a compatible low- or intermediate-level instrument grade disinfectant after cleaning	Store in a clean, dry place	Noninvasive acupuncture devices Stethoscopes Sphygmomanometers Blood pressure cuffs Mercury thermometers Abdominal ultrasound

CJD = Creutzfeldt-Jakob disease; ERCP = endoscopic retrograde cholangiopancreatography

[a]An invasive procedure is defined as surgical entry into tissues, cavities, or organs, or repair of traumatic injuries. Invasive dental procedures include placement of matrix-retaining bands, orthodontic bands and copper bands as well as root canal procedures.

[b]These items enter sterile sites and should therefore be sterile. However, in practice, they are made from materials that do not withstand steam sterilisation. If a low-temperature chemical sterilisation system is available it should be used for these items, otherwise they should be high-level chemical disinfected (see **Section 17** for further details). (See discussion box in **Section 16.2.2**)

[c]These categories reflect current practice – sterilisation is preferred where possible. Processing standards should evolve to accommodate changes in equipment design and emerging technologies in sterilisation processes.

Notes: To preserve the surfaces and composition of the instruments, separate dissimilar metals before cleaning. Avoid use of abrasive materials. Do not store instruments in disinfectant before or after any form of processing.

Breathing circuits must be mechanically dried before storage; see AS 4187 (1998) *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.*

16.2.3 Storage of equipment

All items must be stored in such as way that their level of processing is maintained (eg sterile, high-level disinfected). Dry, sterile, packaged instruments and equipment should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging (see AS 4187 and AS/NZS 4815). This is essential for instruments and equipment that are intended for use on critical sites and which must be sterile.

16.2.4 Single-use instruments and equipment

Single-use sterile instruments and equipment should be used wherever the clinical situation dictates such practice. The following are some examples of single-use instruments and equipment and procedures for their use.

- Injecting apparatus (including hypodermic syringes, needles, dental local anaesthetic cartridges and dental needles, intravenous (IV) lines and giving sets) must be sterile and single use only. A new cannula must be used for each attempt at IV cannulation. Reusable syringe holders used for single-use anaesthetic cartridges must be steam sterilised between patients. Incompletely used anaesthetic cartridges, ampoules and vials must be discarded after each patient use.

- Dressings, suture materials, suture needles, scalpels, intracranial electrodes (or any probe used in intracranial examinations), pins or needles used for neurological sensory testing, spatulas and razors, including disposable razor blades on electric clippers, may be used for one patient and only once.

- Any single-use article or instrument that has penetrated the skin, mucous membrane or other tissue must be discarded immediately after use or at the end of the procedure, whichever is more appropriate.

There are some single-use implantable items which may have specific approval from the Therapeutic Goods Administration (TGA) for reprocessing if they are opened but

not used (ie have had no contact with tissue), as part of the device-registration process. In these instances, the manufacturer must provide appropriate instructions for reprocessing the devices, and these instructions must be followed explicitly. (See also **Sections 6.3.3 and 17.12**)

For information on single-use medications and solutions see **Section 6.3.1**.

There are some expensive instruments labelled "single-use device" (eg. cardiac solid electrodes) for which institutions may wish to consider reprocessing. Advice on this issue is given in Section 17.13.

16.2.5 Patient care equipment

Patient care equipment, such as bedpans and urinals, are generally in contact with intact skin (noncritical sites). They should be cleaned, thermally disinfected (see **Section 16.4.2**), dried and stored appropriately. Alternatively, a bedpan washer–disinfector may be used (AS 2437[29]).

16.3 Cleaning

16.3.1 General principles

Cleaning is an essential prerequisite for all effective disinfection and sterilisation processes, because organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants (Muscarella 1998). It cannot be stressed too strongly that if the item cannot be cleaned, it cannot be disinfected or sterilised. Full details of cleaning are given in AS 4187 and AS/NZS 4815. Standard precautions must be followed during the cleaning procedure (see **Section 2.2**).

16.3.2 Cleaning area

The cleaning area must be dedicated for that purpose only. Consideration should be given to directed work flow (see AS 4187, AS/NZS 4815 and **Section 11.4.2** of this document).

16.3.3 Initial cleaning

Immediately after use, and as close as possible to the point of use, gross soil must be removed from instruments and equipment. Instruments and equipment should be

[29] AS 2437 (1987) and Amendment 1 (1988) *Flusher/sanitizers for bed pans and urine bottles*

cleaned as soon as possible after use. They should not be allowed to dry before cleaning. Detergent and water is generally sufficient for routine cleaning.

16.3.4 Manual cleaning procedures

Cleaning procedures and suitable cleaning agents are discussed in appendixes to AS 4187. See also **Section 16.3.5** for information about hazardous enzymatic cleaners.

All channels or bores of instruments or equipment such as rigid or flexible endoscopes must be cleaned thoroughly (see **Section 17**).

Instruments that are washed manually should be rinsed and cleaned in a sink or bowl specifically designed for that purpose, using the following procedures;

- Wear a plastic apron, general purpose utility gloves and face protection (protective eyewear and mask or face shield). Take care to prevent splashing of mucous membranes or penetration of the skin by sharp instruments.
- Remove gross soiling by carefully rinsing in warm (15-18 degrees C) water.
- Fully disassemble instruments and immerse in warm water and a suitable detergent that is biodegradable, noncorrosive, nonabrasive, low foaming and free-rinsing (or an enzymatic cleaner if indicated: see below).
- Remove all visible soiling from the instrument or equipment using established methods and with reference to the manufacturer's recommendations.
- Rinse instruments in hot water to assist the drying process, unless contraindicated.
- Dry mechanically in a drying cabinet or hand dry with a clean, lint-free cloth (note: items must not be left to dry in ambient air).
- Inspect instruments and equipment to establish that the item is clean before further processing or storage.
- Cleaning brushes should be identified for cleaning only and should be washed, thermally disinfected, and stored dry.

Items should be thoroughly rinsed after cleaning with warm water and detergent, as detergent residue may reduce the effectiveness of the disinfectant. Items to be disinfected should be dried before immersion in disinfectant solution to avoid dilution of the disinfectant (which can make it less effective over the prescribed time for disinfection). Items must also be dried before inspection and packaging.

DISCUSSION POINT

Drying and CJD agents (prions)

CJD infectivity may be stabilised by drying on metal surfaces (Zobeley et al, 1999; WHO 2000) and become more difficult to inactivate. Instruments potentially contaminated with CJD agents should be kept immersed in a dedicated container in an anionic detergent solution, at ambient temperature, until they are manually cleaned and reprocessed using the methods shown in Table 31.14.1. Instruments should not be exposed to instrument-grade disinfectants or sterilants prior to the manual cleaning procedures. Ultrasonic cleaners and automatic washing appliances should not be used in the preparatory cleaning process.
Contaminated instruments from each patient should be cleaned and reprocessed in separate batches, and not mixed with other surgical instruments at any stage of the reprocessing cycle.

16.3.5 Use of enzymatic cleaners

Enzymatic cleaners are hazardous and should only be used for fibreoptic instruments and accessories and for other instruments where design characteristics make routine cleaning difficult. If enzymatic cleaners are used, HCWs should be made aware of associated hazards, and material safety data sheets should be displayed.

16.3.6 Ultrasonic cleaners

Ultrasonic cleaners and automated washing appliances reduce the handling of instruments and are recommended for cleaning basic instruments (eg artery forceps, scissors, needle holders) that can withstand the process. Ultrasonic cleaners must comply with AS 2773.1[30] or AS 2773.2.[31]

Further details on the use of ultrasonic cleaners and testing procedures are given in AS 4187. Where available, manufacturers' instructions should be followed.

Studies on dental appliances indicate that presoaking, followed by cleaning in ultrasonic or automated washer–disinfectors with thorough rinse cycles, eliminates almost all traces of contamination on the equipment (Sanchez and Macdonald 1995).

Ultrasonic cleaners do not disinfect instruments. They work by subjecting instruments to high frequency, high energy sound waves, causing soil to be dislodged from instruments and drop to the bottom of the tank, or to be sufficiently loosened to be removed during the rinsing process. They can be used to assist with cleaning of

[30] AS 2773.1 (1998) *Ultrasonic cleaners for health care facilities — non-portable*
[31] AS 2773.2 *Ultrasonic cleaners for health care facilities — non-portable — benchtop*

jointed and serrated stainless steel instruments. Internal surfaces of cannulated instruments, plastics and other similar materials cannot be successfully cleaned by this method. Cemented glass syringes and lenses will be damaged if repeatedly subjected to this process. Dissimilar metals should not be processed together, as they are prone to electrolytic corrosion. The fine mechanical shaking can also blunt fine points by impaction. To minimise handling of sharp instruments, a cassette system, compatible with ultrasonic cleaning baths, may be used.

Ultrasonic cleaners should not be operated without a close-fitting lid in place, as the high sound frequency may cause damage to hearing (Pye 1984) and allow potentially infective aerosols to escape from the unit. Operators should not submerge any part of their body in the ultrasonic cleaning unit during its operation.

The efficiency of the ultrasonic cleaner should be tested daily, or when used, according to the manufacturer's instructions (where available), and documented.

16.3.7 Automated washer–disinfectors

Some innovative automated washer–disinfectors, which are now available in Australia, include cleaning mechanisms in their cycles. Refer to the manufacturer's technical manual for reprocessing directions specific to this type of equipment.

16.4 Disinfection

16.4.1 General principles

Disinfection is a process that inactivates nonsporing infectious agents, using either thermal (moist or dry heat) or chemical means. The level of chemical disinfection achieved depends on the temperature, exposure time and/or type of chemical disinfectant used. *Thermal disinfection* can be achieved in an automated thermal washer-disinfector by choosing the appropriate cycle. *Chemical disinfection* can be achieved with a compatible TGA-registered instrument grade disinfectant of the required level, used alone or in conjunction with an automated chemical washer–disinfector.

- *High-level disinfection* — this is the minimum treatment recommended for reprocessing instruments and devices for use in semicritical sites that cannot be sterilised.

- *Intermediate-level disinfection* — this is the minimum treatment recommended for reprocessing instruments and devices for use in noncritical sites, or when there are specific concerns regarding contamination of surfaces with species of mycobacteria, for example *Mycobacterium tuberculosis*.

- *Low-level disinfection* — this is the alternative treatment to cleaning alone when reprocessing devices for use in noncritical sites and only vegetative bactericidal activity is needed. These disinfectants are not necessarily fungicidal for all forms of fungi or virucidal for all viruses.

Disinfection is not a sterilising process. Thermal disinfection and high-level chemical disinfection must not be carried out as convenient substitutes for sterilisation (see AS 4187 and AS/NZS 4815). If it is possible to sterilise items to be used in semicritical sites, or to use single-use items, this should be done.

Thermal disinfection is not suitable for instruments that are to be used in critical sites as these instruments must be sterile. However, thermal disinfection should be used in preference to chemical disinfection whenever practicable (see **Table 16.1**).

16.4.2 Thermal disinfection

Principles

If items can withstand heat and moisture and do not require sterilisation, then thermal disinfection, or pasteurisation, using heat and water at temperatures and times that destroy pathogenic, vegetative agents is the simplest, most efficient and cost-effective method of disinfection.

Heat is readily conducted (by water and by most metals) and thus is able to penetrate and disinfect items more efficiently than chemicals. However, the microbicidal effect of heat can be compromised by inadequate cleaning.

Pasteurisation is a thermal disinfection process using hot water at a temperature of 75°C for a contact-time of at least 30 minutes. These conditions, or the equivalent conditions shown in **Table 16.2** are necessary for thermal disinfection of items to be used in semicritical sites.

Automated equipment

Automated equipment, such as washer–sanitisers, pasteurisation equipment, washer–decontaminators and washer–disinfectors, are recommended for use in thermal disinfection processes. The level of disinfection depends on the water temperature and the exposure time. Thermal washer–disinfectors may be programmed to deliver a range of disinfection levels, depending on the cycle selected (ie set temperature and exposure times). This type of equipment is regulated by the TGA, and users should follow the manufacturer's directions to achieve the required level of disinfection.

Batch type washer–disinfectors, complying with AS 2945[32] should be used. Such disinfectors require preventative maintenance programs, including monitoring of water quality (see AS 4187).

Table 16.2 Minimum surface temperature/time relationship for thermal disinfection

Surface temperature (°C)	Minimum disinfection time (minutes)
90	1
80	10
75	30
70	100

Notes: The temperatures and times given in this table are the minimum required to achieve an A_0 of 600. This concept is described in detail in AS/NZS 4815. The approach to thermal disinfection is currently under review by the International Organization for Standardization and the European Committee on Standardization.

Source: ISO DIS/prEN 15883-1 (1999)[33] and AS/NZ 4815

16.4.3 Chemical disinfection

The types of chemical disinfectants and their uses are described in detail in **Section 7** and summarised in **Table 7.1**. Occupational health and safety considerations for the use of chemicals are described in **Section 7.4**.

The ability of chemical disinfectants to effectively inactivate contaminating infectious agents depends on a number of factors, including the initial number of agents present, temperature, pH and concentration (Chiba 1994).

Organic material that is not removed by cleaning before disinfection can bind and inactivate many chemical disinfectants (Cremieux 1986). Some disinfectants, such as glutaraldehyde, fix protein and thus may create a physical barrier of denatured protein that can protect infectious agents coated with organic material. A disinfectant cannot be effective against infectious agents it cannot reach, and thus thorough cleaning before disinfection is essential. All instruments and equipment must be cleaned and dried before chemical disinfection to prevent inactivation or dilution of the disinfectant (see **Section 16.3**).

Different grades of disinfectants are used for different purposes (see **Section 7**). Only instrument grade disinfectants or sterilants are suitable for use with medical instruments. Hospital or household/commercial grade disinfectants must not be used on instruments, as they are only suitable for use on environmental surfaces (eg walls, floors, cupboards). If users of high-level disinfectants are unsure of the TGA-

[32] AS 2945 (1998) *Batch-type washer/disinfectors for health care facilities*
[33] International Organization for Standardization (ISO) Draft International Standard (DIS)/Preliminary Norme (prEN) 15883-1 (October 1999) *Washer–disinfectors – Part 1: General requirements, definitions and tests*

approved status of a product, they should ask the manufacturer initially to supply the product's AUST R code number (see **Section 7.2**).

Chemical disinfectants intended to cover a range of different levels of disinfection may specify different exposure and/or temperature combinations on the product label. Care should be taken to select the appropriate conditions for the desired level of disinfection. The active ingredients of the disinfectant in use must also be closely monitored on at least a daily basis. Monitoring is particularly important for multiple-use solutions. However, consideration should be given to more frequent monitoring when large volumes of items are being processed.

16.5 Sterilisation

16.5.1 General principles

Instruments and equipment will only be sterile if one of the following sterilisation processes is used:

- steam under pressure (moist heat);
- dry heat;
- ethylene oxide;
- automated environmentally sealed low-temperature peracetic acid, hydrogen peroxide plasma and other chemical sterilant systems or sterilants; and
- irradiation.

All of the above methods are designed to give a sterility assurance level (SAL) of at least 10^{-6} (see Glossary), provided that the sterilisation process is validated by the user. AS 4187 and AS/NZS 4815 include detailed information on the sterilisation methods most commonly used in health care establishments and office-based practices, respectively.

Steam under pressure at the standard temperature and pressure settings used in health care establishments or the other methods listed above, are not suitable for reprocessing items potentially contaminated with the infectious agents for CJD. The only suitable methods for inactivating these agents are described in **Section 31.14 and Table 31.14.14**.

Ultraviolet light units, incubators, microwave ovens, domestic ovens and pressure cookers must not be used for sterilisation purposes.

Before processing any item for steam sterilisation, ensure that it can withstand steam under pressure. Cleaning is the most important prerequisite for sterilisation. Items should therefore be cleaned thoroughly as soon as practicable after use, before sterilising (see **Section 16.3**).

In hospitals and larger health care establishments, sterilisation service/supply units (SSUs) are responsible for providing sterile items within the establishment. The National Co-ordinating Committee on Therapeutic Goods has developed guidelines for SSUs: *Standard for the Operation of Sterile Supply/Services in Health Care Facilities* (NCCTG 1995). It is possible that SSUs in larger establishments may also provide this service for smaller establishments, including office-based practices, on a contractual basis.

Records of sterilisation must be kept for a time period to comply with Commonwealth and State/Territory legislation. These records enable traceability of items to an individual patient. Details of the documentation required for quality systems management are given in AS 4187 and AS/NZS 4815.

16.5.2 Steam-under-pressure (moist heat) sterilisation

Principles

The most efficient and reliable form of sterilisation of instruments and equipment is by steam under pressure, which dries packaged sterile items as part of the cycle before unloading. This is therefore, the preferred and most widely used method of sterilisation for items used in critical and semicritical sites (as long as they can withstand heat and moisture). Steam under pressure is the preferred method of sterilisation in office-based practice.

The microbiocidal effect of steam sterilisation is due to the latent heat of condensation being transferred to the load, causing it to heat rapidly. Steam under pressure causes coagulation of protein structures, thus inactivating infectious agents.

There are several types of steam-under-pressure sterilisers (formerly called autoclaves), including:

- downward (gravity) displacement (jacketed and nonjacketed);
- self-contained (‘benchtop’);
- prevacuum (porous load); and
- operator-convertible.

Downward displacement steam sterilisers are designed for general sterilisation of waste, solutions and instruments. They function by displacing air with steam, via a port in the bottom of the chamber. Prevacuum steam sterilisers, on the other hand, are not suited for liquid sterilisation but are optimised for sterilisation of clean instruments, gowns, drapes, towelling and other dry materials required for surgery. In prevacuum steam sterilisers, air is exhausted by a mechanical pump, which creates a vacuum that is replaced by steam.

AS 4187 and AS/NZS 4815 give further details of the different types of steam sterilisers. All steam sterilisers must meet the requirements of AS 2192,[34] AS 1410[35] or AS 2182[36] and be operated according to AS 4187 and AS/NZS 4815. Details of different types of packaging material suitable for use in health care facilities are given in AS 1079.[37]

Benchtop steam sterilisers

Benchtop (portable) steam sterilisers are regulated by the TGA. Models that comply with AS 2182 are the most efficient and reliable sterilising units for use in office-based practice. Benchtop sterilisers are suitable for sterilisation of small quantities of relatively simple items, both packaged and unpackaged. Items that are not packaged should be used immediately following sterilisation. Packaged items should only be processed in a steam steriliser that has a built-in drying cycle. Benchtop sterilisers that do not have a built-in drying cycle are only appropriate for the sterilisation of unwrapped items, which must be used immediately after removal from the steriliser using aseptic technique (see AS 4187 and AS/NZS 4815).

Some benchtop sterilisers, as well as most larger units, have a built-in drying cycle that dries packaged sterile items before unloading. The advantages of packaged and wrapped instruments are that they are easier to unload without contamination and do not have to be used immediately. Such sterilisers should have a drying stage complying with the requirements of AS 2182. Office-based practices intending to purchase new benchtop sterilisers for the sterilisation of wrapped instruments and porous loads should check that a built-in drying cycle is featured and that the sterilisers are listed by the TGA. If possible, older models should be modified to include a drying cycle.

Newer models of benchtop sterilisers also have printout facilities for monitoring temperature and pressure (as applicable) and holding time. Existing, older-style benchtop sterilisers should be fitted with a mechanism to allow the observation and immediate transfer of information (eg time at temperature, temperature, pressure) to an electronic data storage facility. Records produced must be kept for a period of time in accordance with Commonwealth and State/Territory regulations. In the event of printout or electronic data storage malfunction, manual monitoring of the steam sterilisation cycle must be performed, and a written log of cycles maintained.

When purchasing a steam steriliser for use in office-based practice, consideration must be given to HCW training and quality control (see AS 4187 and AS/NZS 4815) as well as running costs. Such ongoing expenditure may make the use of an external service

[34] AS 2192 (1991) *Sterilizers – Steam – Downward displacement*
[35] AS 1410 (1987) and Amendments 1 and 2 (1987) *Sterilization – Steam – Pre-vacuum*
[36] AS 2182 (1998) *Sterilisers – Steam – Benchtop*
[37] AS 1079 *Packaging of items (sterile) for patient care* (Parts 1–5; see Appendix 3)

(other office-based practice, hospital or commercial facility) or disposable single-use items more practical and cost-effective alternatives for smaller practices.

Sterilisers must be used in accordance with the manufacturer's instructions. It may be necessary to contact relevant State/Territory occupational health and safety authorities regarding registration and inspection of steam sterilisers.

Users of benchtop sterilisers should be aware that the recycled water from previous cycles causes deterioration in the water quality for each successive cycle. Accumulated debris in recycled sterilising feed water may compromise the sterility of instruments. The water reservoir should be emptied, cleaned and flushed each week and filled with a fresh supply of water. The use of distilled or deionised water is recommended.

16.5.3 Dry heat sterilisation

Principles

Dry heat sterilisation by means of hot dry air destroys infectious agents by the process of oxidation. However, dry heat sterilisers (mechanical air convection and fan-assisted) have had limited application. It is difficult to maintain an even temperature throughout the load and the high temperatures and prolonged times required to achieve sterility makes this method of sterilisation undesirable for office-based practices.

AS 2487[38] specifies the requirements for dry heat sterilisers. The manufacturer's instructions must be followed for operation of dry heat sterilisation equipment. The door of the steriliser must not be opened during the sterilising cycle.

Dry heat sterilisation is used for anhydrous items and items sealed within impermeable containers that cannot be sterilised by steam under pressure, but can withstand a temperature of 160°C for a minimum of 120 minutes plus penetration time. Dry heat sterilisers use mechanical convection, which provides forced air circulation with uniform temperature distribution throughout the chamber. Some materials and instruments, particularly those with moving parts, may suffer damage or loss of lubrication through dry heat sterilisation. Sterilising practitioners should check with the manufacturer about the suitability of dry heat sterilisation for specific items.

Dry heat sterilisation is not recommended for CJD-contaminated items (see **Section 31.14**).

[38] AS 2487 (1981) *Dry heat sterilizers (hot air type)*

16.5.4 Commercial irradiation sterilisation systems

Sterilisation by gamma radiation is available only from commercial gamma irradiation facilities. Other forms of radiation sterilisation (eg electron beam) are not currently available in Australia.

Radiation sterilisation is not recommended for CJD-contaminated items (see **Section 31.14**).

16.5.5 Ethylene oxide sterilisation systems

Ethylene oxide (EO) gas can be used for sterilisation of articles that are made partly or entirely from heat-labile materials, or that contain electronic components. Sterilisation is achieved by alkylation of the protein in the microbial cell. Processing time is dependent on the temperature, relative humidity and gas concentration, and can only be effective if the gas can penetrate the packaging and reach all surfaces of the articles requiring sterilisation. The process generally takes 12 hours to more than 24 hours, which includes the time needed for aeration to rid the articles of any residual EO gas. Due to its high toxicity, the use of EO in health care establishments is restricted. Special requirements in siting, monitoring and operation are applicable if placed in health care facilities.

EO sterilisation is not recommended for CJD-contaminated items (see **Section 31.14**).

16.5.6 Low-temperature automated chemical sterilisation systems

Hydrogen peroxide plasma

Low-temperature hydrogen peroxide plasma (HPP) sterilisation works by alkylation of the protein in the microbial cell.

Low-temperature glow HPP sterilisers use HPP in a fully automated cycle to achieve low-temperature, low-moisture sterilisation within a 45–80-minute cycle, depending on the model of steriliser used. The system requires the use of nonwoven (noncellulose) polypropylene wraps/packaging.

HPP sterilisation is not recommended for CJD-contaminated items (see **Section 31.14**).

Peracetic acid

Low-temperature peracetic acid (PAA) sterilisation works by oxidation of microbial cell proteins.

Sterilisation is achieved with 0.2% PAA in an environmentally sealed chamber and a fully automated processing system. The process generally achieves moist, low-

temperature sterilisation within 25–30 minutes, depending on conditions at the establishment where the equipment is installed. The items are not wrapped for this process, however they are sterilised in special containers.

PAA sterilisation is not recommended for CJD-contaminated items (see **Section 31.14**).

16.5.7 Other chemical sterilants

Information on chemical sterilants is given in **Section 7.2**. To achieve sterilisation with aldehyde-based products, such as glutaraldehyde, at ambient temperature, a prolonged contact time is generally necessary depending on the formulation and the TGA-approved labelling.

If users of sterilants are unsure of the TGA-approved status of a product, they should ask the manufacturer initially to supply the product's AUST R code number (see **Section 7.2**).

IMPORTANT NOTE

Endoscopes and accessories that are soaked for the shorter of the two labelled exposure periods in a multiuse sterilant/high-level chemical disinfectant before use cannot be considered to be sterile (AS 4187).

Glutaraldehyde, other aldehydes, acetone and alcohols are not recommended for CJD-contaminated items (see **Table 7.1 and Section 31.14**).

17 Instruments and equipment requiring special processing

Key points

- Specialised equipment, such as flexible fibreoptic scopes, respiratory apparatus and diagnostic ultrasound probes may not withstand steam sterilisation, thermal disinfection or some chemical agents. Such equipment can also be complex and delicate, making it difficult to reprocess and sample microbiologically.
- Such equipment should only be used in health care establishments with proper reprocessing facilities, quality management systems to ensure full compliance with cleaning, disinfection and sterilisation protocols, and fully-trained staff.
- Records must be kept to allow retrospective identification of instrument use for specific patients
- Instruments that will be used in critical sites (penetration into sterile tissue) or semicritical sites (contact with mucosal or nonintact skin) should be sterilised with steam under pressure if they withstand heat.
- For instruments that will not withstand steam sterilisation, a low-temperature sterilisation system should be used if it is available (or a *minimum* of high-level chemical disinfection). For invasive procedures, all accessories must also be sterilised.
- Manufacturers' instructions regarding sterilisation and disinfection should be taken into account. However, at the present time, some manufacturers specify chemical agents that are not registered for use as instrument grade disinfectants. Within the next five years, medical device manufacturers will be obliged to provide reprocessing instructions.
- Flexible scopes should be reprocessed again on the day of use to kill environmental organisms that may have proliferated in any residual dampness (for duodenoscopes used for ERCP procedures, this reprocessing should be *immediately* before use).
- It is preferable to use a disposable breathing circuit during anaesthesia. If this is not possible, either a single-use filter must be used, or the breathing circuit (including the carbon dioxide absorber) must be discarded after each procedure. These items and other respiratory equipment are semicritical and the minimum reprocessing required is therefore high-level chemical or thermal disinfection.

- Asthma spacers should be single-patient use only. In a community setting, they should be reprocessed by high-level disinfection (in health care establishments) or thermally disinfected (in lower-risk settings such as home care or schools)
- Implantable items must be sterile at the time of use, and should not be 'flash' sterilised.

17.1 Endoscopes (general)

Detailed information on processing of endoscopes and accessories is given in:

- *Infection Control in Endoscopy, 4th edition* (Cowen et al 1999) published jointly by the Gastroenterological Society of Australia (GESA) and the Gastroenterological Nurses College of Australia (GENCA). A copy of these guidelines can be obtained from the GESA office (see **Appendix 7**); and
- AS 4187[39] on the care and handling of flexible and rigid endoscopes and accessory equipment.

17.1.1 Types of scopes

Scopes can be classified as rigid or flexible according to their construction. Specialised endoscopes are named in relation to the sites in the body that they are intended to visualise. For example: cystoscope (bladder), nephroscope (kidney), ureterscope (ureter), urethrascope (urethra), bronchoscope (bronchi), laryngoscope (larynx), otoscope (ear), arthroscope (joint), laparoscope (abdomen) and gastrointestinal endoscope (gastrointestinal tract).

Depending upon the procedure, gastrointestinal endoscopes may be further categorised as colonoscopes, gastroscopes, duodenoscopes (used for endoscopic retrograde cholangiopancreatography, or ERCP), sigmoidoscopes and so on.

Some endoscopes, such as bronchoscopes and sigmoidoscopes, are available in both flexible and rigid constructions.

Modern flexible fibreoptic scopes (including flexible bronchoscopes, colonoscopes, cystoscopes, duodenoscopes, gastroscopes and flexible sigmoidoscopes) are made from materials (eg plastics) that are unable to withstand temperatures above 60ºC or many chemicals, which may lead to degradation of materials (eg lens cement). The endoscope is honeycombed with multiple small channels, some with blind endings, none of which can be adequately inspected following cleaning. The equipment is physically delicate, difficult to dry and difficult to sample microbiologically.

ERCP is a tool used to assist in the diagnosis of liver, bile duct, gallbladder and pancreatic diseases. The flexible side-viewing duodenoscope used for ERCP is inserted into the small intestine via the mouth, oesophagus and stomach. A catheter is passed through the endoscope and manipulated into the bile and pancreatic ducts. Dye is injected into the ducts to enable X-ray imaging.

[39] AS 4187 (1998) *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*

17.1.2 Quality control, traceability and surveillance

There is substantial evidence that endoscope and accessory reprocessing procedures are often not fully followed (Raymond et al 1990, Reynolds et al 1992, Collignon and Graham 1991, Bronowicki et al 1997). All centres that reprocess endoscopes and accessories should have clear and detailed quality management systems to ensure there is full compliance with all aspects of the cleaning and disinfection protocol. Clear, detailed and specific quality control processes for endoscope and accessory reprocessing are provided in *Infection Control in Endoscopy* (Cowen et al 1999). The reprocessing centre data may be critical in a retrospective investigation about the possible transmission of infectious agents by endoscopy and in the interpretation of cultures from endoscopes and automatic processors. In general, the purposes of the quality control system are:

- to ensure that HCWs responsible for reprocessing endoscopes and accessories have a clear understanding of the important principles involved and fully understand each of the steps necessary in reprocessing;
- to record measurable parameters, such as disinfectant immersion time and disinfectant concentration; and
- to maintain accurate records of each reprocessing encounter that allows appropriate retrospective linkage analysis.

Periodical bacteriological surveillance should be carried out according to the following guidelines (see AS4187 and Cowen et al 1999 for further details):

- *recommended* for gastroscopes and colonoscopes following reprocessing, as part of a quality assurance program;
- *essential* for duodenoscopes and bronchoscopes; and
- *essential* for inner surfaces of automated endoscope reprocessors (washer–disinfectors).

Additional precautions are required for scopes that have been used on patients in the risk groups for CJD (**Section 31.9**). For further information about instruments that cannot be adequately reprocessed in respect of CJD infectious agents see **Section 31.14.6.** If a scope has been reused after use on a patient who is subsequently diagnosed with CJD a lookback investigation may be necessary (see **Section 31.16**).

17.2 Endoscopes (gastrointestinal tract)

17.2.1 Risk factors for endoscope infection

Clinical infections associated with the use of endoscopes may occur because infectious agents are transmitted from one patient and introduced into the patient during examination via the endoscope, or its accessory equipment. Contamination of scopes can also occur from the general hospital environment, from the water supply or from disinfecting machines (Axon 1991). Introduction of infectious agents into sterile (critical) sites in the ducts in the organs under investigation during ERCP, pose a higher risk of infection than endoscopic procedures that involve semicritical or noncritical sites.

The important risk factors are:

- the number and type of infectious agents present on or in the scope, its water-feed system and accessories;
- the particular type of procedure to be undertaken and whether tissue penetration or disruption occurs, for example, with procedures such as dilatation and polypectomy; and
- patient factors, including immune status, endovascular integrity, indwelling foreign material such as prostheses, and the presence of infective foci.

Flexible fibreoptic endoscopes are made from materials that cannot be steam sterilised or withstand many chemicals (see Section 17.1.1). However, despite the difficulties associated with endoscopy, there have not been many reported clinical infections due to endoscopic procedures. ERCP is the only endoscopic procedure that has been associated with a consistently significant rate of procedure-induced infection (Cowen et al 1999).

Infectious agents that can contaminate endoscopes

The following microorganisms can contaminate endoscopes.

- Bacteria that are resident in the gastrointestinal tract, such as salmonella, shigella, campylobacter and related species (O'Connor et al 1982, Dwyer et al 1987), *Serratia marcescens* (Webb and Vall-Spinosa 1975, Vandenbroucke-Grauls et al 1993), *Helicobacter pylori* (Gledhill et al 1985, Langenberg et al 1990) and *Clostridium difficile* (Patterson et al 1984, Hughes et al 1986).
- Other bacteria (usually derived from the environment), such as pseudomonas or similar bacteria, including *Proteus* spp). These bacteria, which are responsible for most reported endoscopy infections (Greene 1974, Bianco et al 1990), are resident hospital pathogens that colonise almost any damp surface, including channels

within the endoscope itself, although in practice this has only been a problem for ERCP and endoscopy in severely immunocompromised patients where tissue disruption has occurred;

- Viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). When HIV is protected within a dried protein coagulum some chemical disinfectants such as glutaraldehyde may fail to inactivate the virus (Hanson et al 1989a). This emphasises the necessity of ensuring that all traces of blood and proteinaceous material are removed by scrupulous manual cleaning without delay after the procedure is completed (Hanson et al 1989b, 1990). Despite the high infectivity of HBV, there are few well-documented cases of transmission by endoscopy in the literature (Ferrari et al 1991). With HCV, however, there are now many documented cases (Crenn et al 1988, Kim et al 1996, Bronowicki et al 1997).

- Other infectious agents, such as fungi, protozoa and other bacteria and viruses, could potentially be transmitted by endoscopy. In practice, however, infectious agents such as cryptosporidia usually only pose a significant threat to immunocompromised patients.

- The infectious agent causing CJD presents a theoretical risk for all types of endoscopy (see **Section 17.2.4**).

Water-feed systems and rinse water

Hospital tap water may be contaminated with a variety of infectious agents including pseudomonads and mycobacteria. This can pose a risk to patients if sterile cavities are entered, if there is extensive disruption of tissue or if the patient is immunocompromised. The following rinsing procedures are therefore recommended:

- after mechanical cleaning and disinfection, gastrointestinal endoscopes should be rinsed with filtered potable water of low mineral content; and

- duodenoscopes and endoscopes used in ERCP should be rinsed in water that is filtered through 0.2-µm filters, or with sterile bottled water. A coarse prefilter may be used to prolong the life of the 0.2-µm filter. (Note: bottled supermarket water is not sterile and is not suitable for this purpose.)

Patients with increased susceptibility to infection

A variety of clinical circumstances may increase the danger of infection associated with endoscopy, including:

- compromised immune status such as HIV infection, neoplastic disease, cancer therapy, transplantation and advanced systemic disease, for example, liver or renal failure;

- procedurally induced tissue damage such as oesophageal dilation, polypectomy, and sphincterotomy at ERCP;
- intrinsic sources of infection such as diverticulitis or abscess, cholangitis or infected pancreatic pseudocyst; and
- increased risk of bacterial lodgment such as cardiac valve prosthesis, rheumatic heart disease, or indwelling devices such as Hickman catheters. Septic arthritis of prosthetic joints has been reported only rarely after endoscopic procedures.

17.2.2 Level of reprocessing required

The bile and pancreatic ducts are sterile (critical) sites and anything that enters these sites, such as accessories or catheters used within ERCP duodenoscopes, must be sterile.

As flexible fibreoptic duodenoscopes do not withstand steam sterilisation, low-temperature chemical sterilisation should be used, if available, to sterilise the duodenoscopes. If this is not available, high-level disinfection is the *minimum* level of reprocessing required for the duodenoscope itself. Accessories and catheters must be sterile.

Other endoscopes are used in mucosal (semicritical) sites, and the *minimum* level of reprocessing for endoscopes that cannot withstand sterilisation is therefore high-level disinfection.

Endoscope accessories designed for reuse, and other items that penetrate tissue (eg biopsy forceps), or are associated with tissue disruption or introduction of devices into duct systems, must be sterile at the time of use. Where this process cannot be achieved, sterile single-use only accessories must be used. These single-use items cannot be reused.

IMPORTANT NOTE

Endoscopes and sheaths

Sheaths that cover endoscopes have recently become available to help reduce endoscope contamination. Use of these sheaths does not remove the necessity for correct cleaning and reprocessing of endoscopes between patient uses. Due to the potential for sheaths to be torn, broken or have holes that are invisible to the naked eye, all endoscopes must be reprocessed according to the recommendations below regardless of whether sheaths are used or not.

17.2.3 Reprocessing methods

The reprocessing of flexible endoscopes is a difficult and complex task. Therefore:

- endoscopy should only be undertaken in centres that have adequate facilities for cleaning and disinfection; and
- only fully-trained HCWs should perform the critical task of processing endoscopic equipment and accessories.

Full explanation and details of the cleaning and disinfecting processes can be found in the GESA/GENCA guidelines (Cowen et al 1999), AS 4187 and at http://www.health.qld.gov.au/EndoscopeReprocessing

Manual processing

Standard precautions should be used for the manual cleaning of endoscopes and accessories. Appropriate personal protective equipment (gloves, impervious gowns, plastic aprons, splash resistant masks, safety eyewear and face protection) should be worn.

For duodenoscopes, inadequate cleaning and disinfection of the forceps-raising channel, and contamination of the water feed system, has been linked to infection in ERCP procedures (Cowen et al 1999). The water bottle and connecting tube must be sterilised and changed between each patient use. Sterile bottled or 0.2-µm filtered water must be used. (Note: bottled supermarket water is not sterile and is not suitable for this purpose.)

Cleaning

- The most important step in the process of endoscope reprocessing is scrupulous manual cleaning before disinfection.
- Endoscopes and accessories must be immersed in an anionic detergent solution, at ambient temperature, immediately after removal from the patient, and cleaned and reprocessed as soon as possible.
-
- Equipment must be fully disassembled before reprocessing. All endoscopes are supplied with appropriate cleaning adaptors and accessories. Manufacturers' instructions must be followed.
- Cleaning should be carried out according to the detailed guidelines in *Infection Control in Endoscopy* (Cowen et al 1999). The fine channels within endoscopes

are difficult to clean, and a variety of internal disruptions, including surface abrasions, splitting and cracking of channels and partial joint springing of accessories, may impair the cleaning process.

Disinfection and sterilisation

- For duodenoscopes used for ERCP (which are in contact with critical sites) a low-temperature sterilisation process, such as hydrogen peroxide plasma (HPP) or peracetic acid (PAA) in an automated microprocessor-controlled closed system, is preferred, if this equipment is available and the scopes can tolerate this treatment. The key principle is that instruments that enter sterile tissues are sterile.

- High-level chemical disinfection is the *minimum* reprocessing standard for all endoscopes because the instruments are in contact with the mucosal surface (semicritical sites). This may be achieved, for example, by complete immersion in a solution of a chemical disinfectant, registered by the Therapeutic Goods Administration (TGA) as a high-level instrument-grade disinfectant solution. Further details are given in **Section 16** of these guidelines.

- Following low-temperature sterilisation or high-level disinfection, endoscopes must be rinsed in an acceptable grade of water (see **Section 17.2.1**), purged with alcohol and thoroughly air-dried before storage on hangers designed specifically for that purpose. A minimum of 150 mL of water should be flushed through each channel of the endoscope to remove all traces of disinfectant residue. A greater volume may be required according to the length of the instrument. Because they are used in sterile (critical) sites, each channel of a duodenoscope must be rinsed with sterile bottled or 0.2-µm filtered water (not bottled supermarket water) to avoid contamination with environmental organisms such as pseudomonads and mycobacteria.

- Sterile water must be used in endoscope water feed systems.

- All endoscopes should be leak tested after immersion and before cleaning and disinfection or sterilisation, to identify problems that may result in damage to the scope during reprocessing.

- After effective cleaning and disinfection, the instrument must be dried before storage to prevent environmental organisms (eg pseudomonads) from multiplying in the channels before the endoscope is reused. However, as any residual dampness may allow proliferation of organisms, scopes should be reprocessed again after storage (see heading **'Reprocessing again before use'** that follows).

With rapidly evolving technologies and the dynamic nature of product development in the area of infection control, instruments that can be easily dismantled and steam sterilised may become widely available in the future, bringing major advantages.

Automated reprocessing

Washer–disinfectors

Automated endoscope reprocessors (washer–disinfectors) may be used effectively in the reprocessing of endoscopes. It is critical that HCWs using automated washer–disinfectors understand the principles of machine operation and the limitations of each machine (eg some do not have flow alarms). Currently, brushing the internal channels of the endoscope is required before placing in the washer–disinfector. However, some innovative automated washer–disinfectors, now available in Australia, include cleaning mechanisms in their cycles (see **Section 16.3.7**).

Further details of automated endescope reprocessorscan be found in *Infection Control in Endoscopy* (Cowen et al 1999).

Automated low-temperature chemical sterilisation processing

Automated PAA- and HPP-based chemical processing systems offer highly effective systems of endoscope disinfection and sterilisation, provided the chemicals are compatible with the endoscopes (see **Section 16.5.6**). Use of these systems does not preclude the need to preclean instruments and equipment. Where automated systems are used, the system must be regularly monitored for efficacy and performance in accordance with the manufacturer's technical instructions. Occupational health and safety issues involved for the handling of the chemicals should be considered (see **Section 7.4**).

Reprocessing again before use

Because of the risk of residual dampness allowing proliferation of remaining organisms, all scopes that have not been terminally sterilised (ie packaged) must be reprocessed (preferably sterilisation or a minimum of high-level disinfection) after patient use and then a second time on the day of use. Duodenoscopes used for ERCP must be reprocessed as close as possible to the procedure (Cowen et al 1999) because this is a high risk procedure and the possible recontamination time should be kept to a minimum.

17.2.4 Prevention of CJD transmission

Endoscopes cannot be adequately processed for CJD infectious agents. If a scope is used in a patient in a risk group for CJD (**Section 31.9**), it should be handled as described in Section 31.14.6. In CJD risk patients, alternative options to endoscopic diagnosis should be sought without prejudice to patient care.

If a scope has been reused after use on a patient who is subsequently diagnosed with CJD, a lookback investigation may be necessary to identify at-risk patients (see **Section 31.16**).

17.3 Bronchoscopes

Flexible or rigid bronchoscopes may be used for direct visualisation of the tracheobronchial tree. Flexible fibreoptic bronchoscopes are commonly used in diagnostic procedures with the patient under sedation. Rigid bronchoscopes are usually used in operating room situations, with the patient under general anaesthetic.

17.3.1 Risk factors

When patients with active tuberculosis have a bronchoscopy, there is a risk of transmission of *Mycobacterium tuberculosis* (see **Sections 11.5.5 and 29.8**). When this has occurred, it appears to have been due mainly to inadequate cleaning before disinfection or sterilisation (Wheeler et al 1989, Bryce et al 1993, Fraser et al 1992, Reeves and Brown 1995).

Atypical mycobacteria, which are frequently present in tap water, can contribute to biofilm formation in older models of automated washer–disinfectors without self-disinfection cycles (Middleton 1997). The organisms may be transmitted to bronchoscopes during reprocessing and then to the patient during bronchoscopy. This can lead to misdiagnosis and inappropriate treatment of tuberculosis because of the appearance of acid-fast stained bacilli in cultures or on direct microscopy. In addition, immunocompromised patients are at a higher risk of succumbing to infections caused by atypical mycobacteria and other opportunistic respiratory pathogens.

The infectious agent causing CJD presents a theoretical risk for contamination of bronchoscopes (see **Section 17.3.4**).

17.3.2 Level of processing required

Because the lower airways are usually sterile (critical site), sterilisation is required if available. High-level disinfection is the *minimum* level of reprocessing required.

When an invasive procedure (eg biopsy) is planned, all accessories must also be sterilised before the procedure.

17.3.3 Reprocessing procedures

Rigid bronchoscopes should be sterilised by steam sterilisation.

Flexible bronchoscopes should be reprocessed with a low-temperature sterilisation system, such as PAA or HPP, if it is available and provided the scopes are compatible with the process.

For high-level disinfection, after appropriate cleaning, bronchoscopes should be soaked in a high-level instrument-grade disinfectant for the time stated on the manufacturer's label to eradicate *Mycobacterium tuberculosis*. After disinfection, the instrument and its channels should be immersed and rinsed thoroughly with sterile water, rinsed with 70% alcohol and dried with compressed air.

Disposable covers are recommended for use on bronchoscopes and accessories (eg detachable camera heads), when available.

Bronchoscopes that have not been terminally sterilised (ie packaged) should be reprocessed again on the day of use, as for endoscopes (see **Section 17.2.3**).

17.3.4 Prevention of CJD transmission

Bronchoscopes cannot be adequately processed for CJD infectious agents. If a scope is used in a patient in a risk group for CJD, it should be handled as described in Section 31.14.6.

If a scope has been reused after use on a patient who is subsequently diagnosed with CJD, a lookback investigation may be necessary to identify at-risk patients (see **Section 31.16**).

17.4 Other fibreoptic scopes and associated equipment

17.4.1 Types of instruments

Instruments used in sterile sites

Other fibreoptic scopes that are used in sterile (critical) sites, include laparoscopes, cystoscopes, thorascopes, hysteroscopes, ureterscopes and arthroscopes. Ancillary equipment for these procedures includes cameras, biopsy forceps and light leads.

Instruments used in nonsterile sites

Other fibreoptic scopes used in mucosal (semicritical) sites include sinoscopes, laryngoscopes, oesophagoscopes and urethrascopes. Ancillary equipment is the same as that for sterile sites.

17.4.2 Risk factors

Items that breach the protective integrity of the skin and mucous membranes provide infectious agents with direct access to sterile tissue sites.

The infectious agent for CJD presents a theoretical risk in the use of fibreoptic scopes (see Section 17.4.5).

17.4.3 Level of processing required

For use in sterile (critical) sites, fibreoptic scopes and their associated auxiliary equipment must be sterile at the time of use, as indicated in **Table 16.1**. Where access for cleaning is difficult, or the invasive accessories are heat sensitive, the use of sterile single-use accessories is preferred.

For use in mucosal (semicritical) sites, fibreoptic scopes and their associated auxiliary equipment should be sterile at the time of use or, as a minimum, high-level disinfected, as indicated in **Table 16.1**.

17.4.4 Reprocessing procedures

Equipment must be thoroughly cleaned and dried before sterilisation.

Sterilisation should be by a low-temperature sterilisation system such as PAA or HPP, if it is available, or by high-level disinfection. The reprocessing procedures should be the same as those described for other endoscopes and bronchoscopes (Sections 17.2 and 17.3).

Associated invasive accessories should be packaged for steam sterilisation or used immediately following their removal from a low-temperature sterilisation process.

All fibreoptic scopes that have not been terminally sterilised (ie packaged) should be reprocessed again on the day of use, as for endoscopes (see Section 17.2.3).

17.4.5 Prevention of CJD transmission

Fibreoptic scopes cannot be adequately processed for CJD infectious agents. If a scope is used in a patient in a risk group for CJD, it should be handled as described in Section 31.14.6. If a scope has been reused after use on a patient who is subsequently diagnosed with CJD, a lookback investigation may be necessary to identify at-risk patients (see **Section 31.16**).

17.5 Respiratory and anaesthetic apparatus

17.5.1 Types of equipment and risk factors

Items of equipment that are introduced into the patient's airway can provide direct access for potential pathogens. There is a potential for patient-to-patient transmission of infection (such as tuberculosis).

Aerosol transmission of infectious agents has been documented via respiratory equipment, including spirometry or pulmonary function testing apparatus (Hazeleus

et al 1991) and anaesthetic apparatus (Joseph 1952). Moist gases can transport infectious agents along breathing circuits and nebulisers can harbour infectious agents. Transmission of infection may also occur with use of resuscitation and analgesic respiratory equipment used in hospitals (operating rooms, intensive care units, accident and emergency departments, and delivery suites), medical and dental practices, ambulances and first aid areas.

17.5.2 Level of processing required

Respiratory, anaesthetic, resuscitation and similar apparatus and ventilators used in anaesthesia and in intensive care units are generally classed for use in mucosal (semicritical) sites and therefore should be sterilised wherever possible. If items cannot withstand sterilisation, they must be exposed to at least thermal disinfection or high-level chemical disinfection (see **Table 16.1**).

Whilst there may be an additional cost involved in sterilising semicritical components of the breathing system, using disposable circuitry and incorporating filters, this should be balanced against the reduced risk of transmission of infection.

17.5.3 Reprocessing procedures

Items of equipment that may be contaminated by patient-to-patient transmission of infections, such as tuberculosis, should be single-use. Re-useable equipment should be capable of at least thermal disinfection or high-level chemical disinfection (see Table 16.1).

It is preferable that all patient circuits contain a filter capable of removing particulates and aerosols from the gas pathway. The common position for this filter is in the reciprocating gas flow immediately adjacent to the patient. If this is not done (but filtering is positioned on the expiratory limb between the expiratory hose and the absorber head), a second protective filter must be placed on the inspiratory limb because the gas flow is not totally unidirectional.

If a filter is used, all items between the patient and the filter, including the filter must be discarded after a single patient use. Items isolated from the patient should be drained and dried from condensed moisture on a regular basis. A visual inspection should be undertaken to ensure that no moisture is present that could compromise the filter's integrity.

If no filter is used, the disinfection must include all of the breathing circuit ie the mask or tube and connections, the inspiratory and expiratory hoses, the inspiratory and expiratory connections, the carbon dioxide absorber and one-way valves, the reservoir hose and reservoir bag and any monitoring devices within the breathing circuit exposed

to the respiratory gases. Components, which cannot be disinfected, should be discarded and replaced.

If lubricant is used on tubes for insertion into the patient's airway, it should be obtained from single use sachets that are then discarded. Tracheal tubes, laryngeal masks, pharyngeal airways, suckers and equipment used to introduce these items such as laryngoscope blades and introducers, must be cleaned, sterilised and dried before reuse, or discarded after a single use. Demand and inhalation valves used in resuscitation and analgesic equipment should be dismantled, cleaned, sterilised and dried and then checked for performance after each patient use. It is very important that these items of equipment are dry before use.

Further information may be obtained from the Australian and New Zealand College of Anaesthetists (ANZCA), the Australian Society of Anaesthetists (ASA), the Thoracic Society of Australia and New Zealand (TSANZ) (see **Appendix 7**), and AS 4187.

17.5.4 Respiratory function laboratories

All items must be cleaned and reprocessed according to manufacturers' instructions because heat, chemicals and gases may damage some equipment. After cleaning and disinfection, it is essential that all items are rinsed with sterile water and air-dried before use. Reprocessed equipment should be stored in covered containers.

Barrier filters are single-use items and may be used to protect all equipment that may be contaminated with patient expirates unless the equipment is disinfected or replaced between patients. There is evidence that the use of barrier filters will reduce the risk of transmission of infection (Side et al 1999). It is important to be aware that the use of filters does not preclude the need for cleaning. Mouthpieces, nose clips, tubing and other equipment on the patient side of a filter should be replaced with clean, sterilised or high-level disinfected components between patients.

When choosing barrier filters it is important to verify the resistance and efficacy of filtration at flow rates up to at least 14 L/second. The resistance of the breathing circuit including the filter should be < 2.5 cm water per litre per second at flow rates up to 14 L/second (American Thoracic Society standard). The filter should have a low effective deadspace (50 mL).

In respiratory function laboratories, equipment considered to be semicritical includes reusable mouthpieces, reusable nose clips, one-way breathing valves, pneumotachograph screens, turbine assemblies, mouth shutters and specialised nebulisers used for bronchial challenge tests. These items must be disassembled and thoroughly cleaned before reprocessing using either sterilisation or high-level disinfection. Gloves should be worn when handling equipment contaminated with saliva (standard precaution). Equipment distal to a barrier filter or one-way breathing

valves should be cleaned at least once daily to remove particulate matter and moisture (Crockett and Grimmond 1993).

The outside surface of tubing that is in direct contact with or handled by patients should be cleaned between patients. The environment of the laboratory should be maintained by regular cleaning with detergent and be kept dust free.

Routine handwashing should be performed before and after each patient contact.

Items labelled as 'single patient use', including peak flow meters and nebulisers used for bronchodilators and oesophageal balloons, must not be reprocessed.

The effectiveness of infection control procedures can be independently verified by culturing swabs taken from respiratory equipment (internal surfaces of spirometers and the proximal side of flow spirometers). While some laboratories do this regularly it is sufficient to carry out random spot checks.

17.5.5 Items and equipment for use in noncritical sites

Noncritical sites are defined as intact skin but not intact mucosa. Items or equipment for use in noncritical sites (eg anaesthetic armboards and stethoscopes), or which do not come into direct contact with patients (eg the surface of the anaesthetic machine or resuscitator), should be cleaned after each use (see **Table 16.1**).

Anaesthetic and respiratory washer–disinfectors that comply with AS 2945[40] can be used to process anaesthetic and respiratory equipment that is not required to be sterile at the time of use (see AS 4187 and AS/NZS 4815 for details).

17.6 Asthma spacers used with metered-dose inhalers (MDI)

17.6.1 Risk factors

An asthma spacer should be used with a metered-dose inhaler (MDI) in the following instances:

- by all adults who have poor coordination when using an MDI
- by children of all ages. Children under four years can use a MDI and a small-volume valved-spacer with a face mask
- during acute attacks
- by patients using inhaled steroids by MDI, particularly at higher doses (National Asthma Council 2002)

[40] AS 2945 (1998) *Batch-type washer/disinfectors for health care facilities*

Caution: Although there have been no instances reported, deep inhalation of medication from spacer devices used with MDIs could result in cross infection. Respiratory devices are considered semicritical and should be reprocessed appropriately (see Section 16.2.2). To minimise the risk of cross infection from water-borne organisms such as *Legionella pneumophilia* (CDC 1997a) following the cleaning process, care should be taken to drain the spacer and ensure no residual water is left in the spacer chamber.

17.6.2 Reprocessing standards for health care settings

Hands should be thoroughly washed and dried before handling these items.

Spacers should be for the exclusive use of a single individual. Organisations should maintain a store of spacers to ensure that new spacers are always available when required. If multi-use is necessary (in an emergency) the spacer should be reprocessed using thermal disinfection (see **Section 16.4.2)**.

Spacers should be washed in a hot water and a detergent solution prior to steam sterilisation and pasteurisation. Dip spacer in a diluted detergent solution and leave to drain (without rinsing) until dry ensuring that no residual water is left in the spacer. If steam sterilisation is unavailable then spacers should be pasteurised. If pasteurisation is not possible see **Section 17.6.3**.

NB. Do not use a cloth to dry the spacer as this could produce an electrostatic charge that may cause drug particles to adhere to the walls of the spacer resulting in less deposition in the lungs.

17.6.3 Reprocessing procedures in a community setting

Home use

A spacer is a personal item and should be for the exclusive use of an individual and not shared with anyone else. Hands should be washed and dried before using these items. Every 1-2 weeks, spacers be should washed in a hot water and detergent solution and left to drain without rinsing, ensuring that no residual water is left in the spacer.

NB. Do not use a cloth to dry the spacer as this could produce an electrostatic charge that may cause drug particles to adhere to the walls of the spacer instead of delivering the correct dose to the lungs.

First-Aid kits in community settings including schools

First-Aid kits should contain an MDI and matching spacer device. A spacer should be used to administer asthma medication to a child. Normally a person should carry their own MDI and spacer. In and emergency, an MDI and spacer from a First Aid Kit may be used and must be reprocessed before re-use (See Section 17.6.3 above).

Spacers should be washed in a hot water and detergent solution and left to drain (without rinsing) until dry. When the spacer is dry the mouthpiece should be wiped thoroughly with a 70% alcohol solution (to prevent electrostatic charge production). Do not use a cloth to dry the spacer as this could produce an electrostatic charge that may cause drug particles to adhere to the walls of the spacer instead of delivering the correct dose to the lungs.

Each child for whom asthma medication has been prescribed, should have their own spacer and a supply of medication at their school, clearly labelled with name of the child and next-of-kin contact details. Parents or caregivers have a responsibility to convey clear instruction from the medical practitioner to the school about the child's medication requirements.

17.7 Resuscitation manikin facepieces and accessories

When resuscitation manikins are used for training purposes those parts of the manikin that come into contact with the oral secretions should be changed or reprocessed between use to avoid transmitting infections between trainees (see Section 17.7.2).

17.7.1 Risk factors

The mucous membranes of the mouth and saliva may be the source of respiratory pathogens such as influenza virus, HBV and streptococci. These pathogens may colonise manikin facepieces after use by a first aid trainee and be transferred to other users if cleaning and disinfection of the facepiece between users is inadequate.

17.7.2 Reprocessing procedures

Manikin facepieces and accessories are used in first aid training. They can be thermally disinfected but this may not be an option in field training situations (eg sportsgrounds, beaches). Such facepieces should therefore be thoroughly cleaned with warm water and detergent, rinsed and dried before disinfection with an appropriate disinfectant. The pieces must be dry before immersion in disinfectant to ensure that the disinfectant solution is not diluted, as this would result in inadequate disinfection over the contact period. It is essential to rinse the item free of residual disinfectant with water before use.

The Australian Resuscitation Council (ARC) and first aid training providers should be contacted for further advice (see **Appendix 7**).

17.8 Diagnostic ultrasound transducers

17.8.1 Risk factors

Diagnostic ultrasound transducers are used in many sterile (critical) situations, including renal, hepatic and hepatobiliary studies, for the review of vascular surgical repairs, and for some endobronchial and gynaecological operations.

They are also used in mucous membrane (semicritical) sites (transvaginal, transrectal and transoesophageal ultrasound).

Potential sources of infection associated with vaginal ultrasound include those infectious agents transmitted by blood and genital secretions such as HIV, HBV, HCV, cytomegalovirus, *Neisseria gonorrhoea*, *Chlamydia trachomatis*, *Trichomonas vaginalis* and human papilloma virus. Other infectious agents are associated with rectal or oesophageal ultrasound.

Abdominal ultrasound examination is generally considered to be a low-risk procedure where this involves contact with intact skin (noncritical site). However, there is a potential transmission of bacteria (such as *Staphylococcus aureus*) to occur, particularly in a patient with an abdominal wound.

The infectious agent for CJD presents a theoretical risk for the use of ultrasound transducers in the brain or spinal cord.

17.8.2 Level of reprocessing required

The external surface or cover of diagnostic ultrasound transducers that are to be used in sterile (critical) sites must be sterile. Wherever possible, transducers that are capable of being sterilised should be used. Low-temperature chemical sterilising technologies suitable for processing heat sensitive items include the PAA and HPP sterilisation systems (see Section 16.5.6). However, some ultrasound transducers may be made of materials that also do not withstand exposure to these chemical agents. (see Section 16.2.2).

Instruments that contact nonsterile mucous membranes (semicritical sites) usually require either sterilisation (if possible) or high-level disinfection with a compatible instrument-grade disinfectant, as a minimum, in accordance with manufacturers' instructions. (Unless sodium hypochlorite is labelled as a high-level instrument grade disinfectant, it may not be suitable for reprocessing these instruments). Further information on high-level disinfectants is given in Section 7.2 and 16.4.3.

Instruments that are only in contact with intact skin (noncritical sites) should be cleaned in accordance with the manufacturer's instructions where available.

17.8.3 Prevention of CJD transmission

Ultrasound transducers cannot be adequately processed for CJD infectious agents. Ultrasound transducers applied to the brain or spinal cord of patient in a risk group for CJD should be destroyed or quarantined as described in **Section 31.14.3**. If the transducer has been applied to low infectivity tissue of a patient in a risk group for CJD, it should be handled as described in Section 31.14.6

If an ultrasound transducer has been reused after use on a patient who is subsequently diagnosed with CJD a lookback investigation may be necessary (see **Section 31.16**).

17.8.4 Precautions during procedures

Standard precautions (see Section 2.2) should always apply where there is a potential for contact with blood or body substances, nonintact skin or mucous membranes, and should therefore be used with transvaginal and transrectal ultrasound procedures.

For transoesophageal ultrasound, disposable sheaths may be available, but care should be taken to ensure that they do not detach during the procedure. Less effective alternative covers include condoms and gloves.

Probes for transvaginal and transrectal ultrasound procedures must be sheathed in a disposable impermeable cover that is changed for each patient. Care should be taken to ensure that the sheath is not overstretched, which may result in perforation, and that it does not detach during the procedure. It is essential that, for each new procedure, the cover should be either sterile or appropriate for use in a semicritical site. The probe itself should be reprocessed according to the manufacturer's instructions where available.

The disposable cover should be thick enough to resist tearing or perforation during use. The preferred option is water-repellent polyethylene surgical drape sheeting (at least 38 µm thick), which can be cut to adequately cover the transducer. Its thickness is a more reliable barrier to water than commercially available plastic wraps. Less effective alternative covers include condoms and gloves (Storment JM et al 1997). Alternative material to latex should be used for patients who are known to be latex-sensitive (Douglas et al 1997).

At the end of each procedure the cover should be removed and discarded, taking care not to contaminate the surface of the instrument. Surgical drape is also preferred for this reason. After removing all the gel from the transducer, the instrument should then be cleaned (American Institute of Ultrasound in Medicine 1995) with warm water and a neutral detergent in accordance with manufacturer's instructions. A small brush may be used for crevices or angles on the instrument, depending on its design.

Although use of a disposable cover reduces the level of risk of transmission of infection or contamination, covers can be perforated or contain small unrecognised defects. For these reasons, after thorough cleaning in warm water and detergent, the transducer should be soaked in a high-level instrument-grade disinfectant recommended by the transducer manufacturer for the time required for high-level disinfection. After disinfection, the instrument should be thoroughly rinsed and dried before reuse with a new cover.

For abdominal ultrasound, in cases where there is an open wound, a disposable cover should also be used. The cover should be discarded and the probe reprocessed.

Gel used in ultrasound procedures can also be a potential source of infection and care should be taken to ensure there is no risk of contamination of the gel used during these procedures (Weist K et al 2000). For surgical use, gel should be sterile. Refilling or reuse of gel containers is not permitted because contamination may have occurred.

Further information on ultrasound devices may be found in *Guidelines for Disinfection of Transvaginal Transducers* (ASUM 1999), which may be obtained from the Australasian Society for Ultrasound in Medicine (see **Appendix 7**). However, these guidelines should be read in conjunction with AS 4187 (and also see Section 17.8.2 concerning the use of high-level instrument grade disinfectants for instruments to be used in semicritical sites).

17.9 Thermometers

Glass thermometers are reusable and should be used on one patient only, for the duration of the patient's stay in the health care establishment. The thermometers should be cleaned and disinfected before use on other patients. Thermometers should be cleaned with warm water and detergent, then disinfected with alcohol (an alcohol wipe is suitable and soaking is not necessary) and stored dry. For home visits, thermometers may be transported in a carry case — this should either be disposable or be cleaned and disinfected together with the thermometer before reuse.

The use of disposable covers for thermometers used in body cavities, including the ear, mouth, vagina or rectum, should be encouraged. The thermometer should be wiped over after each use. However, cleaning and disinfection, as above, is still required on a daily basis as covers may be defective or become damaged during use. Thermometers used in sterile body cavities must be sterile.

DISCUSSION POINT

Reusable thermometers

Glass thermometers containing mercury are not recommended for use because of the hazards associated with breakage. Thermometers that do not contain mercury are preferred.

If tympanic thermometers are used, then a new probe cover should be used for each temperature reading, as small specks of dust or debris on the cover may make readings inaccurate. Manufacturers' instructions for calibration and storing of tympanic thermometers must be followed.

17.10 Cryotherapy

Use of liquid nitrogen during cryotherapy procedures should not allow contamination of the canister, as viruses or bacteria may survive immersion in liquid nitrogen. Where liquid nitrogen is used for routine removal of warts, decant sufficient liquid nitrogen into a styrofoam cup and use a fresh cotton-tipped applicator for each application. Discard any residual or remaining contents of the cup. Similar precautions should apply with carbon dioxide and other cryotherapy systems used in the treatment of skin conditions (see **Section** 34.2.1).

17.11 Ophthalmic and optometry equipment

The cornea and conjunctiva are regarded as semicritical sites. Contact lenses should not be shared. Diagnostic contact lenses should be reprocessed in accordance with the manufacturer's recommendations. Internal components of the eye are sterile. Instruments that enter the eye or contact components that enter the eye (e.g. PHACO-emulsification handpieces) should be reprocessed as sterile instruments.

Because of the known infectivity for CJD in the eye (see Table 31.7.3), special care should be taken when patients in either higher or lower risk categories for CJD (see Section 31.7.3) are undergoing ophthalmic or optometric procedures. Instruments that come into contact with the posterior segment of the eye (retina, optic nerve) in higher or lower risk CJD patients should either be destroyed or reprocessed and quarantined in accordance with the guidelines in Table 31.12.5.

17.12 Implantable items

Implantable items must be sterile at the time of use, and should not be 'flash' sterilised (AS 4187). Explanted devices should not be re-implanted.

Some manufacturers have TGA approval to allow reprocessing of implantable items (see Section 16.2.4) that have been opened but have not had contact with tissue (eg

opened but not used). Manufacturers' instructions for reprocessing must be followed explicitly in these instances.

17.13 Instruments labelled "single use devices"

Instruments labelled "single-use devices" should be discarded after use. This should be in accordance with manufacturer's recommendations and consistent with their TGA approval status.

There are some expensive instruments labelled "single-use device" (e.g. cardiac solid electrodes) for which institutions may wish to consider reprocessing.

The TGA's advice about reprocessing "single use" instruments is as follows –

Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use" should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and that this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices, but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.

This option may only be used for instruments that are capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods without compromising product safety and integrity.

18 Environmental cleaning and spills management

Key points

- Routine cleaning of work areas is important because deposits of dust, soil and microbes on surfaces can transmit infection.
- Health care establishments must have management systems for dealing with blood and body substance spills. Protocols for spills management should be included in procedures manuals and emphasised in ongoing education and training programs.
- The basic principles of spills management are:
  – standard precautions apply where there is a risk of contact with blood or body substances;
  – spills should be cleaned up before the area is disinfected; and
  – aerosolation of spilled material should be avoided.
- Standard cleaning equipment (including solutions, water, buckets, cleaning cloths and mop heads) should be readily available for spills management and stored in a place known to all health care workers.
- All cleaning items should be changed routinely. They should also be changed immediately following the cleaning of blood or body substance spills.
- Contaminated areas such as operating rooms or isolation rooms must be cleaned after each session.

18.1 Routine environmental cleaning

Regular cleaning of work areas is important for the successful application of standard and additional precautions for controlling infection in health care establishments.

Deposits of dust, soil and microbes on environmental surfaces can transmit infection. Routine cleaning and maintenance is therefore necessary to maintain a safe environment in health care establishments. The following basic principles should be followed:

- written cleaning protocols should be prepared, including methods and frequency of cleaning; and

- standard precautions (including wearing of personal protective equipment as applicable) should be implemented when cleaning surfaces and facilities (see Section 2.2).

18.1.1 Surface cleaning

- Floors in hospitals and day care facilities should be cleaned daily, or as necessary, with a vacuum cleaner fitted with a particulate-retaining filter, which should be changed in accordance with the manufacturer's instructions (Ayliffe et al 1999).
- The exhaust air should be directed away from the floor to avoid dust dispersal.
- A ducted vacuum cleaning system can also be used, as long as safe venting of the exhaust air is ensured.
- Damp dusting is acceptable. Brooms disperse dust and bacteria into the air and should not be used in patient/clinical areas. Dust-retaining mops, which are specially treated or manufactured to attract and retain dust particles, do not increase airborne counts as much as ordinary brooms and remove more dust from surfaces (Ayliffe et al 1999). However, brooms and dust-retaining mops should not be used in clinical areas where there is a high risk of infection associated with dust (eg burns units).

Procedure for routine surface cleaning

- Work surfaces should be cleaned and dried before and after each session, or when visibly soiled. Spills should be cleaned up as soon as practical (see Section 18.2).
- A neutral detergent and warm water solution should be used for all routine and general cleaning.
- When a disinfectant is required for surface cleaning, the manufacturer's recommendations for use and OH&S instructions should be followed.
- Buckets should be emptied after use, washed with detergent and warm water and stored dry.
- Mops should be laundered or cleaned in detergent and warm water, then stored dry.

DISCUSSION POINT

The ideal detergent

Detergents used for environmental cleaning should physically remove dirt/soils, suspend it in water and rinse free with little or no residue. Detergents should be low irritant to minimise skin problems for HCWs in contact with them.

Neutral pH detergents are best for environmental cleaning because they are less likely than acid or alkali detergents to damage metals such as stainless steel (Gardner and Peel 1998) or to cause skin irritation.

Wet areas

Toilets, sinks, washbasins, baths, shower cubicles, all fittings attached to ablution facilities and surrounding floor and wall areas should be cleaned at least daily and more frequently as required. Additional cleaning may be required for particular rooms, eg rooms with patients requiring additional precautions.

Cleaning methods should avoid generation of aerosols.

Walls and fittings

Walls, blinds and curtains should be cleaned regularly and when they are visibly soiled. Curtains should be changed regularly and as necessary. Carpets should be vacuumed daily.

Maintenance of cleaning equipment

Cleaning items (including solutions, water, buckets, cleaning cloths and mop heads) should be changed routinely. They should also be changed immediately following the cleaning of blood or body substance spills, or after each session for contaminated areas such as operating rooms or isolation rooms. These items should be washed/cleaned in detergent and warm water, rinsed and stored dry between use. Mops with detachable heads should be laundered between use.

Spills of laboratory cultures of human pathogens

Spills of laboratory cultures should be absorbed on to paper towels and disposed of as clinical waste. The contaminated surfaces should be treated with 2.0-2.5% sodium hypochlorite, left for 1 hour and cleaned again with paper towels that are disposed of as clinical waste.

Cleaning for CJD infectious agents

Table 31.14.1 details recommended reprocessing methods for CJD infectious agents.

Spills of CNS tissue or CSF should be absorbed onto paper towels and disposed of by incineration. The surface should then be soaked with 1 molar sodium hydroxide or 2.0–2.5% sodium hypochlorite, left for 1 hour and cleaned again with paper towels that are disposed of by incineration.

Spills of blood or other body fluids and tissues should be cleaned using standard spills management procedures.

Gloves used as PPE when cleaning contaminated surfaces should be incinerated after use.

DISCUSSION POINT

To disinfect or not to disinfect?

Disinfectants are often used to decrease the risk of exposure to bloodborne viruses (BBV) after spills of blood or body substances onto environmental surfaces. However, viruses are more fragile than bacteria and require a living cell to remain viable. Therefore, removing physical debris, including any proteinaceous matter, cleaning with detergent and water and leaving dry is all that is routinely required to remove viruses.

Where there is the possibility of some material remaining on a surface where cleaning is difficult (eg between tiles) and there is a possibility of bare skin contact with that surface, then a disinfectant may be used after the surface has been cleaned with detergent and water (see Section 18.2.1).

18.2 Management of blood and body substance spills

18.2.1 General

Health care establishments should have management systems for dealing with blood and body substance spills and protocols should be included in procedural manuals and emphasised in ongoing education or training programs. The basic principles of blood and body substance spills management are:

- standard precautions apply (see Section 2.2), including use of personal protective equipment as applicable (see Section 13);
- spills should be cleared up before the area is cleaned (adding cleaning liquids to spills increases the size of the spill and should be avoided); and
- generation of aerosols from spilled material should be avoided.

Using these basic principles, the management of spills should be flexible enough to cope with different types of spills, taking into account the following factors:

- the nature of the spill (eg sputum, vomit, faeces, urine, blood or laboratory culture);
- the pathogens most likely to be involved in these different types of spills (eg stool samples may contain *viruses, bacteria* or *protozoan pathogens*. Sputum may contain *Mycobacterium tuberculosis*);
- the size of the spill (eg spot, small or large spill);

- the type of surface (eg carpet or impervious flooring);
- the area involved (ie whether the spill occurs in a contained area such as a microbiology laboratory or in a public area such as hospital ward or outpatient area); and
- whether there is any likelihood of bare skin contact with the soiled surface.

It is generally unnecessary to use sodium hypochlorite for managing spills but it may be used in specific circumstances (see Section 18.1.1). It is recognised, however, that some HCWs may feel more reassured that the risk of infection is reduced if sodium hypochlorite is used routinely. In that case, the practice need not be discouraged, but the HCW should be made aware that there is no evidence of benefit from an infection control perspective.

If a spill of tissue infected with Creutzfeldt–Jakob disease (CJD) occurs (eg brain tissue), the contaminated item or surface should either be destroyed by incineration or cleaned with either sodium hydroxide or sodium hypochlorite according to the guidelines given in **Table 31.14.1**.

In areas such as hospital wards, waiting rooms, or patient treatment areas, blood and body substance spills should be dealt with as soon as possible. In operating rooms, or in circumstances where medical procedures are under way, spills should be attended to as soon as it is safe to do so.

Spots or drops of blood or other small spills can easily be managed by wiping the area immediately with paper towelling and then cleaning with water and detergent. A hospital grade disinfectant can be used on the spill area after pre-cleaning.

Where large spills have occurred in a 'wet' area, such as a bathroom or toilet area, the spill should be carefully washed off into the sewerage system and the area flushed with water and detergent.

Large blood spills that have occurred in 'dry' areas (such as a hospital ward or a patient treatment area in office practice) should be contained and generation of aerosols should be avoided.

Granular formulations that produce high available chlorine concentrations can contain the spilled material and are useful for preventing aerosols. A scraper and pan should be used to remove the absorbed material. The area of the spill should then be cleaned with a mop and bucket of water and detergent. The bucket and mop should be thoroughly cleaned after use and stored dry.

Care should be taken to thoroughly clean and dry areas where there is any possibility of bare skin contact with the surface (eg on an examination couch).

18.2.2 Cleaning equipment (spills kit)

Standard cleaning equipment, including a mop and cleaning bucket plus cleaning agents, should be readily available for spills management and should be stored in an area known to all HCWs. This is particularly important in patient areas such as hospital wards or treatment areas. To facilitate the management of spills in areas where cleaning materials may not be readily available, a disposable 'spills kit' could be used, with the following items:

- a large (10 L) reusable plastic container or bucket with fitted lid, containing the following items;
- appropriate leakproof bags and containers for disposal of waste material;
- a designated, sturdy scraper and pan for spills (similar to a 'pooper scooper');
- about five sachets of a granular formulation containing 10,000 ppm available chlorine or equivalent (each sachet should contain sufficient granules to cover a 10-cm diameter spill);
- disposable rubber gloves suitable for cleaning (vinyl gloves are not recommended for handling blood);
- eye protection (disposable or reusable);
- a plastic apron; and
- a respiratory protection device (for protection against inhalation of powder from the disinfectant granules, or aerosols, which may be generated from high-risk spills during the cleaning process).

With all spills management protocols, it is essential that the affected area is left clean and dry. Disposable items in the spills kit should be replaced after each use of the spills kit.

Sodium hydroxide spills kits should be available for areas at risk for higher-risk CJD spills, such as neurosurgery units, mortuaries and laboratories.

18.2.3 Spills in laboratories

The handling of spills within laboratories depends on the nature of the material and the volume. Small spills that can be cleaned up without generating aerosols can be managed as outlined in Section 18.2.2. Large spills of high-risk material with generation of aerosols will require the use of personal protective equipment including appropriate respiratory protection.

Further details of spills management in laboratories can be found in AS/NZS 2243.3.[41]

[41] AS/NZS 2243.3 (1995) *Safety in laboratories — Microbiology*

19 Linen, laundry and food services

Key points

Linen and laundry

- Health care establishments and commercial linen services should have documented policies and procedures for the collection, transport and storage of all linen. Appropriate personal protective equipment should be worn when handling soiled linen. Linen heavily soiled with body substances or other fluids should be contained within suitable impermeable bags and securely closed.

Food services

- Special conditions apply to food handling procedures in health care establishments because some patients are at increased risk of contracting severe foodborne illnesses.
- Preparation of food requires particular attention to handling of raw materials, personal hygiene, kitchen hygiene and time-temperature control of all food handling operations including cooking, cooling, reheating and distribution.
- Food handling should comply with relevant State/Territory regulations and with national food safety standards.
- Food service departments should use a food safety plan based on the 'hazard analysis critical control points' (HACCP) approach to food preparation rather than a traditional (recipe-based) approach.
- Trolleys and refrigerators should be used only for their designated purpose.

19.1 Hopsital Laundries and Commercial Linen Services

Health care establishments and commercial linen services should have documented policies and procedures for the collection, transport, processing and storage of all linen. AS/NZS 4146[42] provides guidelines for correct laundry practice. Standard precautions should be followed (see Section 2). The basic principles of linen management are as follows:

[42] AS/NZS 4146 (2000) *Laundry practice*

- place linen in appropriate bags at point of generation;
- linen heavily soiled with body substances or other fluids should be contained within suitable impermeable bags and securely closed;
- do not rinse or sort linen in patient care areas — sort linen in appropriate areas; and
- separate clean from soiled linen and transport/store separately.

Care should be taken to ensure that sharps and other objects are not inadvertently discarded into linen bags. Bags should not be overfilled, as this may prevent closure, increase the risk of rupture of the bags in transit and increase the risk of injury to waste handlers.

AS 4480.1[43] provides guidelines for correct care and laundering of sheepskins.

A hot water and detergent solution is adequate for cleaning most laundry items. Water temperature and time for correct thermal disinfection is stated in AS/NZS 4146. Disposable linen and protective clothing should be used for neurosurgery or interventional neuroradiology on patients in a risk group for Creutzfeldt–Jakob disease (CJD), see **Section 31.9** and **Table 31.12.6**.

19.2 Food services

19.2.1 Introduction

Food service establishments are frequently identified as places where mishandling of food has led to outbreaks of foodborne disease (Bryan 1990). Hospitals and other health care establishments represent a special case of food service operation.

Some patients are at increased risk of severe foodborne illness, and particular care must be taken to minimise the risk of infection or intoxication through the food service system. Historically, *Clostridium perfringens*, a spore-forming anaerobe able to multiply in the temperature range of 12–55°C, has posed special problems in food service situations (Andersson et al 1995, Ryan et al 1996, Meer et al 1997). However, any foodborne pathogen poses some risk and with the array of food service systems now available to health care establishments, no organism can be singled out for special attention. *Salmonella* spp (Dryden et al 1994, L'Ecuyer et al 1996), *Listeria monocytogenes* (Elsner et al 1997) and viruses (Cáceres et al 1998) have been implicated in recent overseas outbreaks of health care associated infections. Some

[43] AS 4480.1 (1998) *Textiles for health care facilities and institutions – Medical lambskins – Product specification and testing*

outbreaks have occurred in foods usually considered to be 'low risk' (Lund 1993, Nguyen and Carlin 1994, Hocking et al 1997), indicating that all foods should be considered to be potential sources of infection and included in the food safety program.

Preparation of food requires attention to raw materials, personal hygiene, kitchen hygiene, and especially time–temperature control of all food handling operations including cooking, cooling, reheating and distribution.

Further details about listeria are given in Section 29.3 and other enteric bacteria in Section 29.1.

19.2.2 Australian food standards

Food preparation and handling in health care establishments should comply with relevant State/Territory regulations. Assuring safe food requires identification and control of microbiological, chemical and physical hazards. The Australia New Zealand Food Authority (ANZFA) has been working since 1995 to develop uniform national food safety standards based on the 'hazard analysis critical control points' (HACCP) approach (see Section 3.2). Four standards have been drafted that require businesses to:

- notify the relevant authority of their existence and the nature of the business;
- develop and comply with a food safety program;
- carry out specific practices in relation to food handling, cleaning/disinfecting and personal hygiene;
- provide for food recalls;
- ensure that staff and supervisors have skills and knowledge in food safety; and
- ensure that food premises and equipment meet with specified design and construction parameters.

This approach gives industry greater flexibility to achieve safe food outcomes, whilst incorporating modern food safety practices based on a preventative approach. When finalised, the standards will be adopted into the Australia New Zealand Food Standards Code (ANZFA 2000, 2001) and incorporated into the food standards legislation of each State/Territory. Each State/Territory is currently at a different stage in implementing these standards.

19.2.3 HACCP-based food safety programs

HACCP is an approach to infection control that identifies specific hazards and specifies measures for their control. It is based on seven basic principles, which can be applied to identify hazards and determine and monitor critical control points.

The Victorian Government has anticipated the national standards, and already requires food businesses to develop HACCP-based food safety programs and register these with local councils (Food Safety Victoria 1999). This includes food service operations in health care establishments, although such establishments may not strictly be food businesses as defined in the draft legislation.

It seems likely that other States/Territories will follow the Victorian position, requiring kitchens in health care establishments to comply with the proposed legislation and have their food safety plans registered and subjected to external audit. If this does not occur, there are sound technical and management reasons for kitchens in health care establishments to develop and implement HACCP-based food safety plans relevant to their processes.

There are many publications available that describe the theory and practice of HACCP-based systems, including those with particular reference to food service (Bryan 1992, Campden & Chorleywood Food Research Association 1997, Codex Alimentarius Commission 1997, Institute of Hospital Catering 1997, Mortimore and Wallace 1998, Food Safety Victoria 1999).

It is recommended that food service departments in health care establishments take a systematic approach to HACCP, instead of the traditional, 'recipe-based' approach based only on cooking procedures, as the latter may not address all the steps that a food product passes through, including receipt of goods, meal service and distribution.

An important aspect of a food safety plan is the development of an accurate flow diagram for each production system or process. A theoretical flow diagram for many food service lines is shown in **Figure 19.1**. Following observation during normal use, the operation is divided into the key activities. Minor activities that occur at each step are also noted for consideration. Using the flow diagram as a guide, the HACCP team should conduct a hazard audit for each process line. An example is given in **Table 19.1**.

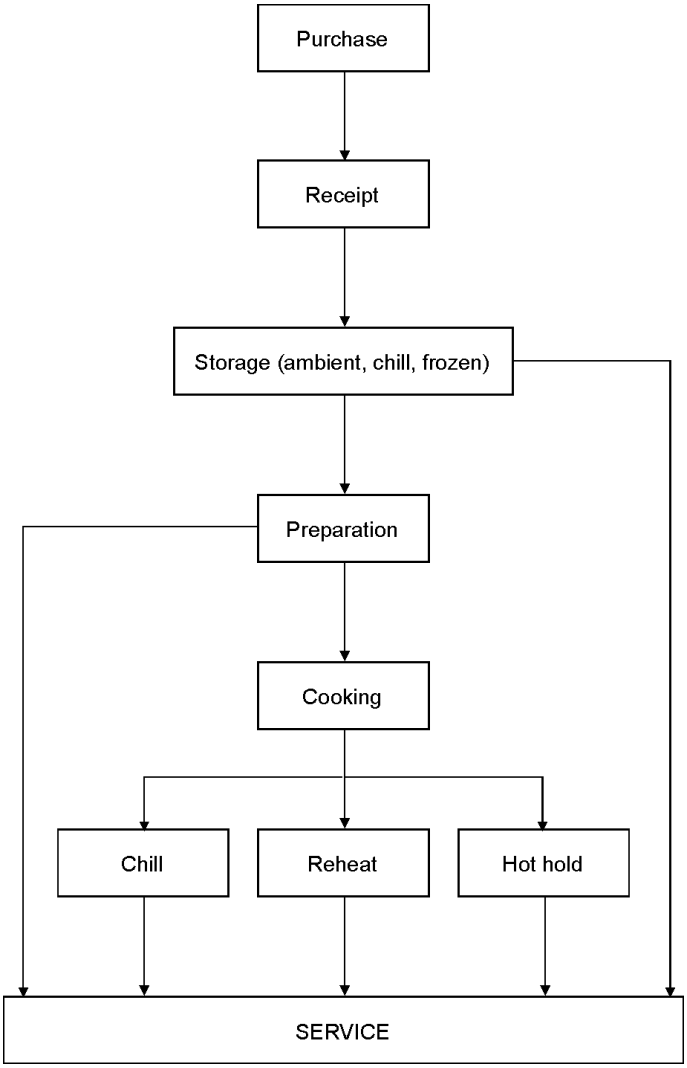


Figure 19.1 Theoretical HACCP flow diagram for many food service lines

Table 19.1 Example hazard audit table for a product

Step	Hazard	Control measure	Critical control points	Critical limit	Monitoring procedure	Corrective action	Records

Source: Campden & Chorleywood Food Research Association (1997)

19.2.4 Support programs

An integral part of a properly constructed HACCP plan is the existence of good manufacturing practice throughout the food service chain. This includes factors that have become known as prerequisite or support programs, including supplier control, cleaning and sanitation, personal hygiene and staff training. The ANZFA Standards

3.2.2 and 3.2.3 cover issues that should be covered by HACCP support programs. Further information is available in the literature (eg Sperbee et al 1998).

Food handlers' personal hygiene is particularly important, as bacteria can be transferred from the handler to the food and food-contact surfaces during preparation. Furthermore, a proportion of people are carriers of pathogenic organisms. For example, 2–6% of people are permanent carriers of *Listeria monocytogenes* (Paul et al 1994, Hocking et al 1997).

19.2.5 Special issues for health care establishments

Cook–chill food production systems

There has been an increasing trend in health care establishments to use 'cook–chill' food service systems to extend the life of prepared food products. The time and temperature control of product chilling and subsequent storage and handling are critical in cook–chill systems because bacteria can grow in the extended time between food production and consumption. The storage temperature for cook–chill systems should be 0–3°C, which is lower than that required for conventional cold storage (Institute of Hospital Catering 1997, NSW Health 1995ab). The storage time (shelf life) also needs to be closely monitored and may vary according to the production method used as well as the storage temperature (Abhayaratna and Zemanovic 1992, NSW Health 1995ab).

Listeria monocytogenes

Although storage below 3°C controls the growth of most pathogenic bacteria, *Listeria monocytogenes* can multiply at temperatures as low as 1°C. Although growth is slow at such low temperatures, prolonged storage of products can result in significant levels of bacteria (Hocking et al 1997).

To control the risk of *Listeria monocytogenes* infection, food safety programs in health care establishments need to use strict time and temperature control, alternative bactericidal processes (eg chlorine sanitation of raw vegetables) and avoidance of certain high-risk foods (Brackett 1987, Hurst and Schuler 1992, Bartlett 1993).

Texture modified meals

Texture modified meals, which are provided to people with chewing and/or swallowing problems, also have a greater risk of bacterial contamination. This includes all food that has been pureed or minced *after* cooking (Tallis et al 1999) Where possible, food should be pureed *before* cooking. Where this is not possible, for example with pureed fruit, particular care must be taken to minimise cross-contamination. Strict time and temperature control must also be maintained (Food Safety Victoria 1999).

Nutritional implications

There have been recommendations that some items should be removed from health care establishments' menus or have restricted shelf lives, due to the potential risk associated with these foods (eg dairy-based desserts and drinks, some salad vegetables, and cold cut meats) (NSW Health 1999).

However, this approach would make it more difficult for health care establishments to provide adequate nutrition to some patient groups, and could increase the incidence of malnutrition (Zador and Truswell 1987, Ferguson et al 1997) and lead to poorer patient outcomes (Reilly et al 1988, Coats et al 1993, Callagher-Allred et al 1996, Chima et al 1997).

With the implementation of an appropriate HACCP-based food safety program that addresses the process issues of the health care establishment concerned, such measures should not be necessary.

19.2.6 Food handlers and hygiene

HCWs who handle food should receive appropriate education about and the importance of personal hygiene and foodborne diseases.

HCWs with active diarrhoea should not handle food until they have been cleared for food handling duties by a medical practitioner. Open skin lesions should be covered to prevent potential food contamination with bacteria (eg staphylococci). HCWs who are carriers of certain enteric pathogens (eg salmonella) should obtain clearance from a medical practitioner before resuming food handling duties. State/Territory health department regulations governing food handlers should be followed.

19.3 Refrigerators

Food should not be stored with contaminated material, clinical specimens or medical products such as drugs, vaccines or blood. Food storage refrigerators for HCWs should be clean and the temperature monitored according to ANZFA 2001.

Vaccines and other medications should be stored in accordance with the manufacturer's instructions and the 'cold chain' maintained as described in Section 1.12, *The Australian Immunisation Handbook 7th Edition* (NHMRC, 2000).

Blood should be stored in accordance with AS 3864 (see **Section 25.3.5**).

19.4 Ice machines

Ice machines in health care establishments have been implicated in outbreaks of infection and as potential reservoirs of infectious agents (Laussucq, et al 1988; Burnett

et al, 1994; Graman et al, 1997) and should comply with AS/NZS 3350.2.24.[44] Ice machines should be maintained and serviced regularly. Implements (eg scoops, tongs) should only be used for their intended purpose. Water supplied to ice machines should comply with State/Territory guidelines for potable water.

19.5 Trolleys

Distributing equipment in hospitals or other large health care establishments is often more efficiently handled by mechanical transport. Trolleys should be appropriate for their intended purpose, be dedicated to one purpose (food, linen, sterile equipment, waste etc) and should be enclosed or draped. Trolleys should comply with OH&S requirements and maintained in a clean hygienic condition by daily cleaning or more frequently when soiled.

[44] AS/NZS 3350.2.24:1998. *Safety of household and similar electrical appliances Part 2.24: Particular requirements — Refrigerating appliances and ice makers*

20 Therapeutic devices

Key points

Indwelling urinary devices

- Indwelling urethral and suprapubic catheters provide a route for infectious microorganisms to enter the urinary tract and bladder.
- Devices should not be left indwelling unless absolutely necessary because the incidence of infection increases with the length of time the catheter is in place (almost 100% by one month).
- Health care establishments should ensure that health care workers are trained in the correct aseptic insertion methods and in the maintenance of devices to reduce the risk of infection.
- Patients should be told about any risks associated with their device and about its maintenance. The importance of noninterference should be stressed.

Intravascular access devices

- Intravascular access devices are potential sites for local infections and provide a route for infectious agents to enter the bloodstream and cause serious bloodstream infections.
- Intravascular devices should only be used when absolutely necessary and must not remain in situ unnecessarily.
- Health care establishments should ensure that HCWs are trained in strategies to minimise the risk of infection, including rigorous use of aseptic technique for insertion and maintenance of the device.

20.1 Indwelling urinary devices — urethral and suprapubic catheters

20.1.1 Description and role

A urinary catheter is a tubular flexible or nonflexible instrument passed into the bladder either through the urethra or through the abdominal wall above the symphysis pubis to:

- empty the contents of the bladder;
- obtain a sterile urine specimen; or
- determine the amount of residual urine in the bladder after voiding.

A flexible urinary catheter inserted into the bladder either via the urethra or abdominal wall may be left 'indwelling' as a passage for drainage.

20.1.2 Infection risks

Indwelling urethral and suprapubic catheters are a potential portal of entry for infectious microorganisms. These can enter the bladder from colonisation at the entry site or by microbes contaminating ports from external sources (eg hands of HCWs or the skin of the patient).

About 10% of hospitalised patients have an indwelling urinary catheter. The incidence of infection is directly related to the length of time that the catheter is in place. For the first two weeks of catheterisation, there is a linear relationship between acquisition of new infections and the duration of catheterisation; 50% of patients become infected by day 15 of catheterisation, and almost 100% by one month (APIC 1999).

A break in aseptic technique during the insertion of the catheter or when entering the drainage/collection system may allow microorganisms to enter and cause a urinary tract infection. Serious infections associated with indwelling urinary devices can occur, with 1–2% proceeding to septicaemia (APIC 1999).

Strategies to avoid infection are:

- device should not be left indwelling unless absolutely necessary;
- the same aseptic precautions should be carried out for urethral or suprapubic catheterisation as for a minor surgical procedure;
- HCWs who perform catheterisation should be trained and competent in the technique (Pratt et al 2001);
- to avoid trauma, select the smallest bore catheter that will not be associated with leakage;

- the urethral insertion site, should be cleaned using either soap or water or a suitable antiseptic solution, then dried;
- sterile water-soluble lubricant must be applied to the catheter before it is inserted in the urethra to reduce friction and trauma to the urethral opening;
- a closed sterile drainage/collection system should be attached to the catheter and maintained at all times;
- if there is no balloon on the catheter (to hold it in place), the device should be stabilised against movement; and
- if the site is to be dressed (eg suprapubic) the dressings surrounding the device must be sterile.

Faecal bacteria can be transported to the urinary meatus. Wiping following bowel movements should be carried out from front to back.

Vaginitis should be treated promptly and effectively to reduce the risk of spreading infection from the vagina to the opening of the urethra.

20.1.3 Management issues

Health care workers

Policies and procedures regarding the insertion, maintenance and changing regimes of indwelling urinary devices should be written and reviewed every three years and/or updated as necessary. These policies should be readily accessible.

Regular education as well as orientation programs should be implemented to include instruction on the importance and principles of catheterisation and the care of the patient with an indwelling urinary device.

Patients

The patient should understand the nature and the reason for the insertion of an indwelling urinary device. Emphasis should be placed on noninterference with the device or the collection system other than by people who are competent in the knowledge of the device and aseptic technique.

In many cases there are no symptoms in catheterised patients who have significant bacteriuria. In others, suprapubic pain and urethral burning may develop. The patient should alert HCWs of pain or discomfort, fever, chills or sweats.

Patient care and maintenance of devices

- Increased intake of fluids should be encouraged (unless medically contraindicated) to facilitate the removal of microorganisms and debris.
- Regular perineal/vulval washing should be carried out twice daily as well as after a bowel motion.
- Regular cleaning of the catheter and the insertion site should be carried out twice daily to avoid encrustation.
- Closed drainage/collection systems should not be opened unless necessary.
- The ports should be aseptically swabbed with an antimicrobial solution and allowed to dry immediately before use in order to prevent the entry of microorganisms into the line.
- Avoid interruption of urine flow, as well as routine irrigation of urinary catheters.
- Urine samples should be collected from the closed system with a syringe and needle (after cleaning the port) and not by breaking the connection between the catheter and the drainage/collection system and never from the drainage tap attached to the collection container itself.
- Hands should be washed then gloves put on before collecting urine samples or emptying the collection container. Hands should be washed after gloves are removed.
- The collection container should neither be raised above the level of the urethra nor allowed to trail on the floor.
- When the patient is being moved, if there is a risk of urinary reflux, the tubing should be clamped temporarily then unclamped afterwards.

Further maintenance issues

Additional measures that have been applied to the management of urinary catheters, but for which there are no data confirming efficacy, include:

- replacing the collecting system when sterile closed drainage has inadvertently been violated;
- separating infected and noninfected catheterised patients; and
- regular bacteriological monitoring of catheterised patients.

Also:

- routine changing of urinary catheters at arbitrarily fixed intervals in the absence of leakage, malfunctioning or palpable concretions in the lumen is not recommended;
- continuous irrigation of the bladder as an infection control measure has not been shown to reduce urinary tract infections;
- applying antimicrobial ointment to the urethral meatus has not reliably been shown to reduce the incidence of urinary tract infections; and
- the addition of antiseptic or antimicrobial agents to the collection system container has not yielded conclusive results (APIC 1999).

Devices

Before use, all equipment must be checked for:

- expiry dates;
- integrity of containers/packages; and
- the correct amount of sterile water required to be inserted if the device has a balloon.

After insertion:

- the catheter and drainage system must be inspected at least daily and the results documented; and
- date and time of catheter changes should be documented.

The optimal time limit for replacing catheters depends upon individual circumstances and the type of catheter used. Health care establishments should have written policies on the time limit.

In establishments, or particular areas within establishments where the incidence of catheter-related urinary tract infections is higher than acceptable standards from national nosocomial infection surveillance data, consideration may be given to silver-hydrogel-impregnated indwelling urinary catheters. In a recent study it was found that this antiseptic impregnated catheter was most effective in reducing catheter-associated urinary tract infections (CAUTIs) if infection was caused by enterococci, coagulase negative staphylococci and candida, but had little effect on CAUTIs caused by gram-negative bacilli (Maki et al 1998).

Environment

Urethral catheterisation is usually carried out in a clinical setting and the environment should be managed as for minor surgical procedures. Before the procedure, effective cleaning of environmental surfaces involved should be undertaken. The same effective

cleaning should be done before the insertion of a supra-pubic catheter, although this procedure is often carried out in an operating room.

Device reprocessing

Indwelling urinary catheters have narrow hollow lumens and cannot satisfactorily be cleaned. Also, the physical characteristics of the latex or plastics may not withstand cleaning and resterilising (Collignon et al 1996). These items, together with drainage/collection systems, are manufactured for single use only and must not be reused.

20.1.4 Monitoring and surveillance

Routine bacteriological testing is not cost-effective. Facilities should devise a sampling system concentrating on departments with higher rates of indwelling urinary device related infections and act upon the results (Meers et al 1997:135).

20.2 Intravascular access devices (catheters)

20.2.1 Description and role

Indwelling intravascular access devices provide a route for administering fluids, blood products, nutrients and intravenous medications, for monitoring haemodynamic function, for maintaining emergency vascular access and for obtaining blood specimens. They are an integral part of patient care (Pearson 1996). Intravascular devices are usually inserted into veins (IV) but can, on occasion, be intra-arterial (eg for blood pressure monitoring). Most venous catheters that are inserted are short (less than 5 cm) and are inserted into peripheral veins (ie smaller veins in the arms). An increasing number of central venous catheters (CVCs) are now being inserted, which are usually much longer (more than 15 cm) and remain in place for longer than peripheral vein catheters. Central veins are defined as those larger veins of the body that lie within the 'central' parts of the body (chest and abdomen). Some CVCs may be inserted via a peripheral vein site and their tip is advanced until it is situated within a central vein (peripherally inserted central catheters, PICCs).

Intravascular access devices provide potential routes for infectious agents to cause local infection or to enter the bloodstream. They are now a common source of serious illness or death for some patients. However, the risk of infection associated with these devices can be minimised by adherence to appropriate infection prevention precautions. The use of intravascular devices is also associated with noninfective risks (eg pneumothorax occurring during CVC insertion via the subclavian vein).

To minimise the risks associated with catheter use, intravascular access devices should be used only when absolutely necessary and must not remain in situ unnecessarily.

20.2.2 Infection risks

Serious infections associated with intravascular devices are common. In Australia over 3500 bloodstream infections occur per year (bacteraemia or fungaemia). In the United States and Europe, there are likely to be over 500,000 bloodstream infections occurring per year. The reported associated mortality rate varies between 5% and 25%. Many of these patients have serious underlying diseases, making them more susceptible to infections. The increased mortality in these seriously ill patients that can be directly attributed to intravascular catheter bloodstream infection is about 10% (Crump and Collignon 2000).

The following independent risk factors for intravascular device-related infections have been demonstrated to increase the risk of infection in two or more prospective studies (APIC 1999):

- prolonged hospitalisation before insertion of the intravascular device;
- prolonged duration of insertion of the device;
- heavy microbial colonisation of the insertion site;
- heavy microbial colonisation of the cannula/catheter hub;
- catheter insertion in the internal jugular vein compared with subclavian or femoral vein insertion; and
- antibiotic use during catheterisation.

Changes in medical and nursing practices can influence many of these risk factors. For example, prolonged duration of catheter insertion is common even when the intravascular catheter is no longer essential. CVCs should not be left in place for intravenous feeding (total parenteral nutrition) when absorption may be possible through a nasogastric tube (Collignon 1995). Heavy colonisation of the catheter hub is not uncommon, but is usually secondary to contamination by the hands of HCWs. This can be reduced by improved aseptic technique and by trying to minimise the number of times the catheter hub is flushed or used.

The majority of infectious agents reach the intravascular device tip from skin flora colonising the entry site wound or microbes contaminating the delivery system hubs from external sources (eg HCWs' hands or the skin of the patient).

Contamination of infusion solutions is currently considered a relatively rare occurrence.

20.2.3 Strategies for minimising infection

The risk of cross-infection by HCWs can be reduced by:

- the use of insertion techniques that ensure sterility of the device while it is being inserted;
- thorough handwashing with an appropriate antimicrobial solution before putting on sterile gloves and inserting the intravascular device or when changing/maintaining solution containers, lines or dressings;
- cleaning the insertion site with an effective antiseptic approved by the health care establishment's pharmacy/drugs and therapeutics committee (the cleaned area must be completely dry before the device is inserted); and
- for CVC catheters, the wearing of sterile barrier attire and the use of large sterile drapes during the insertion of central lines or guide-wire exchange.

Strategies that best reduce the risks are:

- adequate aseptic technique during insertion and maintenance of the device;
- the use of new device materials that decrease the adherence of infectious agents; and
- the setting of appropriate limits on the duration of device use (APIC 1999).

Other strategies for avoiding infection are:

- excess hair removal by clipping (not shaving) before insertion; and
- selection of a catheter with a smaller lumen than that of the vessel to be entered to reduce the incidence of trauma, which predisposes to infection.

20.2.4 Management of devices

Health care workers

Policies and procedures regarding the insertion and maintenance of intravascular access devices should be written and reviewed every three years and or/updated as necessary and approved by an authoritative body (infection control committee and or/drugs and therapeutics committee). These policies must be readily accessible.

Maintenance guidelines should include:

- hub and injection port care;

- whether CVC and peripherally inserted central catheter (PICC) line tips are required to be sent for microbial examination and culture upon removal (usually only those catheters where clinical sepsis was suspected would be sent for culture); and

- the optimal time limit after which solution containers with additives should be changed.

Relevant HCWs should be made aware during orientation programs of the importance and principles of safe intravascular access. The health care establishment should provide planned, regular education programs for all HCWs whose duties include any aspect of intravascular access and management.

Patients

The patient should understand the nature and reason for any intravascular therapy. Emphasis should be placed on noninterference with the cannula/catheter, lines, and solution containers other than by appropriate HCWs.

Devices

- Before use, all equipment must be checked for:
  - expiry dates;
  - integrity of the container/package;
  - macroscopic contamination; and
  - clarity of solution (if meant to be clear).

- The insertion sites must be cleaned with antimicrobial solution and allowed to dry (see Section 7.3). Insertion of the devices must be performed using aseptic technique.

- Stabilisation of the devices (with tape) reduces the potential for complications such as phlebitis, subcutaneous infiltration, sepsis and cannula/catheter movement. Sterile tape only should be used to stabilise the devices. Dressings covering the devices must be sterile.

- The date and time of insertion should be documented in the patient's progress notes, care plans and on the occlusive dressing.

- The injection ports must be aseptically swabbed with an antimicrobial solution immediately before use, in order to prevent the entry of infectious agents into the vascular system.

- The site must be inspected, attended and documented at least daily. Regular, standardised site inspection and dressing change minimises intravascular device-related sepsis.

- It is recommended that administration sets be changed aseptically every 24–48 hours or upon suspected contamination, or when the integrity of the product has been compromised. The type of solution or frequency of drug administration may dictate a more frequent set change.
- The frequency of changes of peripheral venous sites should be every 48 hours, and up to 72 hours if therapy is to cease.
- The device, associated giving set and site of insertion should be changed at the first sign of phlebitis (Collignon et al 1987).
- All catheters inserted in a lower extremity or without proper asepsis during an emergency must be changed as soon as a satisfactory site can be established in an upper extremity.
- Removal of the device should be carried out aseptically and a sterile dressing applied.
- Date and time of site changes must be documented.

The optimal time limit for replacing catheters, administration sets or fluid containers depends upon individual circumstances. Duration of use limits and the priority assigned to corrective measures should be established relative to reported aggregate infection rates and where possible to established benchmarks. Health care establishments that fail to achieve low infection rates should consider adopting more conservative limits (Canada Communicable Disease Report Supplement 1997).

Consideration should be given to commercially available antiseptic-impregnated cuffs and catheters in facilities, or particular areas within facilities, where the incidence of catheter-related bloodstream infection remains significantly greater than 1% or greater than what would be expected based on national nosocomial infections surveillance data. As well, silver-impregnated cuffs or chlorhexidine–silver sulfadiazine-impregnated catheters should be considered if the catheter duration is less than 2–3 weeks (APIC 1999). When prolonged intravenous access via a CVC is likely, catheters such as Hickman — which have a cuff, are tunnelled subcutaneously and are associated with a lower sepsis rate than standard CVCs — should be used.

Environment

Accumulation of dust, soil and microbial contaminants on environmental surfaces is not a very likely potential source of nosocomial infection whilst intravascular access devices are in situ. However, before insertion, maintenance or removal of intravascular devices, effective cleaning of the environmental area and surfaces involved should be undertaken.

Device reprocessing

Intravascular devices are single-use only and must not be reprocessed. The narrow lumens of catheters, catheters and lines cannot be satisfactorily cleaned and the plastic may not withstand cleaning and sterilising (Collignon et al 1996). These items, together with solution containers, are manufactured for single use only and must not be reused.

20.2.5 Monitoring and surveillance

Each health care establishment must tailor its surveillance systems to maximise the use of all health care resources, given outcome priorities, population characteristics and institutional objectives. Clear definitions should be formulated regarding intravascular device-associated infections, documentation required and action to be taken.

Data collection should be tied to action in risk reduction, in process and systems improvement and in the achievement of desired outcomes for patient care.

21 Surveillance and outbreak investigations

Key points

- All health care facilities, including office practices (AS4815), should collect data on health care associated infections, infection control breaches, outbreaks of infectious disease and antimicrobial resistance. The surveillance systems used by different health care establishments depend on the type and size of the establishment, its case mix, and the facilities and resources available.
- Effective surveillance systems can monitor changes in the rate of infection against a baseline rate, evaluate the effectiveness of new infection control policies and facilitate the early detection of outbreaks.
- A comprehensive 'minimum data set' forms the basis of all surveillance systems. Surveillance of health care associated infections draws information about the agent, host, environment and risk factors from a number of data sources (eg medical and pharmacy records, and laboratory data) and should include the incidence and prevalence of antibiotic-resistant bacteria and resistance genes. Post-discharge surveillance and surveillance of community-based health care practices should also be considered.
- When an outbreak is detected, the health care establishment's infection control management system should be notified and an outbreak control team formed. The principles for investigating outbreaks in health care establishments are the same as for community-based outbreaks; an epidemiological investigation is conducted to identify the aetiologic agent, the route(s) of transmission, exposure factors and the population at risk to stop the outbreak and stop it happening again.
- Because of the increasing risk of litigation, all outbreaks, however minor, should be investigated thoroughly and the outcomes of the investigations documented. Therefore all establishments should have adequate resources for the detection and control of outbreaks.

21.1 Introduction

Surveillance of HAI (see Section 1.1.1) or HAI-related events is a continuous or periodic activity of data collection, analysis, interpretation and timely feedback of

results to clinicians so that they may learn and apply appropriate clinical management intervention.

Surveillance of HAI or HAI-related events requires:

- That standardised definitions are used. Where none exist, use definitions that have a peer acceptance that is as wide as possible;
- Utilise standardised methodology for identification of the at-risk patient groups and the cases of HAI or HAI related-events that manifest in these groups;
- Data analysis using rates and/or process control charts. Frequency of analysis wil be dependent on the size of the at-risk patient groups surveyed and the number of cases identified within each group; and
- Timely feedback of interpretation of data to clinical and management staff.
-

Surveillance procedures should be carried out in all health care establishments to obtain baseline information on the frequency and type of health care associated infections at the establishment. Any increase in the rate of infection can then be quickly recognised and appropriate infection control action taken to minimise transmission to other patients and health care workers (HCWs). A change in infection rates against a baseline rate can also be used to evaluate the effectiveness of new infection control policies and procedures.

The risks to patients or health care workers of acquiring a health care associated infection are described in Section 4. The nature and frequency of such infections varies in different health care settings. For example, in acute care hospital patients undergoing a range of invasive procedures and antibiotics, which may facilitate the emergence of antibiotic-resistant bacteria, are used frequently. Patients in long-term care , such as residential aged care, are often immunocompromised due to age or medications. Outbreaks of foodborne infections and skin conditions such as scabies are known to occur in these environments.

Where it is necessary for a patient's personal information, including health information, to be used or disclosed for purposes other than purpose for which the information was originally collected, it will be necessary for establishments to take account of specific requirements under the Privacy Act and any other legislative or ethical guidelines.

For further information on the protection of privacy in relation to compilation or analysis of statistics, for health services management or medical research, the reader is directed to the NHMRC publication 'Guidelines under Section 95 of the Privacy Act 1988, details of which are at www.health.gov.au/nhmrc/

21.1.1 Critical Incidents

If there has been a breakdown in an infection control procedure or protocol, a 'lookback investigation' may be necessary to identify, trace, recall, counsel and test patients or health care workers who may have been exposed to an infection, usually a bloodborne virus. Lookback investigations must be managed with due regard to ethical and legal considerations. In the event of such an incident (eg failure of sterilisation or disinfection), the local public health unit should be advised immediately.

21.2 Surveillance methods

21.2.1 General

Surveillance systems should be flexible enough to accommodate technological changes within health care establishments, shortening lengths of stay, and the necessity to provide post-discharge surveillance, including surveillance of procedures carried out in the community (eg 'hospital in the home' programs). Where possible, denominator data should be collected in all situations for the calculation of rates of infection.

The practice of surveillance programs will differ between health care organisations with regard to the choice of at-risk patient populations to monitor HAI and the frequency with which these populations are surveyed. To work within resources available for surveillance, most health care organisations will choose a 'sentinel' at-risk patient group for routine surveillance. The choice of this group should be made after examining historical surveillance data to identify the group considered most at-risk and those considered 'core' business patient groups (McLaws & Caelli 2000). Where health care organisations do not have historical data, the Infection Control Committee should examine results from laboratory-based data or perform a point prevalence survey of surgical and intravascular line patients in situ, to assist in identifying their at-risk groups. Surveillance programs may employ:

- Active surveillance by Infection Control Practitioners (ICPs) to perform direct observation of the selected at-risk patients and their medical records to collect denominator and numerator data. This practice is suited to the important HAIs such as surgical site infections (SSI) and intravascular line-related blood stream infections (BSI).

- Passive surveillance using case-mix (DRG) and/or laboratory-based data. Or, for example to monitor antibiotic resistance patterns, especially the frequency of multi-resistant organisms (eg *Extended B-lactamase producing gram-negative bacteria*

(ESBL), *methicillin resistant Staphylococcus aureus (MRSA)* and *vancomycin resistant enterococci* (VRE).

- An alternative to active surveillance of intravascular related BSI is the use of passive laboratory-based surveillance for the identification of BSI with a quarterly audit of patients to establish the type and the number of intravascular line-days. The calculation of BSI rate per 1000 line-days by specific line types can then be performed.

Hospital and public health (reference) laboratories have an important role in health care associated infection surveillance.

A 'minimum data set' for the surveillance of health care associated infections should include:

- details of the infected individual (name or other unique identifier)
- gender
- hospital record number
- ward or location in the hospital
- name of the consultant and/or unit involved
- date of admission, date of onset of infection and date of discharge or death (so that length of stay attributed to the health care associated infection can be calculated and community acquired infections excluded from further analysis)
- site of infection/colonisation
- organism isolated or otherwise identified (eg serology)
- relevant characterisitcs of organism/s such as antibiotic sensitivity, bio-type or genotype
- acknowledgment of appropriate data use against relevant privacy legislation

This minimum data set should also include information on medical treatment/procedures at the time of infection, any other information relevant to why the infection may have occurred, including the patient's underlying medical risk factors, clinical outcome and an assessment of whether the incident was preventable.

21.2.2 Occupational exposure and accidents with infection

Incidents of occupational exposure to blood and body fluids should be identified in all health care establishments. In addition, they should be incorporated in State/Territory and national systems for surveillance. An enhanced dataset for occupational exposure to risk materials should include the extent of the exposure, the site and severity of the injury, the nature of the exposure (percutaneous or mucous membrane exposure), the location in the establishment (ward or other location), the activity or procedure, the implement causing the injury, the infectious agent involved if known, details of treatment and prophylaxis given, and the outcome of the incident. In addition, in the event of needle stick and similar injuries, identifying details of the source patient must also be recorded as well as information on blood borne virus risk and/or other relevant infectious disease risks. These items are also relevant for recording potential transmission from an infected HCW to a patient.

21.2.3 Benchmarking and comparison

Comparison of infection rates between establishments and the publication of such comparisons is a contentious issue and needs careful consideration and sensitive handling. In large establishments, surveillance targeted for areas of high infection risk is preferable and most effective. However, such data need to be appropriately risk-adjusted for the generation of meaningful infection rates, especially when the data are released beyond the institution. Surveillance systems in small institutions should collect data on health care associated infections across the whole range of services provided. Data collated to form a national picture must be interpreted with caution because the data may not be comparable, and the range of institutions involved will introduce confounding factors inherent in all surveillance systems. Differences specific to health care establishments include the catchment area of referral, the level of referral, the size of the institution and the specialty services provided. Problems of data interpretation can be overcome when surveillance systems are set up with clearly defined surveillance objectives, including the expected outputs of surveillance.

21.2.4 Surveillance of antibiotic-resistant organisms

Hospitals and diagnostic pathology laboratories should support comprehensive programs for the surveillance and management of antibiotic resistant organisms.

Currently available systems that are collecting national data include:

- Since 1985, the Australian Group on Antibiotic Resistance (AGAR) has collected data on the antibiotic susceptibility of Staphylococcus aureus from hospital laboratories around the country;

- The Australian Gonococcal Surveillance Program (AGSP) was established as a long-term collaborative program conducted by reference laboratories in each State and Territory, to monitor the antibiotic susceptibility of gonococcal isolates. Data has been published quarterly from 1981 and annual reports since 1996;

- The Surveillance Network (TSN) – is a United States based organisation which collects qualitative and quantitative antimicrobial test results. A representative group of Australian laboratories and Hospitals began contributing data in 1999;

The Commonwealth Government Response to the Report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) recommends that a comprehensive antibiotic resistance surveillance system be established as part of a national antibiotic resistance management program (recommendations No 10 and 11 – full report available from http://www.health.gov.au/pubhlth/strateg/jetacar/reports.htm). The overall surveillance system should include medical (including nosocomial), food-producing animal and veterinary areas with an emphasis on food-chain, molecular studies of resistance genes and environmental connections.

21.2.5 Health care associated infection surveillance in Australia

The surveillance of health care associated infections, in particular surgical site infections and bloodstream infections, has been conducted by many hospitals participating in the accreditation system with the Australian Council on Healthcare Standards. States and Territories are encouraged to establish mechanisms suitable to oversee the development, standardisation, collection and collation of health care associated infection data in their jurisdiction. Such State based systems are currently being developed. The use of standardised surveillance definitions and methods will facilitate the collection of data at a national level and examples of consensus definitions for surgical site infection and bloodstream infections are provided in **Appendix 1**.

In establishing a national surveillance system, the objectives should be clearly defined. These may include:

- reducing infection rates within health care establishments;
- establishing endemic infection rates;
- identifying outbreaks;

- driving evidence-based changes in clinicalpractice;
- improving clinical performance in health care establishments; and
- evaluating control measures.

21.3 Outbreak investigation

21.3.1 Outbreak identification

An outbreak may be defined as the occurrence of infections at a rate greater than that expected within a specific geographical area and over a defined period of time. Ideally, surveillance systems should facilitate the early detection of outbreaks. Increasingly, microbiological data are being relied on for this purpose, although outbreaks may be detected using other sources such as pharmacy records. In some instances, the occurrence of an outbreak may be obvious, such as in an episode of food poisoning that affects both HCWs and patients. It is more usual, however, for the outbreak to have an insidious onset that may not be immediately apparent.

The existence of an outbreak should be brought to the attention of the health care establishment's infection control management system and, where necessary, the relevant health authority. An outbreak control team should be formed, consisting of a minimum of a senior representative from the affected clinical service, an infection control practitioner (or equivalent) and an infectious diseases physician/microbiologist with infection control experience. Depending on the size and severity of the outbreak, it may be necessary to involve occupational health and safety staff, hospital administrators, engineers and public health officials. One person (often the infection control practitioner; see Section 8.3) should be given the responsibility for coordinating the investigation and subsequent control activities. In the case of outbreaks related to notifiable infections it is a legislative requirement that the public health authority is informed. It may also be prudent to involve public health officers at an early stage if an outbreak is likely to come to the attention of the media.

There needs to be adequate laboratory support — if not locally, then from a reference laboratory. It is particularly important to ensure that outbreak isolates are stored for further investigation. This is because many of the infectious agents that cause outbreaks in health care establishments are endemic organisms, and it may be necessary to use a typing system to evaluate which isolates are part of any putative outbreak. Although simple antimicrobial susceptibility testing may be enough to distinguish isolates, against a background of increasing resistance other more sophisticated methods of typing, such as randomly amplified polymorphic DNA and pulse field gel electrophoresis, may be necessary. These may only be available from a specialised facility such as a reference laboratory, tertiary care hospitals or some universities.

21.3.2 Investigation procedures

The principles for investigating outbreaks in health care establishments are the same as for community-based outbreaks. There are three basic steps:

- describing the outbreak;
- developing a hypothesis; and
- testing the hypothesis with analytical epidemiology.

The tasks involved in any investigation can be summarised as follows.

- Confirm that an outbreak is occurring.
- Determine the background rate of infection, as a temporal cluster of cases may be due to chance alone.
- Confirm the diagnosis using the microbiological methods. If possible, confirm that cases are related by typing methods that may require reference laboratory facilities.
- Define a case and count cases. Develop a case definition that may include clinical and laboratory data. Start with a broad definition that can be redefined at a later date. Case finding in health care establishments can be relatively easy, with data available through laboratory records and infection control surveillance data. Remember that cases may have been discharged from the establishment.
- Describe the data in terms of time, place and person and construct an epidemic curve. In health care establishments, age, gender and underlying disease are the most useful 'person' attributes to record. The location may suggest risk factors.
- Determine who is at risk of becoming ill.
- Look at changes that may have affected the rate of infection (eg new staff, new procedures, new tests, new units and HCW:patient ratios).
- Develop a hypothesis and test it by comparison with the facts.
- Analytical epidemiology, such as a case-control or retrospective cohort study, can be undertaken quickly to test the hypothesis.
- After interim control measures are in place a larger, more systematic study may be warranted, possibly with a different analytical methodology.
- Evaluate and prepare a written report.

- Implement longer-term infection control measures for prevention of similar outbreaks.

In the interests of public safety (and the threat of litigation), all outbreaks, however minor, should be investigated thoroughly and the outcomes of such investigations documented. All institutions should therfore have adequate resources for the detection and control of outbreaks.

21.4 Outbreak control

Preliminary control measures should be introduced as soon as possible and in association with the local health authority . Heightened surveillance should be introduced to assess the impact of all control measures. As soon as possible, information about the outbreak, the investigation and the results should be conveyed to the committee that deals with infection control issues in the institution.

All outbreaks provide the opportunity to educate HCWs about infection control matters.

21.5 Lookback investigations

'Lookback investigation' refers to the process of identifying, tracing, recalling, counselling and testing patients or HCWs who may have been exposed to an infection, in a health care setting.

One example is the case of an HCW who has undertaken exposure-prone procedures on surgical patients and is later found to be positive on a test hepatitis B virus (HBV). If it is determined that the HCW was infectious at the time the exposure-prone procedures were undertaken, the patients with whom he or she had contact could have been infected and would need to be informed of this risk and offered testing and counselling.

Another example is a breakdown in the normal processes of cleaning and disinfection or sterilisation of instruments (such as endoscopes) which may allow the transfer of infection from one patient to another.

Lookback investigations are undertaken by blood transfusion services when it has been determined that a person who has donated blood or tissue has subsequently tested positive for a bloodborne virus that was not detected at the time of the donation

Any type of lookback investigation has the potential to result in a great deal of publicity. This can cause unnecessary anxiety in patients treated at the establishment who have not been exposed to the risk of infection, as well as anger and distress among patients who were put at risk of infection.

As well as provoking publicity and anxiety, lookback investigations can take up a great deal of time and resources and should not be undertaken lightly. The level of infectivity

of the affected individual, the type and extent of procedures undertaken and the probable risk to patients need to be carefully considered by those with expertise in these matters. The State/Territory health department should be involved at the outset, and a planning team established with members who have expertise in infection control, microbiology, the discipline involved (surgery, obstetrics, etc), public relations and legal and indemnity issues. Representatives of the management of the health care establishment concerned and the State/Territory health department should also be included.

The procedures to be undertaken and how these are presented to risk patients at risk and the public should be clearly established at the outset. These procedures should also clearly set out in protocols for tracing, counselling and referral of potentially exposed individuals in a timely manner. Test results should be made available with minimal delay, and the planning team should ensure that the project is completed and a final report produced as soon as possible.

21.6 Haemovigilance

Haemovigilance is a surveillance system for monitoring and analysing transfusion hazards of blood and plasma products in order to improve the safety of the transfusion process. The term haemovigilance was first used in Europe and over the last few years a number of countries including France and the United Kingdom have established such national surveillance systems for monitoring adverse effects of transfusions.

In France there is a compulsory haemovigilance system that collects information from physicians and hospitals on serious and nonserious incidents. In the United Kingdom, there is a voluntary confidential scheme referred to as the Serious Hazards of Transfusion Scheme (SHOT). In 1998, the Australian Red Cross Blood Service (ARCBS) established the Haemovigilance Working Party to consider what role haemovigilance may play in leading to any further improvements in what is universally considered to be a very safe blood supply. At the time of writing these guidelines, the working party had not yet produced any recommendations for a national haemovigilance scheme.

Infection issues relating to blood and blood products for transfusion are discussed further in Section 25.

22 Protection for health care workers

Key points

- Health care establishments should provide infection protection measures for all HCWs. These must include physical protection (personal protective equipment and immunisation), appropriate educational material and programs, effective reporting systems for breaches of protocols, implementation of safe work practices and provision of health screening.
- All HCWs should be assessed at the start of their employment and offered testing for specific infections before rostering in high-risk areas. Particular attention should be paid to immune status, skin conditions and pregnancy.
- Health care establishments should ensure that where a HCW is known to be particularly susceptible to HAIs, the HCW's duties are assessed to ensure that the welfare of patients and other HCWs are safeguarded.
- HCW vaccination programs should comply with the most recent edition of *The Australian Immunisation Handbook* (currently NHMRC 2000).
- Employers should provide information on the risks associated with pregnancy and assist pregnant HCWs to avoid Infectious circumstances that may present a risk to the HCW (mother) and/or foetus.

22.1 Introduction

Infection protection for health care workers (HCWs) must be an integral part of the infection control and occupational health and safety programs of any health care establishment (see Section 8). HCWs in this context include all HCWs who have the potential for occupational exposure to infectious material. Measures to protect HCWs from infection fall into five categories:

- physical protection
  - personal protective equipment (see Section 13)
  - immunisation (see Section 22.3.2);
- education;
- reporting systems;

- safe systems of work, design/physical environment and the provision of appropriate facilities for infection control; and
- health screening, where appropriate.

Work practices must be developed and implemented within health care establishments to ensure compliance with infection control standards, appropriate deployment of HCWs and continuing education.

As part of their overall infection control training program, health care establishments must implement specific education on the physical protection and immunisation services provided by the establishment. These programs must emphasise the establishment's policies and the need for compliance. Education should be provided as part of the initial orientation of new HCWs and be reinforced through regular continuing education programs.

Health care establishments must have in place a system for reporting breaches of the infection control protocols for the protection of HCWs. The system should form part of the risk management process for the establishment and be monitored at a senior management level.

The system must ensure accurate and timely reporting of incidents involving a breach of the infection control protocols as they affect HCWs. In addition, the incident report process should include notes on remedial and follow-up action taken before the process is considered complete.

22.2 Health status of health care workers

There are certain medical conditions of HCWs that increase their predisposition to infection if they come into contact with certain infectious patients (eg immune status, certain skin conditions). There are many areas within health care establishments where HCWs with these conditions can work safely and there are few tasks that such HCWs are unable to perform safely. Health care establishments have a responsibility to manage and supervise such HCWs in ways that both acknowledge their right to work, and safeguard the welfare of both patients and HCWs. This responsibility includes the need to identify such HCWs and inform them of the problems they are likely to encounter in particular circumstances.

22.2.1 Immune status of health care workers

Although other factors may also have an effect, substantial depression of immune function predisposes a person to infection. People who are immunosuppressed to this extent would normally be unable to work but if they are employed as clinical contact

workers, they are at risk of acquiring health care associated infections. Examples of predisposing conditions include:

- neutropenia (less than 10^{12} white blood cells/L), which is often associated with cancer chemotherapy;
- disseminated malignancy; and
- infection that produces immunodeficiency (eg human immunodeficiency virus, HIV).

22.2.2 Skin conditions (noninfectious)

HCWs with either shedding and/or weeping skin conditions or damaged skin may readily be colonised by health care associated associated microorganisms. These HCWs may not be harmed by the acquisition of such microorganisms but may disseminate them widely. For example, placement of such HCWs in wards containing patients with methicillin-resistant staphylococci is not recommended. These employees should be identified by personal history screening and advised of the problems posed by their condition.

Examples of noninfectious skin conditions include:

- allergic eczema;
- psoriasis; and
- exfoliative dermatitis.

These conditions are not infectious unless they are secondary to an underlying infection.

22.2.3 Pregnancy

Some infectious agents that cause congenital abnormalities are more commonly encountered in some hospitals than in the community. The precautions recommended in pregnancy are discussed in more detail in Section 22.4.

22.3 HCW health screening

Three types of routine screening and assessment of HCWs are proposed:

- routine personal assessment of disease and immune status;
- immunisation; and
- laboratory and other testing.

The diseases that are important for inclusion in each of these procedures are shown in **Table 22.1** and discussed further in **Sections 22.3.1 to 22.3.3**. Consent must be obtained before screening (see Section 10.6).

On employment, HCWs should be informed of the health care establishment's health screening policies, and should be counselled about appropriate work placement in accordance with these policies.

Table 22.1 Assessment and immunisation of clinical contact health care workers before employment or rostering

Personal medical history	Immunisation	Laboratory/other testing
Disease Tuberculosis Rubella Measles Mumps Chickenpox Herpes simplex Hepatitis B Immune disorders (including medication such as immunosuppressants) Exfoliative and weeping skin conditions[a]	**All HCWs should be offered** Influenza vaccination Td booster[b] **HCWs who have not been previously immunised or naturally infected should be offered the following vaccination:** Hepatitis B MMR Varicella	**All HCWs should be routinely offered -** In Hospitals, pre-employment Tuberculin skin test and regular retesting of tuberculin skin test-negative, depending on level of risk. Tuberculin skin test-positive HCWs should be followed up with a chest X-ray and clinical review
Special circumstances HCWs performing exposure-prone procedures have an ongoing responsibility to know their infectious status for: HIV/AIDS hepatitis B hepatitis C	**Special circumstances** Some microbiology staff should be immunised against diseases caused by infectious agents with which they work, including: Japanese encephalitis Hepatitis A Meningococcal infection Typhoid Q fever Plague Rabies Australian bat lyssavirus HCWs who work in communities with substantial indigenous population, or custodial carers and carers of the intellectually impaired) should be offered hepatitis A vaccination.	**Special circumstances** If there is any doubt about previous infection/immunisation HCWs should be offered testing for - hepatitis A hepatitis B Measles[c] Rubella Varicella Pregnant HCWs in exposure situations and those who refuse vaccination should be offered testing for – Rubella Varicella HCWs should undergo test for seroconversion after immunisation against: hepatitis B Rubella After exposure to blood or body fluids contaminated with blood, including needlestick or sharps injuries with a potential for BBV infections HCWs should be offered testing for[d] HIV hepatitis C hepatitis B

BCG = Bacille Calmette–Guerin vaccine; HCW = health care worker; HIV = human immunodeficiency virus; MMR = measles-mumps-rubella vaccine; Td = adsorbed diphtheria tetanus vaccine — adult formulation

[a]For positive ex foliative conditions, ascertain the diagnosis and current treatment.

[b]Boosters should be given as recommended in the most recent edition of *The Australian Immunisation Handbook*.(NHMRC 2000).

[c]If serological testing can be done quickly and cheaply, it may be cost effective to screen HCWs providing direct patient care during a measles outbreak (CDNANZ 2000).

[d]For further information see Chapter 23, Needlestick and other blood or body fluid incidents and Appendix 8 (ANCAHRD Bulletin No 16)

Note: For further information on immunisation refer to the most recent edition of *The Australian Immunisation Handbook* (currently NHMRC 2000).

22.3.1 Routine assessment of disease and immune status

HCWs should be assessed before employment or rostering in specific areas (eg women of child-bearing age working in neonatal/oncology or intensive care units where they may be at risk of exposure to infectious reproductive hazards such as cytomegalovirus). This personal assessment should take the form of an interview (verbal questionnaire). On occasion serological``` testing may also be useful. HCWs involved in exposure-prone procedures, should know their HIV, HBV and hepatitis C virus (HCV) status (see Section 24). Following substantial exposure to blood or potentially blood-contaminated secretions, HCWs should be provided with the opportunity of being tested for antibodies to HIV, HBV and HCV (see Section 23).

22.3.2 Laboratory testing

Mantoux testing should be part of routine testing for all HCWs with patient contact. All HCWs with patient contact should have a routine tuberculin skin test before starting a new job. Staff working in high-risk areas (eg microbiology laboratory, respiratory ward) should be retested yearly if their initial test was negative. Others who initially test negative should be regularly retested, or if exposed to a patient with tuberculosis. The frequency of the screening for people who have not had a BCG vaccine should depend on the level of risk.

Routine screening for staphylococcal, streptococcal and salmonella carriers is not recommended. Screening may be instituted if an outbreak or epidemic occurs, and if HCWs are felt to be either at risk or potentially associated with spread of the infection. Carriers of the bacteria involved would not normally transmit infection unless they were excreting bacteria in high numbers (eg from paronychia or chronic sinusitis).

22.3.3 Immunisation

The most recent edition of *The Australian Immunisation Handbook* (currently NHMRC 2000) provides detailed information on immunisation schedules and vaccines. Staff vaccination programs should comply with these procedures, which acknowledge that there may be some circumstances that require special consideration before vaccination; for example, where a HCW is pregnant.

- HBV immunisation should be offered to all nonimmune HCWs, particularly those with potential exposure to blood or body substances, preferably before starting employment or as soon as possible afterwards. Postimmunisation testing should be carried out to identify nonresponders.

- Measles–mumps–rubella (MMR), influenza and adsorbed diphtheria tetanus vaccine — adult formulation (Td) immunisations should be offered to all

nonimmune clinical contact HCWs. The new national policy will be to offer an MMR booster to all (nonpregnant) persons aged between 18 and 30 years as recommended in the Commonwealth Measles Elimination Strategy (DHAC 2000).

- Chickenpox (varicella) immunisation should also be offered to nonimmune HCWs with no history or serological evidence of chickenpox or shingles.
- At the start of their employment, all HCWs should be screened for previous infection by personal medical history or immunisation and should undergo an initial two-step tuberculin skin test. Bacille Calmette–Guerin (BCG) vaccine is of uncertain value, but may be offered to tuberculin skin test-negative HCWs at high risk, or in accordance with State/Territory guidelines (see Section 29.8.3)
- Laboratory staff should be immunised against any other pathogenic organisms that they may encounter in their facility, such as Japanese encephalitis virus, hepatitis A virus (HAV), meningococcus, typhoid, Q fever, plague and rabies (see **Table 22.1**).
- Child care staff should also be immunised against HAV, measles, mumps, rubella and varicella-zoster (nonimmune HCWs with no history of chicken pox or shingles).

Health care establishments should have education programs to support their immunisation strategy and reinforce the need for compliance. Refusal of immunisation by any HCW should be recorded together with a reason for such refusal, if provided. Further details are given in **Table 22.1**.

22.3.4 Immunisation/health screening records

Health care establishments should develop, maintain and regularly update immunisation/health screening cards and/or records for all HCWs during the period of their employment. These records should be maintained in accordance with the establishment's policy for the retention of medical records. HCWs should have access to their individual medical screening records on request and extracts of these screening records should be available to HCWs whenever they change their place of employment.

It is recommended that HCWs maintain their own personal records of all immunisations and screening (see Section 5.2).

22.3.5 Infection exposure management

Details of the postexposure prophylactic management required for specific infections is shown in **Table 22.2**.

DISCUSSION POINT

Blood collected but not tested

An option that may be offered to HCWs who do not wish to undergo testing at the time of the exposure is to have blood collected and stored but not tested. Blood that is collected and stored for this purpose must be retained for a minimum of 12 months.

Table 22.2 Postexposure prophylaxis and precautions for health care workers

Infectious agent	Recommended test (s)	Situation in which prophylaxis/precautions are recommended	Prophylaxis/precautions available
Cytomegalovirus (CMV)		Particularly for HCWs working in neonatal units, transplant units and caring for HIV-positive patients. For nonimmune pregnant HCWs.	Wash hands after all patient contact and after contact with urine and saliva.
Haemophilus influenza type B virus (HIB)		Not advised	Not advised
Hepatitis A virus (HAV)		For those who have had close contact with a case during the two weeks before, and up to one week after, the onset of jaundice (eg handled faecal waste).	Give NIGH within two weeks of exposure. Hepatitis A vaccine should also be given. If more than 2 weeks has elapsed since exposure, hepatitis A vaccine could be given alone but there is no evidence it will be effective.
Hepatitis B virus (HBV)	HCWs undertaking exposure-prone procedures should know their HBV status. Test source of blood as soon as possible for HBsAg. Test blood of the recipient for antibodies to HBsAg, or store blood for future testing, and then retest at 3 and 6 months if source is positive.	For those who have had significant exposure (percutaneous, ocular or mucous membrane) to blood or potentially blood-contaminated secretions.	Wash site of exposure with soap and water. Flush affected mucous membranes with large volumes of water. If recipient does not have antibodies to hepatitis B (HBsAg), and source is HBsAg-positive or cannot be identified and tested rapidly, give a single dose of HBIG[a] within 48–72 hours and start a course of HBV immunisation at the same time in susceptible HCWs who have not previously been immunised. HBV vaccine should be given within 7 days of exposure, repeated at 1–2 months and at 6 months after the first dose. If HCW is a known nonresponder to HBV immunisation, HBIG should be given within 72 hours (NHMRC Immunisation Handbook 2000).
Hepatitis C virus	HCWs undertaking exposure-	For those who have had	Wash site of exposure with soap

Infectious agent	Recommended test (s)	Situation in which prophylaxis/precautions are recommended	Prophylaxis/precautions available
(HCV) – These are interim recommendations pending release of *National Hepatitis C Testing Policy.*	prone procedures should know their HCV status. Test source of blood as soon as possible for antibodies to HCV. Blood should also be taken from the recipient as soon as possible (baseline sample) and either tested immediately or stored for future testing. If the source is HCV antibody positive, the recipient should be tested at 3 and 6 months, in addition to the baseline test.	significant exposure (percutaneous, ocular, or mucous membrane) to blood or potentially blood-contaminated secretions.	and water. Flush affected mucous membranes with large volumes of water. No specific PEP for HCV. See Appendix 8 (ANCAHRD Bulletin No 16) for further information.
Human immunodeficiency virus (HIV)	HCWs undertaking exposure-prone procedures should know their HIV status. Test source of blood as soon as possible for antibodies to HIV. If source is HIV positive, gather information on stage of infection, current and previous antiretroviral therapy to decide on appropriate PEP regimen. Test blood of the recipient for antibodies to HIV, or store blood for future testing; retest at 1, 3 and 6 months if source is positive. Follow-up to detect any febrile illness occurring within 3 months of exposure.	For those who have had significant exposure (percutaneous, ocular or mucous membrane) to blood or potentially blood-contaminated secretions.	Wash site of exposure with soap and water. Flush affected mucous membranes with large volumes of water. If source is HIV positive or cannot be identified and tested rapidly or is at high risk of seroconverting, 2 or 3 antiretroviral drugs (including ZVD or lamivudine) should be administered to recipient within 24–36 hours after exposure[b] (preferably within 2 hours). Continue therapy for 4 weeks.
		For pregnant HCWs, be aware that patient may shed CMV.	Gloves should be used and hands washed regularly.
Measles virus[c]	Active surveillance for measles among HCWs who may have been exposed during a measles outbreak.	For nonpregnant, nonimmune HCWs.	MMR within 72 hours of exposure or NIGH if 3–7 days after exposure.[d] Ensure nonimmune HCWs are immunised. All exposed non-immune HCWs should be excluded from direct patient contact from 5 days after first exposure to 21 days after last exposure, or until 7 days after rash appears if measles develops (Bolyard et al 1998).

Infectious agent	Recommended test (s)	Situation in which prophylaxis/precautions are recommended	Prophylaxis/precautions available
		For nonimmune pregnant HCWs and people with underlying immunological disorders.	NIGH soon after exposure.[d]
Neisseria meningitidis (meningococcus)		Only if HCW engaged in close contact with infected person (eg mouth-to-mouth resuscitation)	Chemoprophylaxis with rifampicin.[e] If unsuitable, use ceftriaxone or ciprofloxacin.
Prion (Creutzfeld-Jakob disease; CJD)	None available	For those who have contamination of unbroken skin with blood or body fluids from, or needlestick injuries and lacerations from patients with known or suspected CJD.	Wash skin with detergents and copious quantities of warm water. Avoid vigorous scrubbing.
		For those who have had ocular exposure to blood or CSF from patients at high risk of CJD.	Immediately institute normal eye washing procedures using warm water.
Rubella virus	Serological follow-up of NIGH recipients for up to 8 weeks.	For pregnant HCWs if nonimmune (ie no previous natural infection or immunisation).[f]	NIGH soon after exposure. Ensure nonimmune HCWs are immunised.
		All HCWs	All exposed non-immune HCWs should be excluded from direct patient contact from 7 days after first exposure until 21 days after the last exposure, or until 5 days after rash appears if rubella develops (Bolyard et al 1998).
Clostridium tetani (tetanus)		For those determined to be at risk of infection depending on circumstances of exposure (eg. deep penetrating wound, wound with extensive tissue damage or wound containing foreign bodies).	Clean and disinfect wound. If 5 or more years have elapsed since HCW was last immunised, a booster dose of a tetanus-toxoid-containing vaccine should be administered as soon as possible. Where the recipient has not received 3 or more doses of a tetanus toxoid-containing vaccine or where there is doubt about their tetanus immunisation status, TIG

Infectious agent	Recommended test (s)	Situation in which prophylaxis/precautions are recommended	Prophylaxis/precautions available
			and a tetanus toxoid-containing vaccine should be administered as soon as possible (double TIG dose if more than 24 hours have elapsed since injury).
Varicella-zoster virus (VZV)	Test pregnant HCWs for anti-VZV antibodies.[g]	For pregnant HCWs who are susceptible to varicella infection.	ZIG[h] within 96 hours of exposure. If unavailable, use NIGH. Ensure nonimmune HCWs are immunised.
		All HCWs	All exposed nonimmune HCWs should be excluded form direct patient contact from 10 days after first exposure to 21 days after last exposure, or until all lesions are dry if they develop varicella (Bolyard et al 1998).

CSF = cerebrospinal fluid; ddI = dideoxyinosine; ddC = dideoxycytidine; HBIG = hepatitis B virus immunoglobulin; HBsAg = hepatitis B virus surface antigen; HCW = health care worker; MMR = measles-mumps-rubella vaccine; NIGH = normal immunoglobulin (human); PCR = polymerase chain reaction; PEP = postexposure prophylaxis; TIG = tetanus immunoglobulin; ZDV = zidovudine (also called azidothymidine or AZT); ZIG = high-titre varicella-zoster immunoglobulin

[a] Requests for HBIG should be directed to the local State/Territory Director of the Australian Red Cross Blood Service.

[b] The decision to use antiretroviral PEP should be made promptly, in conjunction with a specialist HIV physician, and with the full consent of the affected person. Doctors should stress to the affected person the importance of strict compliance with the treatment regimen and describe the potential side effects and the appropriate course of action if these are experienced.

[c] Further details are given in the *Guidelines for the Control of Measles Outbreaks in Australia* (CDNANZ 2000).

[d] Following advice from the local infection control officer, susceptible HCWs who refuse immunisation may be redeployed to duties not requiring direct patient care. Alternatively, until the HCW receives either the MMR vaccine or a dose of NIGH, within the specified time frames, the HCW may be excluded from the facility until 14 days after their last exposure. Furthermore, if a susceptible HCW has not previously received any doses of a measles-containing vaccine they should be offered a second dose of MMR four weeks after the first dose.

[e] Rifampicin is not recommended for use in pregnant women. The side-effects of rifampicin should be explained to recipients. Ceftriaxone is potentially safer in pregnancy.

[f] NIGH does not prevent rubella infection. It may, however, prolong the incubation period, which may marginally reduce the risk to the foetus and reduce the likelihood of clinical symptoms in the mother.

[g] The use of varicella vaccine for immunisation of HCWs is currently under consideration by the Australian Technical Advisory Group on Immunisation (ATAGI). The recommendations will be published as soon as they are finalised.

[h] ZIG is available from the local State/Territory Director of the Australian Red Cross Blood Transfusion Service on a restricted basis

Note: The current edition of *The Australian Immunisation Handbook* (NHMRC 2000) should be consulted for further detail about vaccines and immunoglobulins.

22.4 Pregnant health care workers

Both the employer and pregnant HCW have an obligation to reduce risks to the fetus. Certain infections can pose a risk to pregnant women and fetuses if acquired during pregnancy. Some of these infections can potentially be acquired in the workplace, for example cytomegalovirus (CMV), hepatitis viruses, HIV, parvovirus, rubella virus and varicella zoster virus. In general, adherence to standard and additional precautions, vaccination and high standards of general hygiene in the workplace should protect HCWs.

Information on the risks associated with pregnancy should be available in the workplace in the form of pamphlets or other information. It is the responsibility of pregnant HCWs to advise their medical practitioner and employer of their pregnancy.

The employer should advise pregnant HCWs of the special risks associated with pregnancy and give them an opportunity to avoid patients with specific infections. All women of child-bearing age should be counselled regarding their immune status in relation to *varicella*, *Hepatitis B* and, if necessary, should be offered immunisation before they become pregnant. All information about immune status and pregnancy of HCWs must remain confidential: a HCW is only required to provide information about her pregnancy for her own benefit.

The following information relates to infections that are both significant in pregnancy and have some possibility of being acquired through patient care. It is not meant to be a comprehensive account of all infections having relevance to pregnant women. For this reason, infections due to herpes simplex virus, *Toxoplasma gondii, Treponema pallidum, Neisseria gonorrhoeae, Chlamydia trachomatis, Listeria monocytogenes* and human papilloma virus are not considered since these are likely to represent incidental infections rather than those acquired through patient contact.

The following information is based on advice given in *The Australian Immunisation Handbook, 7th edition* (NHMRC 2000), the current edition of which should be consulted for further details.

22.4.1 Rubella

Confirming rubella immunity is part of routine antenatal screening, with consent. However, serious congenital abnormalities most commonly follow rubella infection occurring in the first trimester. For this reason, rubella antibody status should be checked for HCWs at employment, particularly for women of child-bearing age (see Section 28.13.3). If rubella antibody is absent or below protective levels, then the HCW should be offered vaccination on beginning employment. Rubella vaccination should be avoided in early pregnancy, and conception should be avoided for two months following vaccination, although no case of congenital rubella syndrome has

been reported following inadvertent vaccination shortly before or during pregnancy. Where necessary, those vaccinated can be tested for seroconversion two months after vaccination, and be revaccinated if necessary.

Postexposure prophylaxis with human normal immunoglobulin (NIGH) will not prevent infection in nonimmune contacts and is therefore of little value for protection of pregnant women exposed to rubella. It may, however, prolong the incubation period, which may marginally reduce the risk to the fetus. It may also reduce the likelihood of clinical symptoms in the mother. NIGH should only be used if termination of pregnancy due to confirmed rubella infection would be unacceptable. In such cases, it should be given soon after exposure. Serological follow-up of recipients is essential, and should continue for up to eight weeks. Further details on the occurrence, prevention and management of rubella virus infection are given in Section 28.13.

22.4.2 Hepatitis B

Recommended routine HBV screening/testing, immunisation and response to needlestick injuries are described in Section 28.4.3. Routine antenatal screening to determine HBV immune status is commonly performed, with the consent of the person being tested.

While the safety of the HBV vaccine for the developing fetus has not yet been confirmed by a large-scale trial, HBV infection in a pregnant woman may result in severe disease for the newborn. Pregnancy should therefore not be considered a contraindication to administration of HBV immunoglobulin (HBIG) or HBV vaccination.

Further details on the occurrence, prevention and management of HBV infection are given in Section 28.4.

22.4.3 Cytomegalovirus

While CMV may commonly be encountered in urine and saliva, there is little evidence that this virus has been acquired by female HCWs and, in particular, that it has resulted in foetal infection (Lipscomb et al 1984, Murph et al 1998). Routine antenatal screening is not recommended even in HCWs in high-risk areas, but can be offered on an individual basis.

Pregnant HCWs, or those contemplating pregnancy, should be counselled about the risks of CMV infection, mode of transmission and safe work practices.

Further details on the occurrence, prevention and management of CMV infection are given in Section 28.1.

22.4.4 Varicella-zoster virus (chickenpox and shingles)

There is also some evidence that infection with varicella-zoster virus (VZV) may be more severe in pregnant than in nonpregnant women (Pierre et al 1992, Enders et al 1994, Baren 1996). Fewer than 5% of women of child-bearing age do not have immunity to VZV. Even individuals who cannot recall having had chickenpox have an 80% chance of having had VZV. Each establishment should decide whether to test for VZV status, on the basis of risk in the particular setting (not on the basis of potential pregnancy).

If chickenpox occurs during the first 20 weeks of gestation, intrauterine foetal infection and occasionally foetal damage can occur (Enders et al 1994, Lecuru et al 1995). Foetal varicella syndrome is rare (2–3% of affected pregnancies) and clues to its presence may be found at a 20-week ultrasound scan. The most dangerous time to acquire chickenpox during pregnancy is at term or immediately after term (Lecuru et al 1994, 1995) This is because there is a high chance that the newborn infant may be exposed and may have little or no immunity. The newborn may then become seriously ill with VZV infection.

For these reasons pregnant HCWs who are not immune should not care for patients with chickenpox or shingles. If the HCW is unsure whether or not she has had chickenpox and she is pregnant, or contemplating pregnancy, then she may have her VZV antibody status checked. VZV vaccine is not recommended during pregnancy and those who have received the vaccine should not become pregnant for one month after vaccination. If inadvertent exposure occurs, VZV immunoglobulin (ZIG) may be given to the pregnant HCW within 96 hours of exposure to the virus. If unavailable, NIGH may be given.

Acyclovir and related agents (eg famivir or valciclovir) are available for the treatment of acute VZV infection. The decision to give a pregnant woman either ZIG or acycolvir is controversial, however, and should be made by the specialist on an individual case basis.

Further details on the occurrence, prevention and management of VZV infection are given in Section 28.14.

22.4.5 Parvovirus

Parvovirus (B19) infection early in pregnancy may affect the fetus, causing aplastic anaemia that later becomes manifest as midsemester hydrops foetalis. If possible, pregnant HCWs should avoid contact with patients who are infected with human parvovirus. However, this is hard to achieve in practice, apart from avoiding immunosupressed patients who may experience prolonged shedding of the virus. For other patients infectivity usually ceases before there is evidence of B19 infection.

Further details on the occurrence, prevention and management of B19 infection are given in Section 28.10.

22.5 Tuberculosis

Australia has been particularly fortunate in its low incidence of tuberculosis (TB) (Dawson 1998) As a result, few young HCWs have been exposed to the disease in childhood and, as a group, they are particularly vulnerable to infection.

HCWs have varying risks for TB. Those working in TB-risk areas (medical wards, chest clinics, bronchoscopy units, radiology units, TB laboratories, HIV-dedicated wards and autopsy rooms) are at greatest risk of occupational exposure.

However, the prevalence of TB in trainee HCWs is likely to rise as a higher proportion of immigrants from countries in which TB is endemic participate in the workforce. In addition, an increase in TB, and in particular drug-resistant cases, is reported worldwide and it is possible that this will be reflected in an increase of cases amongst HCWs generally.

Details on the occurrence, prevention and management of TB infection are given in Section 29.8.

22.6 Laboratory and mortuary staff

Laboratory and mortuary staff should be offered immunisation against the potential infectious hazards they may encounter in their working environment. AS/NZS 2243.3[45] provides a summary for specific immunisation which should be considered for these workers.

[45] AS/NZS 2243.3 1995 *Safety in laboratories Part 3 — Microbiology*

23 Needlestick and other blood or body fluid incidents

Key points

- Health care establishments must have protocols for dealing with needlestick and other blood or body fluid incidents involving either patients or health care workers (HCWs).
- Occupational hazards for HCWs from needlestick and other blood or body fluid incidents include human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus.
- HCWs must report occupational exposures immediately. Treatment protocols should include removal of contaminated clothing and thorough washing of the injured area with soap and water. Affected mucous membranes should be flushed with large amounts of water.
- The exposed person should have a medical evaluation, including information about medications they are taking and underlying medical conditions or circumstances. Postexposure prophylaxis and counselling should be available and offered.
- Patients exposed to blood or other body fluids must be informed of the exposure by a designated professional, while maintaining confidentiality about the source of the blood. Baseline serum should be collected from the patient and expert counselling provided on the implications of what has happened. Patient refusal for testing and serum storage should be documented.
- The person whose blood or body fluids are the source of an occupational exposure or other injury should be evaluated for infection with HIV, HBV and HCV.
- Australian National Council for AIDS, Hepatitis C and Related Diseases (ANCAHARD)[46] published a comprehensive bulletin for the management of exposure to blood/body fluids contaminated with blood, including needlestick/sharp injuries. Bulletin No 16: *Needlestick and Blood Accidents* is attached to this document as Appendix 8 and should be referred used as a guide when establishing an organisational protocol for managing this type of injury.

[46] Formerly knows as Australian National Council on AIDS (ANCA)

23.1 Protocols for needlestick and other blood or body fluid incidents

All health care establishments must develop their own infection control protocols for communicable diseases, including clear written instructions on the appropriate action to take in the event of needlestick and other blood or body fluid incidents involving either patients or HCWs, including:

- the physician, medical officer or other suitably qualified professional to be contacted;
- the laboratory which will process emergency specimens;
- the pharmacy which stocks prophylactic medication; and
- procedures for investigating the circumstances of the incident and measures to prevent recurrence (this may include changes to work practices, changes to equipment, and/or training).

The protocols should also include details for prompt reporting, evaluation, counselling, treatment and follow-up of occupational exposures to bloodborne viruses. Treatment should be available during all working hours, and on call after hours (eg through an on-call infectious diseases physician). HCWs should be educated to report occupational exposures immediately after they occur.

Patients exposed to blood or other body fluids must be informed of the exposure by a designated professional, while maintaining confidentiality about the individual source of the blood. Baseline serum should be collected from the patient and expert counselling provided on the implications of the event. Postexposure prophylaxis and appropriate long-term follow-up should be offered where applicable. Patient refusal for testing and serum storage should be documented. In the event of seroconversion, all reasonable attempts should be made to confirm that the virus strain transmitted is identical in both the patient and the source.

Health care establishments should provide support and counselling, and advise that further counselling can be arranged with occupational health nurses, infection control nurses, infectious diseases physicians or HIV liaison officers at teaching hospitals or sexually transmitted disease clinics.

People nominated to provide support to affected individuals should have an appropriate knowledge of factors concerning transmission of HIV, HBV and HCV, and have counselling expertise. Where this is not possible (eg. in rural and remote areas a person with appropriate knowledge of disease transmission should counsel and support affected individuals.

Note: it is most important that, for confidentiality of the exposed person and the source, individual records must be maintained.

23.2 Definitions

The following body fluids pose a risk for bloodborne virus transmission:

- blood, serum, plasma and all biological fluids visibly contaminated with blood;
- laboratory specimens that contain concentrated virus;
- pleural, amniotic, pericardial, peritoneal, synovial and cerebrospinal fluids; and
- uterine/vaginal secretions or semen.

Affected person — the person exposed to blood or body fluid.

Source individual — the person whose blood or body fluid was inoculated or splashed onto the affected person. The source individual may sometimes not be identifiable, for example, when an affected person has been injured by a needle/instrument and it is not known on whom it was used.

Exposure —an injury that involves direct skin contact with a body fluid listed above and there is compromised skin integrity such as an open wound, abrasion or dermatitis, or if there is direct mucous membrane contact. For exposure to skin, the larger the area of skin exposed and the longer the time of contact, the more important it is to verify that all the relevant skin area is intact.

23.3 Risk of transmission of bloodborne viruses

23.3.1 Human immunodeficiency virus

Prospective studies of HCWs occupationally exposed to human immunodeficiency virus (HIV) have estimated that the average risk of HIV transmission after an exposure to HIV-infected blood is 0.3% (3 in 1000) (Bell 1997, Boaventura 1997, Tokars et al 1993, Patz and Jodrey 1995, Cardo et al 1997) and after a mucous membrane exposure is 0.09% (9 in 10,000) (Ippolito et al 1993) Although there have been cases of HIV infection reported after skin exposure to HIV infected blood, the average risk of HIV transmission after this exposure is extremely low, and no HCWs enrolled in prospective studies have seroconverted after isolated skin exposures (CDC 1998a, Weiss 1988)(see Section 28.7).

Epidemiologic and laboratory studies suggest that the following factors may be associated with an increased risk of HIV transmission (Cardo 1997):

- injury with a device visibly contaminated with blood;
- injury with a hollow bore needle that has been placed directly in an artery or vein of the source patient;
- deep injury to the exposed person; and

- a source patient with advanced HIV disease or high viral load (however, transmission to a HCW has been demonstrated in at least one case from a person with undetectable plasma viral load).

23.3.2 Hepatitis B virus

Hepatitis B virus (HBV) infection is a recognised occupational hazard for workers who are exposed to blood or body fluids (see Section 28.4). In source patients who are positive for HBV surface antigen (HBsAg), transmission rates are much higher than for HIV (about 6–30%), particularly if the source is also HBV e antigen (HBeAg) positive (Zuckerman 1995, Patz and Jodrey 1995).

23.3.3 Hepatitis C virus

Since the introduction of HBV vaccination over the past decade, hepatitis C virus (HCV) has replaced HBV as the most commonly identified cause of viral hepatitis among HCWs (Zuckerman et al 1994, Petrosillo et al 1995) (see Section 28.5). When a source patient is positive for anti-HCV, transmission rates are higher than for HIV. The risk of transmission is relatively low (about 3–10%) in comparison to HBV (Patz and Jodrey 1995).

23.4 Management of the source individual

The person whose blood or body fluids are the source of an occupational exposure or other injury should be evaluated for infection with HIV, HBV and HCV. Information available in the medical record or from the source person may suggest or rule out infection with each virus. If the source is known to have HIV infection, then information on stage of infection and current and previous antiretroviral therapy should be gathered and used in deciding the most appropriate regimen of postexposure prophylaxis (PEP). If the HIV, HBV or HCV status of the source person is unknown, then the source person should be informed of the incident, and their consent sought to test for these viruses, with appropriate pre- and post-test counselling. If consent cannot be obtained, for example if the patient is unconscious, then procedures should be followed which comply with legislation in the relevant State/Territory.

The source individual should be tested as follows at the time of injury:

- HIV antibody;
- HBsAg; and
- HCV antibody.

If the HCV antibody test is positive, then HCV polymerase chain reaction (PCR) should be performed to test for HCV RNA. Transmission is much less likely to occur from a source who is PCR negative.

The status of the source individual may be known at the time of the incident. In this case the affected person should be managed as described in Section 23.1.5. If the source is unknown, the case should be managed as described below.

Source unknown

Reasonable efforts should be made to identify the source. If the source remains unknown, appropriate follow-up should be determined on an individual basis depending on:

- the type of exposure;
- the likelihood of the source being positive for a blood pathogen; and
- the prevalence of HIV, HBV and HCV in the community of the likely source on whom the instrument or needle was used.

23.5 Management of the exposed person

23.5.1 Immediate management

Immediate care of the exposure site

Contaminated clothing should be removed, and the injured area should be washed well with soap and water (an antiseptic could also be applied). Any affected mucous membranes should be flushed with large amounts of water. If the eyes are contaminated, they should be rinsed gently but thoroughly with water or normal saline, while kept open.

Evaluation of the exposure

The exposed person should be examined to confirm the nature of exposure and counselled about the possibility of transmission of bloodborne disease.

Evaluation and testing of the exposed person

The exposed person should have a medical evaluation, including information about medications they are taking and underlying medical conditions or circumstances. All exposed people should be assessed to determine the risk of tetanus. Depending on the circumstances of the exposure, the following may need to be considered:

- tetanus immunoglobulin;
- a course of adsorbed diphtheria tetanus vaccine — adult formulation (Td) vaccine; or

- Td booster.

The current edition of *The Australian Immunisation Handbook* should be consulted for further details (see NHMRC 2000).

The exposed person would normally be tested for HIV antibody, HCV antibody and antibody to HBV surface antigen (HBsAg) at the time of the injury, to establish their serostatus at the time of the exposure. Expert counselling on the implications of the event, PEP and appropriate long-term follow-up should be offered.

An option that may be offered to HCWs who do not wish to undergo testing at the time of the exposure is to have blood collected and stored but not tested. Blood that is collected and stored for this purpose must be retained for a minimum period of 12 months (see Section 22.3.5).

If the source person is found to be HIV, HBV and HCV negative, no further follow-up of the exposed person is generally necessary, unless there is reason to suspect the source person is seroconverting to one of these viruses, or was at high risk of bloodborne viral infection at the time of the exposure. If source is positive for one of these viruses, pregnancy testing should be offered to women of child-bearing age who have been exposed and whose pregnancy status is unknown.

23.5.2 Postexposure prophylaxis (PEP)

Human immunodeficiency virus PEP

Depending on the circumstances of exposure to HIV, and the characteristics of the source, PEP may be either recommended, offered but not actively recommended, or not offered (CDC 1998a).

- ***HIV PEP recommended*** — for percutaneous exposure to potentially infectious blood or body fluids (increased risk of HIV transmission).
- ***HIV PEP offered (but not actively recommended)*** — for ocular mucous membrane or nonintact skin exposure to potentially infectious blood or body fluids (less increased risk of HIV transmission).
- ***HIV PEP not offered*** — for any exposure to non-bloodstained urine, saliva or faeces (not potentially infectious for HIV). bloodstained

As only a small proportion of occupational exposures to HIV result in transmission of the virus, the toxicity of PEP must be carefully considered against its efficacy. The exposed person should be informed of these side effects, and that there are only limited data on the efficacy of PEP. If the exposed person is pregnant, she should be

informed about the available limited data on the toxicity of these drugs in pregnant women.

Choice of drugs

HIV PEP is a complex area of treatment and PEP should only be prescribed by, or after consultation with, a doctor experienced in the use of antretroviral drugs. Currently, most HIV exposures are treated with a two-drug regime (CDC 1997b). As the data for efficacy are strongest for zidovudine (ZDV), also known as azidothymidine (AZT) (Cardo et al 1997) the drugs used are usually ZDV and lamivudine (also known as 3TC). The antiretroviral drug history of the source patient should be considered in making this decision. The addition of a third antiretroviral drug (usually a protease inhibitor) may be considered for exposures that are particularly high risk (CDC 1998a). These are those percutaneous exposures with either high-risk source or injury characteristics such as:

- source characteristics of advanced acquired immunodeficiency syndrome (AIDS), primary HIV infection, low CD4 lymphocyte count and known high viral load; and
- injury characteristics of hollow-bore needle, deep puncture, visible blood on device and needle used in source patient's artery or vein.

Didanosine and ddC currently have no role in PEP.

Timing

The HIV/AIDS Clinical Trials and Treatments Advisory Committee, of the Australian National Council on AIDS and Related Diseases, has recommended that chemoprophylaxis should ideally be started within 1–2 hours of the exposure. However, recent data showing complete viral suppression with triple therapy in primary HIV infection suggest that this therapy can appropriately be considered at any point after exposure. They also suggest that the exposed individual should receive counselling as soon as possible after the exposure, then be offered repeat counselling within 48–72 hours. It must be emphasised that knowledge of the efficacy, short and long-term toxicity of PEP is incomplete and the safety of most of the new antiretroviral agents in pregnancy is unknown. Therapy should be continued for four weeks (CTTAC 1997).

Hepatitis B virus PEP

If the source is positive for HBsAg, then, depending upon the type of exposure, HBV PEP may be considered if the exposed person is not already immune. However, no further action is required if the person is already known to be immune to HBV (antiHBsAg $\geq$ 10 mIU/mL), or if testing within 48 hours of the injury shows the exposed person to be immune to HBV. Testing for hepB e antigen and/or HBV DNA

in persons who are HBS antigen positive can assist in determining risk of transmission.

If the exposed person is not immune to HBV, or is of unknown immune status, then HBV immunoglobulin should be given within 48–72 hours of exposure. In addition, HBV vaccine should be started for HCWs who are susceptible and have not received HBV vaccine. If the exposed person is a known nonresponder to HBV vaccination, then HBV immunoglobulin (HBIG) should be given within 48–72 hours (MMWR 1997); see **Table 22.2**. Blood should be drawn for testing before HBV PEP is given (ATAGI 2000).

Hepatitis C virus PEP

At the time of writing, there is no PEP for HCV. Expert advice should be sought following a needlestick injury. When the donor in a needle stick injury is positive for HCV antibody, HCV RNA testing should be undertaken to assess likelihood of transmission. The option of interferon – ribavirin and prophylaxis is under review.

23.5.3 Postexposure counselling

A specialist with knowledge of bloodborne infections should undertake follow-up. If it is demonstrated that a person has been exposed to a bloodborne pathogen, they should not donate blood, semen, organs or tissue for six months, and should not share implements that may be contaminated with even a small amount of blood (eg razors or toothbrushes). For HIV and HBV, they should be informed of the risk of transmission to sexual and injecting partners for a six-month period, and be counselled about issues of safe sex and safe injecting. If PEP is indicated, or there is a risk of acute infection with HIV, HCV or HBV, advice should be offered on pregnancy and breastfeeding based on an individual risk assessment. In the case of HIV, patients should be advised of the remote risk of seroconversion up to 12 months post-exposure, particularly if specific PEP was undertaken.

23.5.4 Follow-up for the exposed person

If the source person is seronegative for HIV, HbsAg and HCV, baseline testing or further follow-up of the HCW normally is not necessary. If the source person has recently engaged in behaviours that are associated with a risk for transmission of these viruses, baseline and follow-up HIV-antibody testing of the HCW should be considered (See Appendix 8)

23.6 Incidents involving blood or body fluids contaminated with the infectious agent for CJD

23.6.1 Needlestick or other body fluid exposure

If a needlestick or other exposure to blood or body fluids from a patient with known or suspected CJD occurs:

- immediately wash the wound/area with copious amounts of soap and water (Brown et al 1984); and
- report the incident according to normal procedures for the health care establishment.

Washing with sodium hydroxide

Some authorities have suggested using sodium hydroxide (NaOH) to wash areas contaminated with blood or other fluids from patients in a risk group for CJD. NaOH should not be used on the skin as PEP as:

- high concentrations could cause a deterioration of the skin surface allowing further absorption of infectious agents; and
- low concentrations have questionable value against the activity of prions.

23.6.2 Postexposure counselling and follow-up

The exposed person should seek further counselling and information from their employer and general practitioner. For surveillance information see **Section 31.16**. Information may also be obtained from the Commonwealth Department of Health and Ageing (**Freecall: 1800 802 306**).

24 Bloodborne viruses: issues for infected health care workersand students

Key points

- HCWs who undertake exposure-prone procedures are professionally and ethically obliged to know their infectious status for HIV, HBV and HCV and should seek voluntary testing where appropriate.
- HCWs must not perform exposure-prone procedures if they are:
  - human immunodeficiency virus (HIV) antibody positive;
  - hepB e antigen (HBeAg) positive; and/or HBV DNA positive at high titres
  - hepatitis C virus (HCV) antibody positive and HCV RNA positive (by polymerase chain reaction or similar test).
- Under current notification requirements, medical practitioners must notify the chief medical officer or State/Territory health department of cases of HIV, HBV and HCV, either by name or code.
- A medical practitioner may also be legally obliged to bring to the attention of the appropriate registration board any registered professional who is unable to practise competently and/or poses a threat to public safety.
- Similar infection control precautions, professional conduct codes, protection of privacy and confidentiality procedures apply to health care trainees as to qualified HCWs.
- Health care establishments should have comprehensive occupational health programs to manage HCWs with functional impairment from any cause. HCWs who need to modify their work practices because they are infected with a bloodborne virus should be provided, where practical, with opportunities to continue appropriate patient care activities either in their current position or in a redeployed position, or to obtain alternative career training.

24.1 General issues

Concern from both the community and from health care workers (HCWs) about the risk of acquiring bloodborne viruses in health care settings has led to a review of infection control policies and procedures. It has also highlighted the need for national guidelines for HCWs, including students, who may be infected with bloodborne

viruses such as HIV, hepatitis B virus (HBV) or hepatitis C virus (HCV). The rights of both the patient (to know the bloodborne virus status of their HCW) and HCW (to privacy) need to be carefully considered. Measures to protect patients and HCWs should be compatible with existing protection available to citizens under legislation and common law. These measures must also give due consideration to the training and expertise of HCWs infected with a bloodborne virus.

Transmission of bloodborne viruses from HCWs to patients in the health care setting is extremely rare (LaBrecque et al 1986, Bell et al 1995, Health Canada 1998). However, all reasonable measures must be taken to ensure that patients are protected from the risk of acquiring life-threatening infections as a consequence of their treatment, and that HCWs have a safe working environment (ACT Department of Health and Community Care 1999)

Part 4 (Infectious diseases in the health care setting) provides specific information on HBV, HCV and HIV. Reports that there are other hepatitis viruses (eg hepatitis G virus) associated with persistent viraemia and needlestick injury suggest that blanket rules are likely to create many administrative and practical dilemmas. Individual case assessment by State/Territory and/or professional advisory boards is therefore recommended.

Implementation of standard precautions and adoption of nationally recommended procedures for sterilisation and disinfection will minimise the risk of transmission of bloodborne viruses in the health care setting. Additional precautions may be required where there are complicating circumstances, such as HIV-positive patients with infectious pulmonary tuberculosis. Viral co-infections, such as HIV co-infection with HBV and/or HCV can lead to increased individual viral load and therefore infectivity.

Preoperative testing of a patient for infectious agents should be on the basis of clinical indication, and medical practitioners should exercise their professional judgment in ordering any clinically relevant test, with patient consent and appropriate pre and post test counselling.

24.2 Testing and reporting of health care workers

24.2.1 Infectious status

Although there is no mandatory requirement for testing, there is a strong emphasis on the professional and ethical obligations of HCWs who perform exposure-prone procedures to know their infectious status for bloodborne diseases (see Section 24.3).

There is no consensus on how often regular testing should be carried out but it should, as a minimum, be done after an incident occurs (eg sharps injury). All HCWs should assess their individual risk of exposure to bloodborne viruses, including HIV, HBV

and HCV, and seek voluntary testing where appropriate. In addition, HCWs who have completed their full course of hepatitis B virus immunisation should seek post immunisation testing to identify poor responders. The current edition of *The Australian Immunisation Handbook* should be consulted for further details (NHMRC 2000).

Testing of patients, although commonly perceived as a means of identifying the level of risk, does not diminish the risk, and is not a substitute for infection control. HIV testing does not take into account the problem of the window period for HIV, when a patient may be infectious but this is undetectable by testing. The window period for HIV is usually three months but it can, very rarely, be longer (Petersen 1994, Ciesielski and Metter 1997). Delayed seroconversion was reported eight months after a needlestick injury to a hospital cleaner in France (Meyohas et al 1995). The use of polymerase chain reaction (PCR) testing for HIV/viral RNA can identify 90% of infections within four weeks, significantly reducing this waiting period.

Routine screening has other disadvantages. For HIV testing, nonspecific reactivity in enzyme-linked immunosorbent assay (ELISA) testing will occur much more frequently than true positive results in the Australian population, which has a very low prevalence of unidentified HIV-infected people. In addition, reliance on testing may diminish emphasis on more important strategies that prevent cross-infection, such as standard precautions.

24.2.2 Responsibilities of infected health care workers

HCWs have an obligation to care for the safety of others in the workplace (this includes fellow workers and patients) under both common law and also the *Occupational Health and Safety and Welfare Act 1986*.

24.2.2.1 Nominated Risk Categories

HCWs must not perform exposure-prone procedures if they are:

- human immunodeficiency virus (HIV) antibody positive;
- hepB e antigen (HBeAg) positive; and/or HBV DNA positive at high titres. The titre of HBV DNA that represents significant risk has not been identified with certainty. The UK Department of Health suggested that greater than 1000 genome equivalents per mL represents a risk (see next Discussion Point) It is likely that further information will be forthcoming in this area.
- hepatitis C virus (HCV) antibody positive and HCV RNA positive (by polymerase chain reaction or similar test).

In most States/Territories bloodborne viruses (BBV) such as human immunodeficiency virus (HIV/AIDS), hepatitis B (HBV) and hepatitis C (HCV) are all legally notifiable diseases and should be notified to the Chief Health Officer or State/Territory health department by name or by code (see **Appendix 2**).

A HCW infected with a BBV should be assessed in consultation with their treating medical practitioner who should make a recommendation about the continued involvement of the HCW in direct patient care. The practitioner should also determine (and make recommendations to the employer) about the infected HCW's -

- capability of performing to the accepted professional standard without compromising the safety of others or themselves in the workplace; and
- ability to continue to comply with State/Territory health regulations.

A HCW who undertakes exposure-prone procedures (see Section 4.3.2 and Glossary for definition) and who is infected with a BBV should modify their work practices so that they no longer participate in EPPs where there is established evidence of a risk of transmission of infection from HCW to patient. They should also undergo frequent medical follow-up by a medical practitioner with appropriate experience. The HCW and/or the medical practitioner may seek confidential advice from a relevant registration board (medical, nursing, dental etc) and/or a State/Territory health department review panel (see Section 24.3 on HCWs who undertake exposure-prone procedures).

HCWs with a BBV are not excluded from employment or functions they can safely perform under policies in place in the facility. However, HCWs infected with a BBV have a clear responsibility to –

- know their infectious status; and
- follow the treatment recommendations of the medical practitioner; and
- modify their involvement in direct patient care to eliminate Exposure Prone Procedures ().

When a HCW (infected with a BBV) accepts these responsibilities, routine disclosure to patients of an individual HCW's infectious status is unnecessary as standard infection control procedures continue to apply in the workplace. There is no increased risk that patients may acquire a BBV from a HCW when standard infection control procedures are applied.

A policy that provides for patients to be informed of an individual infected HCWs status may lead to public confusion about the real and perceived risk of transmitting a BBV between HCW and patient. Maintaining confidentiality should encourage HCWs

to seek appropriate testing, counselling and treatment and disclose their serological status to their employers. There is no onus of confidentiality on a patient who is informed about the infectious status of a HCW.

HCWs could respond to questions about their own health (from people in their workplace) by stating that infection control procedures are in place to protect both HCWs and patients.

24.2.3 Responsibilities of medical practitioners caring for infected health care workers

To conform to present legislation, medical practitioners are legally required to notify the chief medical officer or State/Territory health departments of cases of HIV, HBV and HCV either by name or code (see **Appendix 2**). In addition, the medical practitioner may also be legally obliged to bring to the attention of the appropriate registration board (medical, nursing, dental etc) any registered professional person who is unable to practise competently and/or poses a threat to public safety. Applicable State/Territory legislation must be followed in these instances.

Decisions about the working practices of an HCW infected with a bloodborne virus are complex. Treating medical practitioners may seek expert opinion to assist them by requesting the relevant State/Territory health department to convene an expert panel. This panel should comprise medical practitioners who have relevant experience with patients with the particular bloodborne virus, as well as an expert in infection control and an HCW from the same profession as the infected worker who is familiar with the work practices the HCW is engaged in. The treating medical practitioner may describe the medical and occupational context to the panel to gain advice. The infected HCW should not need to be identified during the initial investigation of potential risk.

Confidential advice may also be sought from the relevant professional registration board involved, although the identity of the HCW should be formally notified to this board only when it is established that the HCW is placing patients at risk of infection with a bloodborne virus. In the case of HCWs not covered by a registration board, treating doctors should direct general inquiries to an appropriate authority (usually the State/Territory medical board or chief health officer).

Treating medical practitioners should not notify employers of the bloodborne virus status of the HCW unless the HCW gives their consent for this to occur. When appropriate, treating doctors should counsel the infected HCW to help them make an appropriate choice about employment. The treating medical practitioner should also take into account the psychosocial needs of the HCW and refer as appropriate for specialist counselling and support.

The medical practitioner caring for the HCW who may be immunodeficient should determine when the level of immunocompromise is significant, and should maintain a high index of suspicion for the appearance of opportunistic infection in the HCW.

24.2.4 Responsibilities of health care establishments

Health care establishments should have comprehensive occupational health programs in place to manage HCWs with functional impairment from any cause. Such programs should evaluate workers' fitness for duty based on competence, ability to perform routine duties and compliance with established guidelines and procedures. Confidentiality must be maintained. HCWs may prefer to consult a medical practitioner outside their workplace, in order to separate occupational health and documentation of clinical care. Confidentiality for the HCW infected with a bloodborne virus not only safeguards personal rights, but is also in the public interest.

It is the responsibility of the HCW's employer (including self-employed HCWs), in consultation with registration boards or health department expert panels, to ensure that HCWs, with consent, have access to appropriate testing, counselling and immunisation programs. Relevant documentation, including written consent, must be maintained for specific screening and immunisation activities.

For their own protection, HCWs with significant immunodeficiency from any cause should not be involved in the care of patients with certain communicable diseases — for example, tuberculosis, varicella-zoster virus, and cytomegalovirus (CMV). Immunodeficient HCWs should also be advised on the possible risks of live vaccines, including Bacille–Calmette Guerin (BCG) vaccine, that are available for HCWs in health care establishments.

Confidentiality and counselling

Confidentiality for any HCW infected with a bloodborne virus not only safeguards personal rights, but is in the public interest. The right to confidentiality will encourage HCWs to seek appropriate testing, counselling and treatment and to consider disclosure of their serologic status to their employers.

Counselling should be offered pre- and post-testing.

24.3 Health care workers who undertake exposure-prone procedures

24.3.1 Infectious status

HCWs undertaking exposure-prone procedures have an ongoing responsibility to know their infectious status for HIV, HBV and HCV, and should not perform exposure-prone procedures where there is established evidence of a risk of

transmission of infection from HCW to patient (see definition of exposure-prone procedures in Section 4.3).

HCWs who engage in exposure-prone procedures should be encouraged to seek routine testing if they believe they are at risk of occupational or other exposures. In particular, HCWs who perform exposure-prone procedures should be encouraged to have voluntary testing if they are:

- untested and presently performing exposure-prone procedures;
- about to begin performing exposure-prone procedures;
- involved in a significant occupational exposure to blood or body substances;
- involved in a significant nonoccupational exposure to blood or body substances (including needle sharing or unprotected sexual intercourse with an individual infected with HIV or HBV, or with a person at increased risk of HIV); and/or
- untested for 12 months.

A significant exposure includes needlestick injuries when deep penetration through skin or mucous membrane, injection of blood or large-bore hollow needles are involved. Other exposure, such as superficial needlesticks, mucosal exposure and contamination of nonintact skin, should be assessed by a clinician to determine if the exposure is considered significant.

If there is any uncertainty about the level of risk involved, the matter should be referred to State/Territory and/or professional advisory boards or in accordance with local legislation/regulations for individual assessment.

Human immunodeficiency virus

Individuals with HIV test results that have been confirmed as positive by a State/Territory reference laboratory must not perform any procedure where there is a significant risk of HIV transmission. All exposure-prone procedures pose significant risks of HIV transmission. In some States/Territories, an HIV-infected HCW will be excluded from performing any exposure-prone procedures. Where there is any uncertainty about the level of risk involved, individuals should be assessed by a State/Territory and/or professional advisory board on a case-by-case basis to determine their continuing participation or modification of work practices.

Hepatitis B virus

HCWs who test positive for hepatitis B virus surface antigen (HBsAg) should seek the advice of a State/Territory health and/or professional advisory board before they perform exposure-prone procedures.

HCWs who test positive for HBeAg must not perform exposure-prone procedures, as people with HBeAg pose a higher risk of infection to contacts than those who are HBsAg positive but HBeAg negative (Zuckerman 1995).

It has also been suggested that viral load, measured by a nucleic acid amplification test, can also be used as an indicator of infectivity for HCWs that are HBsAg positive but HBeAg negative (see discussion point below).

DISCUSSION POINT

Hepatitis B viral load and exposure-prone procedures

Recently, the United Kingdom Department of Health issued a circular outlining the need to further test HBsAg-positive but HBeAg-negative HCWs, and exclude those with a viral load (HBV DNA) of greater than 1000 genome equivalents per mL from performing exposure-prone procedures (NHS Executive London: Department of Health 2000). This United Kingdom circular also suggests retesting all HBsAg-positive but HBeAg-negative HCWs with a viral load of less than 1000 genome equivalents per mL every 12 months, as viral loads may fluctuate over time.

However, these suggested viral load levels are not yet conclusive as a measure of potential infectivity. Other factors such as antiviral treatment may also affect infectivity.

Hepatitis C virus

HCWs with HCV viraemia (ie HCV antibody-positive and PCR-positive) must not perform exposure-prone procedures, as in this situation there is a risk of transmission of infection. Individuals with indeterminate HCV antibody test results should not be excluded from performing exposure-prone procedures on the basis of test results alone. If HCV antibody results are positive or indeterminate, however, HCWs should be clinically assessed by an experienced medical practitioner, over a reasonable period of time, for any sign of current/active infection. Where there is insufficient evidence of current/active infection, the treating medical practitioner, or the individual concerned, should seek the advice of State/Territory and/or professional advisory boards or in accordance with local legislation/regulations.

The situation should be reviewed once further information becomes available about the real risk of inoculation injury of surgeons performing exposure-prone procedures and the risks to patients if infected HCWs perform exposure-prone procedures.

Treatments

Treatments of hepatitis B, HIV and hepatitis C infection has changed the outcome, chronic carriage rate and probably the risks of infection transmission in the setting of blood or body fluid exposure. These factors should also be added to the assessment of the treated HCW with blood born virus infection.

24.4 Assistance for HCWs who have occupationally acquired a bloodborne virus

HCWs whose work practices have been modified because of infection with a bloodborne virus should be provided, where practicable, with opportunities to continue appropriate patient care activities in either their current position or in redeployed positions, or to obtain alternative career training. Health care establishments should consider whether the redeployed post should be 'equivalent' to the previous position and, if so, in what respects.

Health care establishments should address the question of when (or if) treated HCWs who have been infected with HCV and become PCR negative, in conjunction with negative test results from other methods that indicate viral clearance, should be allowed to return to performing exposure-prone procedures. This is also an issue for HCWs with HBV who were previously HBeAg-positive or PCR-positive, but who subsequently become negative for these parameters.

Visiting medical officers and agency nurses who become infected due to occupational exposure should be eligible for assistance under the same conditions as permanent employees.

24.5 Lookback investigations of patients cared for by HCWs infected with a bloodborne virus

Selective lookback investigations should be considered when there is evidence of significant breakdown of standard infection control practices (such as the presence of exudative dermatitis) during the time the HCW was probably infected with the bloodborne virus, to ensure that those cared for were not placed at risk. Current evidence suggests that, in most circumstances, the benefit from lookbacks may be low, but each case should be assessed individually.

Lookback investigations are described in more detail in Section 21.5.

Compliance

States and Territories should have systems in place to ensure compliance with these recommendations.

24.6 Recommendations for HCW students

HCW students should be subject to the same infection control and professional conduct requirements as qualified HCWs and their health status should be accorded the same protection of privacy and confidentiality. Students should not be placed in

risk-exposure situations. Training institutions should develop strategies that allow students to acquire clinical skills without risk to themselves or other people.

Immunisation and testing for BBVs

HCW students are at increased occupational risk for some vaccine preventable diseases. Training institutions should ensure that all HCW students are immunised according to the Special *Risk Group* recommendations in *The Australian Immunisation Handbook 7th Edition* (NHMRC 2000). Students should understand the importance of voluntary testing for BBVs and their ongoing obligation to know their infectious status.

Counselling for students

Courses that provide training in careers that involve invasive procedures should include information, counselling, opportunities for testing and career advice. Pre and post-test counselling should be provided to students who undertake voluntary testing for BBVs. Post-test counselling for students who test positive (for a BBV) who are involved in exposure prone procedures should include career advice and alternative programs for consideration. Consideration should be given to placing some limitations on the subsequent registration (conditional registration) of those students infected with a BBV who agree to a modified program, eg, people infected with a BBV should not perform exposure-prone procedures. Medical students infected with a BBV should be allowed to complete their degree (AMA 1997).

Training institutions should offer support and counselling services to students, including processes for dealing with illness, impairment or disability that may prevent a student from completing their course. Each training institution should clearly outline any course requirements that could be affected by the student's infectious status. The policies and implications of any disability or impairment (including risks to themselves and their patients) should be explained to students *before* admission to the course.

25 Blood and blood products for transfusion

Key points

- Premises where blood is collected for the preparation of plasma supplied to a fractionation centre must operate to agreed standards of good manufacturing practice and be licensed.
- Maintenance of the sterility chain throughout the process of blood collection, blood processing, storage and distribution is essential to minimise blood component contamination. Specimens of blood should be appropriately handled to eliminate or minimise the possibility of inadvertent health care worker or public contact with blood.
- Within Australia, every blood donation collected by the Australian Red Cross Blood Service is currently screened for: human immunodeficiency virus-1 (HIV1) and HIV2 antibodies; hepatitis B virus surface antigen (HBsAg); hepatitis C virus antibody; human T-cell leukemia virus-1 (HTLV-1) antibody; and syphilis.
- Accumulating epidemiological information and laboratory studies have indicated that transmission of the classical forms of the Creutzfeldt–Jakob (CJD) infectious agent by blood products is highly unlikely. However the bovine spongiform encephalopathy (BSE or 'mad cow') epidemic in cattle in the United Kingdom raised new concerns with the emergence of vCJD. In September 2000, Australian Commonwealth and State/Territory health ministers agreed to place a temporary ban on blood donations from people who have resided in the United Kingdom for a cumulative period of six months or more between 1980 and 1996.

25.1 Introduction

Maintenance of the sterility chain throughout the process of blood collection, blood processing, storage and distribution is essential to minimise blood component contamination. This section reviews the specific infection control principles in relation to blood and blood components, including risk reduction strategies. The general principles of infection control should also be applied in this setting.

The potential for the spread of infectious disease though blood transfusion has always been recognised. Syphilis and hepatitis were shown to be transmissible by blood. The use of cold storage and the development of serological tests have decreased the risk of syphilis considerably. The realisation that pooled plasma and fractionated albumin transmitted hepatitis led to Cohn's fractionation method for albumin, incorporating

terminal pasteurisation of the albumin solution to inactivate the infectious agent. This was the first deliberate viral inactivation step in the manufacture of a blood product and it remains a benchmark for safety.

In the 1960s, the infectious agent associated with the main form of transfusion-transmitted hepatitis, then called 'serum hepatitis', was recognised and was later shown to be a virus, which was designated hepatitis B virus (HBV). This virus fortunately has the property of generating a large excess of serologically detectable antigen — the so-called 'Australia antigen' — in its early replication phase. The ability to screen blood for the antigen using increasingly sensitive test methods significantly reduced the disease as a transfusion risk in developed countries. It also highlighted the existence of a smaller incidence of parenterally transmitted hepatitis, which could not be detected and excluded using the HBV antigen test.

Years of investigation and the application of molecular techniques allowed the characterisation and testing of the commonest non-B parenteral hepatitis virus — hepatitis C virus (HCV) — leading to the development of increasingly sensitive tests to considerably decrease this virus as a transfusion risk. Similarly, the diagnostics industry was able to rapidly use the knowledge of the replication and culture of human immunodeficiency virus (HIV) to develop serological tests for the detection of infected donors. This led to a large drop in the incidence of transfusion-associated acquired immunodeficiency syndrome (AIDS), a situation that was further enhanced with the development of improved assays based on synthetic antigens. Some blood services went further and screened for the antigen associated with HIV in order to decrease the 'window period' of infectivity between infection and the development of serologically detectable antibody.

Recent developments in molecular testing techniques have led to the introduction of nucleic acid amplification testing (NAT) for the detection of viral agents in blood. Using this methodology, viral gene sequences are probed and amplified, allowing detection of minute amounts of viral genome at a time before conventional serological markers are detectable. Most health services in developed countries have introduced NAT for HCV. NAT screening for HIV will also soon be a standard of best practice. No doubt other viruses will eventually be screened using this technology. However, these methods are not a substitute for, but a supplement to, current testing regimens.

Scientific advancements in testing and manufacturing chemistry have greatly decreased the infectious risk of blood. Blood donor medical examination and questioning have been mainstay practices of blood banking for many years. It must be recognised that blood today is safer than it has ever been with respect to infectious risks. Nevertheless, pressures brought about by public and political perceptions demand higher and higher safety levels. It is crucial that in pursuing very small reductions in risk from hypothetical risk factors such as the variant form of Creutzfeldt-Jakob disease (vCJD; see **Section 25.5.6**), the blood industry does not introduce additional

risks. While vCJD is a hypothetical and unquantifiable risk, HIV and HCV are real risks with potentially lethal side effects from transfusion with infected blood.

25.2 Regulatory requirements

Under the provisions of the Commonwealth *Therapeutic Goods Act 1989*, premises where blood is collected for the preparation of plasma supplied to a fractionation centre must be licensed. Licences are approved if the blood collection centre producing the source plasma is operating to the agreed standards, which are detailed in the *Australian Code of Good Manufacturing Practice for Therapeutic Goods, Blood and Blood Components* (TGA 1995). The code covers every aspect of manufacture, process control and quality assurance. The Therapeutic Goods Administration (TGA) has recently extended its remit to include fresh blood components, and the revised code (combined Human Blood and Tissue Code) is currently undergoing industry consultation.

The two main areas of international regulatory guidance in blood products are the Food and Drug Administration (FDA) in the United States and the European Medicines Evaluation Agency (EMEA) in Europe. The FDA has jurisdiction over fresh blood components as well as plasma derivatives. The EMEA has jurisdiction over plasma derivatives, while national authorities in Europe are responsible for fresh components.

25.3 Bacterial contamination

Bacterial contamination of blood components was one of the earliest recognised complications of blood transfusion, and it remains a cause of severe transfusion reactions (Goldman and Blajchman 1991, Wagner et al 1994, Hogman and Engstrand 1998). These reactions are more common with platelet transfusions, because room temperature storage permits the proliferation of many bacterial species. The majority of organisms isolated from contaminated platelet concentrates are gram-positive and are part of the normal flora that are thought to enter the bloodbag during venesection (Hogman and Engstrand 1998). Bacterial contamination causing serious septic complications is very rare after red cell transfusion, with approximately half the reported cases being secondary to *Yersinia enterocolitica*. *Y. enterocolitica* contamination probably occurs via donor leucocytes harbouring living infectious agents, which are released when the leucocytes disintegrate. *Y. enterocolitica* can grow well at 4°C and produce a potent endotoxin (Hogman and Engstrand 1998). For both components, the risk increases towards the end of the stored blood shelf life. It is important to consider potential sources of contamination, and implement strategies to reduce transfusion-associated sepsis.

All areas where blood collection, processing, testing, handling and/or storage activities are conducted must be kept clean to minimise microbial load in the environment.

25.3.1 Blood donor selection

Most bacteraemic people are symptomatic and therefore are not usually eligible as blood donors. Occasionally however, 'well' blood donors have episodic bacteraemia, which may occur during the incubation or recovery period from a bacterial illness, during chronic low-grade infection, or may be associated with minor procedures such as dental work.

Blood collection centres must have:

- donor selection guidelines that minimise potential donor bacteraemia, based on medical history and behavioural assessment; and
- a system to allow feedback from donors about postdonation illness (which may result in recall of potentially bacterially contaminated blood components).

25.3.2 Blood collection

Contamination of blood collected in recycled glass bottles has become much less common since the introduction of single-use integrally connected plastic bloodbags (closed systems) and rigorous control of manufacturing (Hogman and Engstrand 1998). Although rarely observed, contamination has been reported from inadequately sterilised bloodbags or bloodbag overwraps (Wagner et al 1994). To minimise the risk of contamination at the time of blood collection, meticulous attention must be paid to disinfection and the use of sterile equipment.

Blood collection centres must ensure that:

- health care workers (HCWs) performing venepuncture are appropriately trained;
- the venepuncture site on the donor's arm, usually the antecubital fossa, is free of any skin lesions, rash or scarring that could cause contamination of the blood unit;
- the venepuncture site is thoroughly cleaned and disinfected using a validated procedure (Goldman et al 1997);
- care is taken not to touch the cleaned venipuncture site before needle insertion;
- blood is collected into an approved bloodbag that is listed on the Australian Register of Therapeutic Goods (ARTG L), is pyrogen-free and sterile and contains sufficient anticoagulant for the quantity of blood to be collected;

- bloodbags and apheresis solutions must be stored according to manufacturers' instructions (TGA 1995); and
- items used during the venepuncture process should be sterile, and where possible single use and disposable.

Gloves must be worn in the following situations:

- for any contact with blood, body substances and mucous membranes, including handling blood or blood-soiled equipment or items and cleaning up blood spills;
- when a HCW who is involved in a possible blood contact has broken skin;
- whilst a HCW is receiving training in venesection;

25.3.3 Blood processing

Blood that will be used for component preparation should be collected into a primary bloodbag with integrally attached satellite bags, so that the contents are not exposed to air or outside elements during preparation and separation of components (ie closed system). Sterile connection docking devices allow the system to be entered and bloodbags and tubing to be introduced without breaking the integrity of the system. The shelf life of the components prepared in this way is the same, in general, as those prepared in a regular closed system. Sterile connection docking devices must be validated and kept clean. If the airtight system is entered, it becomes an open system and the allowable storage times change. Components stored at 2–8°C must be used within 24 hours, or within four hours if stored at 20–24°C (American Association of Blood Banks 1996).

Unless protective shielding is in place, protective eyewear or face-shields must be worn in the following situations:

- when using equipment containing blood under pressure (eg plasma expressors);
- when using heat sealers; and
- when there is a risk of splashing, splattering or spraying of blood or body substances to the face during any procedure or situation.

25.3.4 Bacteriological screening

Microbial contamination testing should be carried out periodically in order to verify the continuing reliability of the quality process (TGA 1995). Where contamination is demonstrated, records must show action has been taken to identify the contaminant and its possible source.

25.3.5 Blood component storage and transport

Refrigeration or freezing minimises proliferation of bacteria that might have entered the unit during venepuncture or were present in the circulation of the donor. Maintaining the temperature of whole blood at up to 24ºC for a short period after collection may reduce bacterial contamination because active leucocytes present in the blood have a clearing effect on contaminating bacteria (Hogman et al 1993).

Blood components need appropriate storage and transport conditions and must meet the conditions outlined in the current *TGA Code of Good Manufacturing Practice for Therapeutic Goods – Blood and Blood Components* (TGA 1995).

Blood should be stored in monitored refrigerators in accordance with AS 3864.[46] Recording thermographs or suitable electronic continuous recording equipment and audible alarms should be installed for all blood storage equipment. The alarm signal must be activated at a temperature that allows HCWs to take proper action before the stored blood reaches undesirable temperatures.

25.3.6 Thawing of frozen plasma

Fresh frozen plasma for transfusion must be thawed either in a water bath at temperatures between 30°C and 37°C, in a nonwater contact bath (which is better than a simple water bath) or in an approved purpose-built microwave device (Goldman and Blajchman 1991). Caution must be taken to maintain sterility when thawing plasma products in a water bath:

- disinfect and empty the waterbath frequently and after any blood spillage (surveillance cultures may be needed to verify a low microbial load); and
- avoid water contamination of bloodbag entry ports by wrapping bloodbags in plastic overwrap or by positioning them upright with entry ports above the water level; and
- bags should be dried with a lint free cloth before use.

25.3.7 Pretransfusion inspection of blood components

All blood and blood components should be inspected before issue for transfusion. Blood collection centres should be notified if contamination is suspected or confirmed. The appearance of red cell components may be altered when bacterial contamination is present (Wagner et al 1994). Unusual appearances may include:

[46] AS 3864 (1997) and Amendment 1 (1998) *Medical refrigeration equipment – For the storage of blood and blood products*

- segment colour much lighter than that of the bloodbag;
- red cell mass more purple or darker than usual;
- zone of haemolysis just above cell mass;
- visible clots;
- murky or discoloured plasma; or
- presence of blood or plasma in the ports or at sealing sites in the tubing, which suggests inadequate sealing or closure.

Bacterial contamination of platelets should be suspected if:

- there are grossly visible aggregates; or
- there has been cessation of platelet 'streaming' or 'swirling'.

The tubing and plastic bag of frozen plasma products should be checked for cracks.

25.3.8 Contamination of bloodbag surfaces

Care must be taken to prevent any substances or dirty or moist surfaces coming into contact with bloodbags, as the plastics used are permeable to some substances. Where a bloodbag surface is contaminated with blood, this may be removed by wiping the bag with lint-free cloth dampened in water, then wiping the bag with alcohol. Bloodbags that are grossly contaminated should be discarded and, where possible, the source of the contamination should be identified and removed.

The plastics used to manufacture the bags for blood and blood product and other intravenous fluids are permeable to some chemicals such as the inks used in felt tipped pens and glues used for labelling. The label only should be written on, as required, and the use of paper strips for infusion times is recommended.

25.3.9 Unused bags of blood or blood products

Unused bags of blood and blood products should be returned to the ARCBB, checked for integrity and, where possible, reissued. Care in the handling of these bags (when not required for a patient) will ensure that their contents are not unnecessarily wasted due to careless handling.

25.4 Viral contamination

Although the safety of the transfusion blood supply has improved dramatically over the past 15 years, there are still risks of infection associated with blood transfusion. In

addition to improvements in donor selection and laboratory testing, there is a need for identifying, developing and implementing methods to inactivate or deplete viruses in blood products.

25.4.1 Donor selection

The guidelines for selection of blood donors developed by the Australian Red Cross Blood Service (ARCBS) assist its HCWs to determine the appropriateness of collecting blood from potential donors and are based on both medical history and lifestyle factors. The decision to accept a blood donation is based on both the safety of the person donating the blood and the safety of the individual receiving the blood. The guidelines are regularly reviewed and updated.

25.4.2 Laboratory screening

Within Australia, every blood donation collected by the ARCBS is currently screened for:

- HIV1 and HIV2 antibodies;
- HBV surface antigen (HBsAg);
- HCV antibody;
- human T-cell leukemia virus-1 (HTLV-1) antibody; and
- syphilis.

The major risk of transfusion-transmitted infection results from the collection of a unit of blood during the infectious window period for these agents. This window period represents the time in early infection when the virus is circulating in the blood but conventional tests are unable to detect viral antigens or antibodies. The window period can be reduced by NAT, including polymerase chain reaction (PCR) or transcription-mediated amplification. Both these procedures amplify segments of viral nucleic acids to the level at which they can be readily detected and NAT procedures for HIV and HCV have been introduced by Australian Blood Banking Services.

25.4.3 Viral inactivation of fresh frozen plasma

There are two alternatives to fresh frozen plasma (FFP) that are provided by some international blood services in an attempt to improve viral safety: however, both have significant limitations. The solvent–detergent (SD) method uses the organic solvent TNBP (tri-*n*-butyl-phosphate) with the nonionic detergent Triton X-100 to disrupt the lipid-containing structures in enveloped viruses, which, as a consequence, lose their infectivity (Edwards et al 1987, Hellstern et al 1992). SD-prepared plasma is manufactured from pools of ABO blood group-specific plasma, from up to 2500 donors. The moderately large numbers of donations pooled to produce SD-plasma

theoretically will increase the risk of transmission of agents not inactivated by the SD process, or of those not neutralised by passive cotransfusion of pathogen-specific antibody. Adding to the potential concern regarding safety are the significant costs of SD-plasma.

Treatment of plasma with methylene blue (MB), a phenothiazine dye, and irradiation with visible light inactivates a wide range of enveloped and nonenveloped viruses. MB binds to nucleic acids, especially guanine residues, by virtue of its highly cationic nature. Illumination leads to the generation of local reactive oxygen species, especially local singlet oxygen, which are the active principles of the photo-oxidative MB viral inactivation process (Eimer and Kelly 1993, Muller-Breitkreutz and Mohr 1995, Muller-Breitkreutz et al 1995). MB-plasma does not require pooling of donations, and thus avoids the risk of potential increase in overall viral transmission rates from transfusion. The MB technique is, however, prone to technical failure and its metabolites are potentially genotoxic.

These products are not currently available in Australia because of the above limitations combined with a poor cost–benefit ratio. This situation is regularly reviewed by ARCBS.

25.4.4 Decontamination of cellular blood components

Over the past 10 years, methods for inactivation of infectious pathogens in cellular components have been extensively investigated.

Development of decontamination processes with activity against a broad array of infectious pathogens, irrespective of type, would provide a measure of safety against transfusion-associated infectious agents undetected by current pretransfusion tests. This could potentially protect against new viral pathogens entering the donor population before effective donor screening assays can be implemented. Several potential inactivation technologies for treatment of platelet concentrates have been described, including psoralens activated with long-wavelength ultraviolet light, merocyanine 540 activated with visible light and phthalocyanines activated with ultraviolet B without a photoactive agent. Several other technologies, such as hypericum, ozone and MB have been applied to red cells. To date only one of these systems (noval psoralen S-59) has begun clinical trials (Corash 1999).

25.4.5 Handling and transport of blood specimens

Specimens of blood should be appropriately handled to eliminate or minimise the possibility of inadvertent HCW or public contact with blood, as follows.

- Specimens should be placed in a leak-proof, sealable primary container: snap-top closures should be avoided. The specimen's primary container should then be transported within a secondary container.
- Request slips should be protected from contamination. The use of a double-compartment clear plastic bag is recommended.
- HCWs receiving specimens should examine all containers for leaks. If outside contamination of the primary container occurs it should be appropriately cleaned.
- If a request form, or paperwork associated with a specimen, is contaminated, it should be placed in a clear plastic bag and a photocopy taken. The copy should then be annotated and the original safely discarded.
- Specific warning labels on specimens collected from patients with known infectious diseases, such as HIV, are not recommended, on the basis that all specimens should be regarded and treated as infectious and to protect the confidentiality of patients.
- Specimens for transport between institutions should be packed and labelled in compliance with the carrier's conditions, government and postal regulations and International Air Transport Association (IATA) regulations, whichever is appropriate.

25.5 Contamination with the infectious agent for CJD

Accumulating epidemiologic information and laboratory studies have indicated that transmission of the classical forms of the CJD infectious agent by blood products is highly unlikely. However, the emergence of vCJD has raised new concerns (see **Section 25.5.6**). Detailed information about CJD is in **Section 31**.

25.5.1 Epidemiological evidence

Five published case–control studies have analysed over 600 CJD cases. None of these studies showed that blood transfusion increased the risk for CJD (Esmonde et al 1993b, Wientjens et al 1996, van Duijn et al 1998). Investigations of recipients of blood components from known CJD donors have not revealed transmission of the CJD agent (Heye et al 1994, Evatt et al 1998), although these cohort studies are limited by the small numbers of such recipients. Because of the need for long-term follow-up, the value of these studies is likely to be limited unless there is a high transmission rate.

National mortality surveillance performed by the United States Centers for Disease Control and Prevention (CDC) indicates that patient populations with increased

exposure to blood or blood products are not at increased risk of CJD (Holman et al 1997). During an 18-year period (1979–96), 4468 cases of CJD were reported to CDC. When death records were searched, none of these cases were reported to have had haemophilia, thalassaemia, or sickle cell disease. More directed evaluation of people with haemophilia has not shown a link to CJD.

In one study, brain tissue from 24 haemophiliacs who died with neurologic disease was examined: none had evidence of CJD (Evatt et al 1998). In a second study, brain tissue from 33 haemophiliacs in the United Kingdom, who died of various causes, was examined, and none had evidence for CJD (Lee et al 1998). Additional surveillance of cryoprecipitate recipients is under way in Seattle in the United States. In 1997, no CJD cases had been reported among 101 patients who together received over 238,000 units of cryoprecipitate between 1979 and 1985: 76 of these subjects are alive between 12.5 and 18.5 years later (CBER 1999). Three of these recipients were known to have received at least one unit of cryoprecipitate from donors known to have developed CJD.

25.5.2 Laboratory studies

Whilst some laboratory experiments have demonstrated that manufacturing significantly lowers the amount of the CJD infectious agent in plasma derivatives, others have shown that blood and plasma fractions from experimentally infected animals transmit CJD to recipient animals when directly injected into the brain, but not through transfusion of blood (Brown et al 1994, 1998, Brown 1995).

25.5.3 Donor selection

Despite the evidence cited above, policies are in place for the exclusion of donors at risk of developing CJD (see **Section 31.9**). However, this is done more on the basis of collecting blood from healthy individuals than because of any perceived risk of CJD transmission by blood. ARCBS permanently defers donors with:

- a diagnosis or family history of transmissible spongiform encephalopathies, including CJD, fatal familial insomnia (FFI) and Gerstmann–Sträussler–Sheinker (GSS) disease;
- donors with possible exposure through treatment with pituitary hormones, including growth hormone and gonadotrophins; and
- recipients of dura mater grafts or corneal grafts (ARCBS 1998).

This is consistent with international practice. In the United States, the FDA requires ‘indefinite’ deferral of donors with a family history of CJD and individuals with a possible exposure through treatment with pituitary hormones, including growth

hormone and gonadotrophins, and recipients of dura mater grafts (ARCBS 1998). The European position permanently defers such individuals (Council of Europe 1995).

25.5.4 Plasma fractionation

Plasma derivatives are unlikely to transmit disease in humans because:

- a CJD-implicated plasma unit would be diluted into a large plasma pool, leading to a low number of infectious units in a dose of the final product;
- intravenous and intramuscular inoculation alone is less efficient than cerebral inoculation for CJD transmission; and
- further processing of plasma pools by Cohn's fractionation and manufacturing processes such as column chromatography, precipitation, and filtration, have been shown to diminish titres of CJD-like agents in spiking experiments using scaled-down manufacturing procedures (TSEAC 1998).

25.5.5 Recall policies

Currently, if a donation from a high-risk CJD donor is included into a pool for manufacture of plasma products, a product recall is not required. Recall of any fresh components from the donor is advisable, however, if the products are still in-date.

The FDA's original guidance required recall of both plasma products and fresh components (CBER 1996). However, this was modified (CBER 1998) to restrict plasma product recall to cases of vCJD (see Section **25.5.6**), but the recall provisions for in-date fresh components were maintained. Thus recall is mandatory for fresh components (such as whole blood) and cellular products if they are still in-date when a donor is identified as being at risk of CJD. The modification of the FDA's policy for plasma products brought the FDA in line with the European policy as stated by the European Medicines Evaluation Agency (EMEA), which has never required recall of plasma products because of CJD (EMEA 1995).

A similar policy for fresh components is followed by most individual national health authorities in Europe, and is reflected in World Health Organization (WHO) consensus statements. This policy is also followed by the ARCBS. As the impact on the blood supply of such a recall is significantly less than a recall of plasma products, this policy is reasonable.

It remains to be seen whether the modification of the FDA's recall policy is reflected in practice. Some European authorities decided to recall plasma products when a CJD donor had contributed to the pool, despite the EMEA's policy.

25.5.6 Variant CJD

The risk of transmission of vCJD by blood or blood products has not been accurately determined although the risk is currently being evaluated by laboratory and epidemiological studies. This new variant (vCJD) appears to be distinct from the classical forms of CJD, both clinically and biologically, and therefore transmissibility cannot confidently be predicted from studies of cCJD. Experimental studies have raised concerns about the potential for the vCJD agent to be transmitted by blood (Houston et al 2000; see **Section 31.7**). A precautionary policy is therefore warranted until more is known about the possibility of vCJD transmission by blood components or plasma derivatives.

Donor selection

As vCJD has so far only significantly affected the United Kingdom, some countries have revised their blood donor policies to exclude donors who have resided in the United Kingdom. Such policies assumed a high profile with the decision by the United States to defer 'indefinitely' donors who have resided in the United Kingdom for a six-month period during 1980–96. This policy was immediately mirrored by Canada (Therapeutic Products Program) and New Zealand followed shortly thereafter. In Australia in September 2000, the Commonwealth and State/Territory health ministers agreed to place a temporary ban on blood donations from people who have lived in the United Kingdom for more than a six-month period during 1980–96. The risks in relation to vCJD will be kept under review by a special expert committee of the NHMRC established to monitor the condition.

Recall policies

Both the FDA and the EMEA require product recall if plasma products are manufactured from a pool subsequently shown to include a vCJD donation (CBER 1999, CPMP 1998). This policy extends to excipients included in certain biological drugs.

The policy for recalling fresh components is the same as for CJD.

25.6 Emerging infectious agents

ARCBS constantly monitors scientific developments in this area and actively reviews donor selection guidelines, testing strategies and communication with stakeholders to ensure the safety of the Australian blood supply.

26 Organs and tissues for transplantation

Key points

- A wide variety of organs and tissues is transplanted in Australia, including kidney, heart, liver, lungs, pancreas, cornea, bone, bone marrow and placental cord blood. The Transplantation Society of Australia and New Zealand has produced guidelines for the solid organs, cornea and bone, but not for stem cell transplantation by bone marrow or cord blood.
- Transplant recipients vary from patients who need urgent transplantation to save their lives to patients for whom transplantation is not essential but would offer an improved quality of life. The risks that these groups are prepared to face differ significantly.
- A range of testing procedures to screen donors of vascularised organs for hepatitis A, B and C virus infection should be considered so that a decision to transplant or not can be based on the status of the donor and recipient.
- To reduce the risk of transmission of Creutzfeldt–Jakob disease (CJD), people in a risk category for the disease (see **Section 31.10**); people who die in psychiatric hospitals; and people who die with any obscure undiagnosed neurological disorder should be excluded from the routine donation of organs and tissues. If the recipient is elderly, however, has been fully informed of the risk, and the purpose of the transplant procedure is a matter of life or death, tissue donation from a person in the lower-risk CJD group may be used.

26.1 Introduction

A wide variety of organs and tissues are transplanted in Australia, including kidney, heart, liver, lungs, pancreas, cornea, bone, bone marrow and placental cord blood. Guidelines produced by the Transplantation Society of Australia and New Zealand (TSANZ)[47] cover the solid organs, cornea and bone, but not stem cell transplantation by bone marrow or cord blood (HSA/ASBT 1985, TSANZ 1989).

Transplant recipients vary considerably in the seriousness of their underlying organ failure. At one extreme, a patient with hepatic coma in intensive care and a patient on a mechanical ventricular-assist device to maintain cardiac output are both in urgent need

[47] http://www.racp.edu.au/tsanz/index.htm

of transplantation as the only alternative to death. However, the majority of patients on the waiting lists have less urgent needs (eg stable renal dialysis patients, or those with chronic liver failure or cardiac failure). However, 7–20 % of these 'less urgent' patients will also die each year awaiting transplants. Some patients, such as those waiting for a corneal graft, do not have a life-threatening condition, but transplantation would offer substantial improvements to their quality of life.

The risks that each group is prepared to face in order to receive a transplant therefore vary considerably. A patient with fulminant hepatic failure and hepatitis B virus (HBV) infection would probably accept an HBV-infected, but functioning liver. A patient with a less urgent condition, on the other hand, would not want to be exposed to any substantial risk of infectious disease transmission.

It should also be noted that in some instances, the avoidance of infectious disease from some organ donations requires a more stringent standard than for blood. HBV is transmitted from an HBV surface antigen (HBsAg)-negative, HBV core antibody (HBcAb)-positive donor liver in a high proportion of cases (Radomski et al 1996, Van Thiel et al 1999) but is not transmitted with the same frequency from a heart or a kidney from the same donor (Wachs et al 1995).

Transplant recipients are preferably accommodated in single rooms but do not require positive pressure room ventilation unless they are allogeneic bone marrow recipients.

26.2 Donor selection

26.2.1 Hepatitis B virus

Liver donors

All potential liver donors must be tested for HBsAg and HBcAb. All donors positive for either test should be excluded as donors for HBV-negative recipients, other than in exceptional circumstances (when urgent patients are listed for transplantation). Donors positive for HBsAg represent the highest risk for transmission. HBcAb-positive donors should be considered for HBsAg-positive recipients in transplant units with protocols that use lamivudine and HBV immunoglobulin cover for transplantation (Dodson et al 1999, Meisel et al 1999, Van Thiel et al 1999).

Heart, lung, kidney, pancreas or other vascularised organ donors

All potential donors of hearts, lungs, kidneys, pancreas or other vascularised organ donors (except liver – see above), must be tested for HBsAg. Organs from HBsAg-positive donors must not be used for HBsAg-negative recipients. There is no current evidence of transmission of HBV by HBsAg-negative donors in Australia. There is a single case report of 1 in 42 kidney recipients of HBcAb-positive HBsAg-negative

kidneys becoming infected with HBV (Madayag 1997). There is insufficient information at this time to change the current practice of HBsAg testing only.

Nonliver organ recipients from donors known to be HBsAg-negative but HBcAb-positive, should ideally be immune and/or immunised against HBV and must be transplanted only after specific consent has been obtained.

Banked and nonvascularised tissue

All donors of banked and nonvascularised tissue, including cornea, bone and heart valve must be tested for HBsAg and should be tested for HBcAb (testing of donors is due to be introduced in 2001). The nonurgent and nonlife-threatening nature of the indications for tissue transplantation mean that all donors positive for HBsAg represent a potential risk for transmission of HBV and their tissues must not be used. Donors negative for HBsAg but positive for HBcAb represent an unknown risk for the transmission of HBV (Satterthwaite et al 1997) and their tissues should not be used other than in exceptional circumstances. If tissues from positive donors are considered then prophylactic treatment of the recipient should be considered, and consent must be obtained.

Summary recommendations for hepatitis B-infected organ donors and recipients are shown in **Table 26.1**.

Table 26.1 Summary recommendations for hepatitis B-infected organ donors and recipients

Organs/tissues	Testing required	Donor	Recipient	Recommendation
Liver	HBsAg and HBcAb	HBsAg and/or HBcAb-positive	HBV-negative	Not recommended (except in exceptional circumstancs)
		HBcAb-positive	HBsAg-positive	Possible in units that use lamivudine and HBV immunoglobulin cover for transplantation
Heart, lung, kidney, pancreas and other vascularised organs	HBsAg	HBsAg-positive	HBsAg-negative	Not recommended
		HBsAg-negative	Any	Recommended
		HBsAg-negative/ HBcAb-positive (if known)[a]	Any	Possible for immune and/or immunised recipients with specific consent
Banked and nonvascularised tissues	HBsAg and HBcAb	HBsAg-positive	Any	Not recommended
		HBsAg-negative HBcAb-positive	Any	Not recommended except in exceptional circumstances with prophylactic treatment and specific consent.

HBsAg = HBV surface antigen; HBcAb = HBV core antibody

[a]Testing for HBcAg is not recommended for nonliver transplant donors or recipients at this stage.

Sources: HAS and ASBT 1985; Transplantation Society 1989; TSANZ 1989

26.2.2 Hepatitis C virus

Transmission risk from organ donors

Organ donors in the United States have a mean prevalence of being anti-hepatitis C virus antibody (anti-HCVAb)-positive of approximately 5% (Pereira et al 1994). A similar level is found in Australian or New Zealand donors. These figures are significantly greater than random blood donors (0.3%) (Mison et al 1997, Whyte and Savoia 1997, Tanaka et al 1998).

Not all anti-HCVAb-positive subjects are currently HCV infected. It has been estimated that approximately 50% of HCVAb-positive organ donors are HCV polymerase chain reaction (PCR) test-positive (Pereira et al 1994, Pessoa and Wright 1997). Only donors who are positive for HCV RNA (by PCR test) have been shown to transmit infection (Dore et al 1997) and up to 100% of PCR-positive donors

transmit infection to recipients (Pereira et al 1994). There is no demographic data to distinguish anti-HCVAb-positive/PCR-positive versus anti-HCVAb-positive/PCR-negative subjects (Pereira et al 1994).

Nonliver allograft recipients

There is evidence that HCV-infected kidney and cardiac allograft recipients have a significantly worse long-term outcome following transplantation than do HCV noninfected patients (Mathurin et al 1999). There are, however, some short-term studies that do not show this. Only preliminary data are available on cardiac transplants (Roth et al 1994). There are no data yet on lung transplants. It is difficult to distinguish from the literature HCV-positive subjects who were anti-HCVAb-positive before transplant from those who acquired the infection post-transplantation.

Natural history of HCV infection after liver transplant

There is data that HCV infection in this setting may result in significant liver disease. However, five-year survival rates do not, as yet, show significant differences between anti-HCVAb-positive and anti-HCVAb-negative recipients (Gane et al 1996, Everhart et al 1999). Emerging data suggest that patients with higher pretransplant and post-transplant viral loads have worse outcomes (Charlton et al 1998). Earlier data indicated that patients with genotype 1b who required liver transplant also had worse outcomes (Gane et al 1996) but this has not been supported in all studies.

Use of HCV-positive liver allografts

There are data that suggest that recipients of HCV-positive liver allografts do not have a worse outcome (Testa et al 1998). Indeed, when HCV-positive grafts are transplanted into HCV-positive recipients with different genotypes, the recipients who develop the donor genotype have a better outcome (Vargas et al 1999).

A summary of recommendations for the use of HCV-positive organs or tissues is shown in **Table 26.2**.

Table 26.2 Summary of recommendations for hepatitis C-infected organ donors and recipients

Organs/tissues	Donor	Recipient	Recommendation
All tissues: heart, kidney, lung, pancreas, liver	anti-HCVAb-positive	anti-HCVAb-negative	Not recommended
All tissues: heart, kidney, lung, pancreas, liver	anti-HCVAb-positive	anti-HCVAb-positive, PCR-negative	Not recommended
Nonliver	anti-HCVAb-positive	anti-HCVAb-positive, PCR-positive	May be considered following specific consent
Liver	anti-HCVAb-positive	anti-HCVAb-positive, PCR-positive	May be considered following specific consent

anti-HCVAb = anti-HCV antibody; HCV = hepatitis C virus; PCR = polymerase chain reaction

Source: HAS and ASBT 1985; Transplantation Society 1989; TSANZ 1989

26.3 Creutzfeldt–Jakob disease and transmissible spongiform encephalopathies

To reduce the risk of transmission of CJD, the following people should be excluded from the routine donation of organs and tissues:

- people in the higher and lower-risk groups (see **Section 31.9** for risk group definitions);
- people who die in psychiatric hospitals, with the exception of those in whom CJD has been specifically excluded; and
- people who die with any obscure undiagnosed neurological disorder, including dementia (AGMPSE 1981, (Lazarus 1993).

Agencies that are responsible for recruiting organ/tissue donors, and for the banking of tissues (eg corneas, heart valves, skin) should be aware of the risk of CJD and should have criteria and procedures in place for exclusion of tissues from individuals in the above groups (Busch et al 1997, Eastlund 1995, Hogan 1999, Lazarus 1993).

In all cases where materials for transplantation, grafting or tissue banking are derived from postmortem material, it is strongly recommended that the brain of the donor be assessed and cleared by a specialist neuropathologist. Paraffin blocks of brain tissue from such donors should be archived for future reference. It is likely that rapid screening tests based on immunoassays for PrP^{Sc} will become available in the near future.

Materials from the above patient groups should not be used for the preparation of any therapeutic products or laboratory reagents (eg thromboplastin or Kveim test material) (de Silva and Will 1993, du Bois et al 1993). The question of organ donation

from people at risk of variant CJD, such as those who have lived in the United Kingdom for over six months between 1980 and 1996, is currently under review.

Part 4

Managing Infectious diseases in the health care setting

27 Overview of diseases

Key points

- Any strategy used for infection control should be based on the use of standard precautions, as a minimum level of control, supplemented by additional precautions where standards precautions may be considered insufficient to prevent infection.
- Additional precautions are based on three specific routes of disease transmission (airborne, droplet and contact). Infection control practices for each specific disease must take account of its mode of transmission.

27.1 Introduction

This part of the guidelines includes specific information on diseases that may be encountered as health care associated infections in the health care setting. It contains comments and guidelines on the prevention of transmission of infection, health care worker (HCW) protection issues related to the management of patients with these diseases, and preventive measures for patients and HCWs at particular risk of serious infection.

27.2 Infection control strategy

As outlined in **Section 2** of these guidelines, effective infection control involves a two-tiered approach:

- *standard precautions* for the basic level of infection control (recommended for the treatment and care of all patients – see **Section 2.2**); and
- *additional precautions* for situations where standard precautions may be insufficient to prevent transmission of infection (recommended for specific patients known or suspected to be infected or colonised with highly transmissible pathogens that can cause infection in health care settings — see **Section 2.3**).

The level of precaution required is based on modes of transmission of infectious agents. Standard precautions provide adequate protection for bloodborne diseases and additional precautions relate to three specific routes of transmission:

- airborne transmission;

- droplet transmission; and
- contact transmission.

Table 27.1 shows the three modes of transmission for which additional precautions are required and examples of diseases requiring them. An outline of the procedures involved is given in **Section 2.3**.

Table 27.1 Examples of diseases requiring additional precautions, by mode of transmission

Mode of transmission	Examples of diseases
Airborne transmission	Tuberculosis — suspected or confirmed Varicella (chickenpox)[a] Viral haemorrhagic fevers, eg Ebola fever[b]
Droplet transmission	*Neisseria meningitidis* septicaemia/meningitis[c] Whooping cough (caused by *Bordetella pertussis)* Influenza[d] Measles[a] Parvovirus B19 infection Respiratory syncytial virus infection Rubella[a] Group A streptococcal infections in infants and young children Group A streptococcal pneumonia or scarlet fever in all age groups[c]
Contact transmission (direct or indirect contact with dry skin or contaminated surfaces)	Resistant bacteria (MRSA, VRE and others named by infection control committee)[d] Herpes simplex (neonatal or mucocutaneous) Highly contagious skin infections/infestations (ie impetigo, scabies, pediculosis [lice])[d] Varicella (chickenpox)[a] Zoster (shingles), localised and dissseminated[a] Infants/young children (less than six years), or any incontinent patient with: – enteroviral infection – hepatitis A – rotaviral enteritis, shigellosis, giardiasis or other forms of gastroenteritis

HCW = health care worker; MRSA = methicillin-resistant *Staphylococcus aureus*; VRE = vancomycin-resistant enterococci; VZV = varicella-zoster virus

[a] All HCWs should know their VZV, measles, mumps and rubella immune status (only immune HCWs should care for these patients)

[b] Additional precautions (contact transmission) also apply for these diseases

[c] Droplet transmission precautions for meningococcal infections only need to be continued until the patient has had 24 hours of effective antibiotic treatment. The same applies for Group A streptococcal infections, as far as pharyngeal carriage is concerned. However, Group A streptococcal infections may need to be isolated in special circumstances, such as burns units, until there is evidence of clearance of the organism from the burn.

[d] Refer to specific local policy.

27.3 Diseases for which specific information is included

Not all diseases have been included in **Table 27.1**. The list includes those that have a high risk of transmission in the health care setting, and those that, although rarer, have major implications for public health.

The following viral diseases are described in further detail in **Section 28**:

- cytomegalovirus infection
- infectious mononucleosis (glandular fever)
- viral hepatitis (hepatitis A, hepatitis B, hepatitis C)
- herpes simplex infections
- human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS)
- influenza
- measles
- parvovirus B19 infection
- respiratory syncytial virus infection
- rotaviral enteritis
- rubella
- chickenpox (varicella) and shingles (zoster)
- viral haemorrhagic fevers (Lassa fever, Marburg haemorrhagic fever, Ebola haemorrhagic fever, Crimean–Congo haemorrhagic fever)

The following bacterial diseases are described in **Section 29**:

- gastroenteritis and enteric diseases
- legionellosis
- listeriosis
- meningococcal infection
- whooping cough (caused by *Bordetella pertussis*)
- staphylococcal infection
- streptococcal infection
- tuberculosis

Diseases associated with the following antibiotic-resistant bacteria are considered in **Section 30**:

- methicillin-resistant *Staphylococcus aureus* (MRSA);
- vancomycin-resistant *Enterococcus faecium* and *E. faecalis* (VRE: van A and van B types);
- multidrug-resistant *Mycobacterium tuberculosis*; and
- multiresistant gram-negative bacilli.

Creutzfeldt–Jakob disease (CJD) is considered in **Section 31**. Other diseases (scabies, pediculosis, etc) are considered in **Section 32**.

An overview of recommended precautions for all these diseases is shown in **Table 27.2**.

Table 27.2 Precautions for preventing transmission of infectious diseases

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Viral diseases				
Cytomegalovirus (CMV) infection	Contact (mucosal contact with infectious tissues, secretions and excretions)	Standard precautions and basic hygiene Immunodeficient HCWs should be permitted to minimise contact with known CMV-infected patients	Inform of risks and give opportunity to be tested for susceptibility Counsel about hygiene and permit to minimise contact with CMV-infected patients Seronegative pregnant HCWs may be redeployed to care for patients unlikely to be excreting CMV	Pregnant HCWs may be tested to determine their susceptibility
Infectious mononucleosis (glandular fever)	Contact with saliva (via oropharyngeal route)	Standard precautions and basic hygiene	NA	NA
Hepatitis A	Contact (faecal–oral route)	Standard precautions for continent patients Additional precautions (contact transmission) for incontinent patients — a single room with ensuite toilet is desirable Infected HCWs should avoid contact with nonimmune patients and HCWs	NA	Immunise HCWs at high risk
Hepatitis B	Bloodborne (direct contact with blood or body substances)	Standard precautions	NA	Immunise all HCWs, particularly clinical contact and laboratory staff Test for seroconversion after 3 months. Reimmunise if seronegative or if poor serological response (ie <10 IU/L) HCWs performing EPP have a responsibility to know their HBV status Blood incident testing protocol applies[b]
Hepatitis C	Bloodborne (direct contact with blood or body substances)	Standard precautions	NA	HCWs performing EPP have a responsibility to know their infectious status for HCV Blood incident testing protocol applies[b]

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Herpes simplex virus infection	Contact (droplet spread by direct contact or indirectly by fomites or by contact with infected lesions)	Standard precautions Additional precautions (contact transmission) for patients with lesions disseminating infectious virus HCWs should cover vesicular lesions. When lesions uncovered, exclude HCW from contact with neonates or immuno-compromised patients, and from operating rooms and delivery suite	NA	
HIV/AIDS	Bloodborne (direct contact with blood or body substances)	Standard precautions Additional precautions may be required where complicating conditions (eg tuberculosis) are present. Chemoprophylaxis should be considered after needlestick injury.	In cases of needlestick injury, counsel pregnant HCWs about risks of using zidovudine (ZDV)	HCWs performing EPP have a responsibility to know their HIV status Blood incident testing protocol applies[b]
Influenza	Respiratory (droplet spread)	Additional precautions (droplet transmission) Single room or cohort placement in cases of outbreaks, particularly for children and elderly patients Infected HCWs should not be in contact with patients	NA	Annual immunisation is recommended for HCWs
Measles	Respiratory (droplet spread and direct contact with infected throat or nasal secretions) Highly communicable	Additional precautions (droplet transmission), with a well fitting P2 particulate respirator to be worn A negative pressure single room, with the door closed, for infected patients during infectious period Preclude nonimmune exposed HCWs from direct patient contact from 5 days after first exposure until 21 days after last exposure (see **Table 22.2**) Infected HCWs should be precluded from contact with susceptible persons until 7 days after rash appears (see **Table 22.2**)	MMR should not be given to pregnant women and women should avoid pregnancy for 2 months after immunisation	Screen by verbal medical history. Nonimmune HCWs should be offered MMR vaccine

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Parvovirus B19 infection	Respiratory (droplet spread)	Additional precautions (droplet transmission) for infected people and those at high risk of complications of infection Infected HCWs should take sick leave or be rostered to avoid contact with patients	Roster to avoid contact with infected patients during the first half of the pregnancy term of nonimmune HCWs	NA
Respiratory syncytial virus infection	Contact (direct oral or indirect with fomites) Respiratory (droplet spread)	Additional precautions (droplet and contact transmission) — isolate patients from other at-risk patients and cohort manage Infected HCWs should take sick leave or be rostered to avoid patient contact	NA	NA
Rotaviral enteritis	Contact (faecal-oral route) Respiratory (droplet spread)	Additional precautions (contact transmission) — patients should be isolated from other at-risk patients Hyperimmune bovine colostrum should be given to all patients in ward if several other patients are infected Infected HCWs should be precluded from contact with at-risk patients	NA	NA
Rubella	Respiratory (droplet spread) Contact spread	Additional precautions (droplet transmission) and single room. Preclude nonimmune exposed HCWs ifrom direct patient contact from 7 days after first exposure until 21 after last exposure (see **Table 22.2**) Infected HCWs should avoid contact with susceptible persons until 5 days after rash appears (see **Table 22.2**)	Risk to nonimmune pregnant HCWs (congenital deformities in foetus), so roster to avoid contact with rubella-infected patients MMR should not be given to pregnant women; pregnancy should be avoided for 2 months after immunisation	Screen by verbal medical history and serology Nonimmune HCWs should be offered MMR vaccine Test for seroconversion two months after immunisation and reimmunise if seronegative

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Chickenpox and shingles (varicella–zoster)	*Chickenpox:* Respiratory (airborne) Contact *Shingles (localised):* Contact *Shingles (disseminated):* Respiratory (airborne) Contact *Chickenpox and shingles in immunocompromised patients*: Respiratory (airborne) Contact	Additional precautions (airborne and contact transmission for chickenpox or disseminated shingles; contact transmission for localised shingles) Preclude nonimmune exposed HCWs from direct patient contact from 10 days after first exposure to 21 days after last exposure (see **Table 22.2**) Infected HCWs should avoid contact with susceptible persons until all lesions are dry (see **Table 22.2**) Immunodeficient HCWs should not be involved in the care of varicella-zoster-infected patients	Avoid contact unless immune Vaccine should not be given during pregnancy and vaccinees should not become pregnant for 1 month after immunisation	Screen by verbal medical history and serology. Nonimmune nonpregnant HCWs should be offered varicella vaccine Nonimmune pregnant HCWs should be offered ZIG
Viral haemorrhagic fevers (VHF)	Mucosal or parenteral exposure to contaminated blood or other body fluids Lassa fever also transmitted by aerosols of contaminated body fluids	Contact State/Territory quarantine officer. Additional precautions (airborne and contact transmission) — all specimens from patients with a suspected VHF should be handled at PC4[c] Advice on management of patients and their body fluids should be obtained from State/Territory health authorities	Roster to avoid contact with a possible or confirmed VHF case	NA
Bacterial diseases				
Gastrointestinal infections	Contact (faecal–oral route) Airborne transmission of viral gastrointestinal pathogens	Standard precautions Additional precautions (contact transmission) for incontinent patients — a single room with ensuite toilet is desirable Infected HCWs or food handlers with diarrhoea should take sick leave	NA	NA
Legionellosis	Aerosolised contaminated water (not person to person)	Standard precautions	NA	NA
Listeriosis	Usually via contaminated foods	Standard precautions – ensure hygienic food handling practices are maintained	Pregnant HCWs should avoid contact with potentially infective materials and foods	NA

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Meningococcal infection	Respiratory (droplet spread from nose or throat)	Additional precautions (droplet transmission) for 24 hours after beginning treatment Standard precautions once treatment is initiated Rifampicin or related compounds recommended for close contacts (eg. mouth-to-mouth resuscitation of an infected person)	Rifampicin not recommended for use in pregnant women	Routine immunisation not recommended for HCWs, except in case of outbreaks
Whooping cough (*Bordetella pertussis*)	Respiratory (droplet spread)	Additional precautions (droplet transmission) – single room for known cases for at least 5 days after the start of antibiotic treatment. Exclude suspected cases from contact with young children and infants, particularly those not immunised HCWs with pertussis should avoid contact with susceptible patients until five days after the start of effective antibiotic therapy	NA	Vaccine available, but not recommended for people over 8 years of age
Staphylococcal infection	Contact and droplet	Additional precautions (contact transmission) for MRSA — clean gloves and gown, dedicated or disposable equipment, single room with its own bathroom facilities or cohort patients infected with same strain HCWs with sepsis should be excluded from clinical contact and food preparation unless lesions fully covered. HCWs with predisposing skin conditions should be rostered away from patients with staphylococcus infection	NA	Routine screening for non-MRSA not warranted Screen HCWs for exfoliative skin conditions

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Streptococcal infection	Respiratory (droplet spread)	Standard precautions. If patient is excreting large amounts of the organism, a separate room with its own toilet and bathing facilities should be used. If patient has respiratory tract infection, implement additional precautions (droplet transmission) Cover lesion and provide clinical contact HCWs with systemic and local treatment. HCWs with acute streptococcal pharyngitis should receive antibiotic treatment and be rostered off duty for at least the first 24 hours of treatment	NA	NA
Tuberculosis	Respiratory (airborne spread)	Additional precautions (airborne transmission) – use a P2 particulate respirator (see **Section 29.8**) Negative pressure single room (see State/Territory tuberculosis guidelines) Tuberculin skin test-positive HCWs (with no previous history of a BCG) should be followed up with a chest X-ray and clinical review	NA (BCG administration is not recommended during pregnancy)	Pre-employment and exit screening (tuberculin skin test recommended) Regular screening for tuberculin skin test--negative HCWs depending on level of risk BCG of uncertain value but may be offered to tuberculin skin test-negative HCWs
Transmissible spongiform encephalopathies				
CJD	Contact with infected CNS or neural tissue Health care associated transmission has occurred via corneal graft, dura mater grafts, neurosurgical instruments and from CJD-contaminated human pituitary hormones Zoonotic spread from BSE (vCJD)	Additional precautions Reusable instruments must be destroyed by incineration, or cleaned, reprocessed and quarantined Details of management procedures are given in **Section 31**	NA	Developments in screening and testing are still at an early stage
Other diseases				

Disease	Mode of transmission	Recommended precautions	Precautions for pregnant HCWs	Immunisation [a] and testing
Scabies	Contact (direct skin-to-skin)	Additional precautions (contact transmission) apply for at least 24 hours after beginning appropriate treatment HCWs with scabies should be rostered to avoid patient contact for 24 hours after beginning appropriate treatment	NA	Consider treating on admission all patients from communities with endemic scabies
Pediculosis (head & body lice)	Contact (direct skin-to skin, hair brushes and accessories)	Additional precautions (contact transmission) apply for at least 24 hours after beginning appropriate treatment HCWs with pediculosis should be precluded from direct patient contact until effective treatment has been undertaken (see **Section 32.2**)	NA	Consider treating on admission all patients from communities with endemic pediculosis

AIDS = acquired immunodeficiency syndrome; BCG = Bacille Calmette-Guerin vaccine); BSE = bovine spongiform encephalopathy; CJD = Creutzfeldt–Jakob disease; CNS = central nervous system; EPP = exposure-prone procedures; HBsAg = hepatitis B virus surface antigen; HCV = hepatitis C virus; HCW = health care worker; HIV = human immunodeficiency virus; HSV = herpes simplex virus; MMR = measles-mumps-rubella vaccine; MRSA = methicillin-resistant *Staphylococcus aureus*; NA = not applicable; TSE = transmissible spongiform encephalopathy; ZDV = zidovudine; ZIG = varicella zoster virus immunoglobulin

[a] **Immunisation:** Some details are provided in the text of **Sections 28-29**. For further details and the most up-to-date advice, see the latest edition of *The Australian Immunisation Guidelines* (currently ATAGI 2000).

[b] **Blood incident testing protocol:** Following significant exposure to blood or potentially blood-contaminated secretions, test source for HBsAg, anti-HCV antibodies and anti-HIV antibodies and recipient for antiHBsAg antibodies, anti-HCV antibodies and anti-HIV antibodies. Retest the recipient at one, three and six months (see **Section 23**).

[c] PC4 = Physical Containment Level 4 [see AS/NZS 2243.3 (1995) and Amendments 1 (1996) and 2 (1998) *Safety in laboratories – microbiology*]

28 Viral diseases

Key points

- The major viral diseases of concern in the health care setting are cytomegalovirus infection, infectious mononucleosis (glandular fever), viral hepatitis (caused by hepatitis A, B and C viruses), herpes simplex virus infection, human immunodeficiency virus infection, influenza, measles, parvovirus B19 infection, respiratory syncytial virus infection, rotaviral enteritis, rubella, chickenpox (varicella), shingles (zoster) and viral haemorrhagic fevers.
- Many of these viral diseases are widespread in the community and are not significantly more common in the health care setting. However, without effective infection controls, they may be readily transmitted from patient to patient and, to a much lesser extent, from patient to health care worker and vice versa.
- For some viral diseases, susceptibility is universal, whereas for others, specific groups are at higher risk, including those without immunisation or naturally acquired immunity, immunocompromised patients, the elderly or the very young.
- In all instances of viral diseases in the health care setting, standard precautions and procedures are required. However, in many specific circumstances, additional precautions and procedures are needed. Management of patients, HCWs, instruments and environment varies according to the source of infection and mode of transmission of each viral disease.

28.1 Cytomegalovirus infection

28.1.1 Disease description

Aetiology

Disease is caused by infection with human cytomegalovirus (CMV), which is a herpesvirus.

Clinical manifestations

In most healthy adults, CMV infection is subclinical, but occasionally CMV produces illness similar to glandular fever. If pregnant women become infected there is a small

but significant possibility of foetal damage (Hatherley 1985). CMV (especially primary infection) can cause severe and life-threatening problems in immunosuppressed patients (de Jong et al 1998).

Most neonatal infections are asymptomatic.

Occurrence

CMV is likely to be encountered both in the community and in hospitals. Any age group may acquire the virus. All people, irrespective of age, gender or illness, can excrete virus. About 40% of adults in developed countries and almost 100% of the adult population in developing countries are seropositive (Chin 2000).

Thirty per cent of women of child-bearing age in Australia are seronegative for CMV and thus susceptible to primary CMV infection in pregnancy (Sfameni 1986).

Generally, CMV infection in HCWs, even those working in high-risk areas such as neonatal units, transplant units and those caring for HIV-positive patients, is not significantly more common than that in the general community (Demmler et al 1987). After primary infection, young children excrete CMV in urine and saliva in larger amounts and for longer periods than do adults. There is a high incidence of asymptomatic excretion of CMV among infants and toddlers. For this reason, isolation of children known to be excreting CMV is not recommended. To avoid CMV infection, washing hands after all patient contact and after contact with urine and saliva is essential. Avoidance of direct contact with saliva (eg kissing toddlers on the mouth) is also important.

28.1.2 Transmission

Source of infection

Virus is excreted in urine and saliva for many months after primary infection, and may be shed continually or intermittently for many years by symptomatic patients or asymptomatic carriers. CMV is also excreted in milk, cervical secretions and semen, and may be present in blood. After perinatal or neonatal infection, virus may be shed for up to six years (Chin 2000). Adults tend to excrete the virus for shorter periods but latent infection is common.

Mode of transmission

CMV is transmitted by mucosal contact with infected tissues and body fluids. The foetus may be infected in utero or the infant may acquire the disease perinatally. CMV-seronegative women who care for children over the age of two years have a lower risk of infection than when caring for younger children (Adler 1985, Adler 1989).

High rates of transmission of CMV from infants to adults and cross-infection between children in day care centres have been recorded (Adler 1989). Studies of CMV infection rates among hospital workers have not convincingly demonstrated an increased risk for workers in nurseries for newborns or on paediatric wards (Yeager 1975, Ahlfors et al 1981, Dworsky et al 1983). However, one study (Friedman et al 1984) describes a significantly higher seroconversion rate among nurses working in an intensive care unit of a children's hospital.

Risk of acquisition

All seronegative HCWs are at risk of infection, although most infections are asymptomatic. However, if the HCW is pregnant, consequences to the fetus may be severe. The highest-risk groups for serious disease caused by CMV are: infants born to carrier mothers, patients with debilitating diseases, those being treated with immunosuppressive drugs and those with congenital or acquired immunodeficiency disorders.

28.1.3 Management

Patients

Because there are difficulties in detecting excretors, and because simple hygiene and standard precautions prevent infection of HCWs and patients, the emphasis for control should be placed on education in hygiene rather than on screening of patients.

Health care workers

Immunodeficient and pregnant HCWs should be informed of the risks of CMV infection, and advised to avoid direct and prolonged contact with CMV infection (eg where a person is known to be excreting CMV). However, it is not practicable to identify all such patients, as only a small proportion of antibody-positive patients excrete the virus.

Infection of HCWs with CMV is largely preventable by applying standard precautions (see **Section 2.2**), including the use of gloves and regular handwashing (Pomeroy and England 1987). Pregnant HCWs and those who work in childcare units should be provided with an opportunity to determine their susceptibility by antibody testing. They should be counselled about hygiene and permitted, but not required, to minimise contact with known CMV-infected patients. See **Section 22.4.3** for further details on pregnant HCWs.

CMV-seronegative women who care for children over the age of two years have a lower risk of infection (Pass et al 1990, Bale et al 1999). Rostering seronegative pregnant employees to care for older children may therefore further minimise their risk.

CMV immunoglobulin is available for the prevention and treatment of CMV infection in certain individuals at high-risk of infection. However, its value is unclear.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.2 Infectious mononucleosis (glandular fever)

28.2.1 Disease description

Aetiology

Disease is caused by infection with Epstein–Barr virus (EBV), which is a human herpesvirus.

Clinical manifestations

The disease is an acute illness. Typical clinical symptoms include fever and sore throat. Recovery normally occurs within a few weeks, but a small proportion of patients may take several months to recover fully.

Occurrence

About 80% of young adults are immune, having previously acquired infection asymptomatically. However, a proportion of HCWs, particularly those in the 18–25 year age group, is susceptible to EBV infection.

28.2.2 Transmission

Source of infection

EBV is present in saliva and may be excreted during, or for a prolonged period (more than a year) following, either symptomatic or asymptomatic infection.

Mode of transmission

Close contact is usually required to transmit infection.

Risk of acquisition

All nonimmune people are at risk of infection. Most adults are immune, although a proportion of younger adults may be susceptible.

28.2.3 Management

Patients

Standard precautions should be observed (see **Section 2.2**).

Health care workers

HCWs should employ standard precautions. There is no need to restrict HCWs with active glandular fever from direct patient care (see Health Canada 2000 [draft])

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.3 Hepatitis A

28.3.1 Disease description

Aetiology

Disease is an acute hepatitis caused by the hepatitis A virus (HAV).

Clinical manifestations

Initial symptoms include fever, lethargy, anorexia, nausea and abdominal pain, usually followed within a few days by jaundice. Incubation is 15–50 days depending on the dose (average 28–30 days). Many infections, particularly in children, are asymptomatic and are only diagnosed by laboratory testing. The disease ranges from a mild illness lasting a few weeks to, in rare cases, a severely disabling disease lasting several months. Although severity of symptoms increase with age, the mortality rate is low (< 1/1000) and patients usually recover without sequelae or recurrence of disease. In general complete recovery takes several months (Chin 2000).

Occurrence

HAV is a hepatotropic virus. The disease is likely to be encountered both in the community and in hospitals and may occur as sporadic cases or epidemics.

28.3.2 Transmission

Source of infection

Patients excrete the virus and are infectious during the incubation period and for about a week after jaundice presents. Infants may excrete the virus for up to six months.

Mode of transmission

Transmission is person-to-person by the faecal–oral route, and through food and water contaminated by human faecal material (Rosenblum et al 1991, Balayan et al 1983). Rare cases of transmission through blood or blood products have been reported (Lemon 1994).

Risk of acquisition

Susceptibility to HAV is universal, and natural infection is believed to confer immunity for life.

28.3.3 Management

Patients

Patients suffering from suspected or confirmed HAV, who are faecally continent, should be nursed with standard precautions (see **Section 2.2**). If they are incontinent or have an altered mental state or poor hygiene, a separate room with facilities (including toilets) that are not shared with other patients is advised. Additional precautions (contact transmission) should be observed with such patients (see **Section 2.3**). Adequate handwashing facilities for HCWs and patients are essential.

Immunisation with hepatitis A vaccine is recommended for individuals in the groups outlined below.

Health care workers

HCWs infected with HAV should either take sick leave or be rostered to avoid contact with nonimmune patients and HCWs, as appropriate.

Even though standard precautions should be used at all times, pre-employment hepatitis immunisation is recommended for those in occupational groups at risk of exposure to HAV.

Immunisation

Vaccines are available that give protection against HAV only, or against both HAV and HBV. The combined HAV/HBV vaccine should be considered for those at risk of acquiring both infections, including medical and nursing undergraduate students.

Hepatitis A vaccine is recommended for individuals from the following groups (ATAGI 2000):

- injecting drug users (administered as the combined hepatitis A/ hepatitis B vaccine);
- patients with chronic liver disease;

- haemophiliacs who may receive pooled plasma concentrates;
- people with intellectual impairment; and
- occupational groups at risk of HAV exposure:
  - nursing and medical HCWs in paediatric wards, intensive care units and emergency departments that provide for substantial populations of indigenous children;
  - nursing and medical HCWs in rural and remote indigenous communities;
  - carers and HCWs working for or with people with intellectual impairment;
  - other HCWs and laboratory staff likely to encounter HAV;
  - hospital workers who work with hospital sewerage systems (eg plumbers); and
  - childcare staff.

To avoid the expense of unnecessary immunisation, it is recommended that the following be screened for pre-existing immunity to HAV:

- those born before 1950;
- those who spent their early childhood in HAV-endemic areas, including in indigenous Australian communities; and
- those with an unexplained previous episode of hepatitis or jaundice.

The presence of either total anti-HAV antibodies or anti-HAV IgG on screening shows that the person has presumably had HAV infection (perhaps undiagnosed) and can be assumed to be immune and not in need of HAV immunisation.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.4 Hepatitis B

28.4.1 Disease description

Aetiology

Disease is caused by the hepatitis B virus (HBV).

Clinical manifestations

HBV is a hepatotrophic virus and causes an acute hepatitis after an incubation period that ranges between six weeks and six months. Disease onset is often insidious, with

symptoms including anorexia, nausea, vomiting, abdominal discomfort or pain, rash or joint pain. Fever does not always occur, but jaundice often presents later. Following acute disease most people recover, the mortality rate being about 1% in hospitalised patients.

Presentation of infection ranges from subclinical, which can be diagnosed only by laboratory tests, to fulminant liver disease with necrosis and death.

Occurrence

As many as 10% of infected adults may continue to carry the virus in their blood for a long period of time, even a lifetime. Approximately 90% of infants who acquire the infection perinatally become chronic carriers. These carriers become a potential source of infection to others. Certain population groups have a higher than normal frequency of the carrier state: injecting drug users, chronic haemodialysis patients and those with chronic debilitating illness (eg autoimmune disease and lymphoma) are more likely to become chronic carriers after acute infection than are immunocompetent people. Between 25% and 40% of carriers do not belong to recognised risk groups. Following the introduction of blood donor screening and immunisation for hepatitis B virus, the frequency and risk of infection is diminishing.

28.4.2 Transmission

Source of infection

People acutely or chronically infected with HBV, and who are seropositive for HBV surface antigen (HBsAg) may be infectious to others. The risk of transmission of HBV from carrier mothers to neonates, and from patients to nonimmune HCWs via needlestick injuries depends on the viral titre in the contaminant, and correlates with the presence or absence of HBV 'e' antigen (HBeAg) in the source patient. Estimates of infectivity range from 2% (HBeAg absent) to 40% (HBeAg present) (Alter et al 1976, Gerberding 1995, Werner and Grady 1982). Blood from infected patients with titres of HBsAg below the threshold of laboratory detection is rarely infectious (Alter et al 1972, Gerberding 1995).

Transmission of blood from HCWs to patients only occurs if an injury to the operator causes bleeding during a surgical or dental procedure. It has been estimated that about 1% of surgeons are infected with HBV. See **Section 24** for further discussion of HCWs infected with HBV.

Mode of transmission

HBV is transmitted in the health care setting by parenteral exposure to infected tissues, including blood or other body fluids. The virus may also be transmitted by exposure of mucous membranes, such as eyes, nose and mouth, to infected material.

Risk of acquisition

All people who are seronegative and have not been immunised against HBV or previously infected with HBV are at risk of infection. The rate of transmission by parenteral exposure to infected body tissues or fluids is variable (see 'Source of infection' above).

28.4.3 Management

Patients

Standard precautions (see **Section 2.2**) should be used to minimise risk of exposure to HBV.

There are univalent and combination HBV vaccines approved for use in Australia. In 1996, the NHMRC recommended a universal HBV immunisation program for infants and adolescents and this program is now included in the NHMRC Australian Standard Vaccination Schedule. (NHMRC 2000). This universal program is in addition to recommendations for selective HBV immunisation of the following groups:

- any users of injectable drugs who have not been infected (human immunodeficiency virus (HIV)-positive injecting drug users should receive twice the normal dosage or a standard dose of the double-strength dialysis formulation of vaccine);
- haemodialysis patients (immunise patients with twice the normal dose of vaccine or three separate doses of double-strength dialysis formulation, preferably before enrolment into the haemodialysis program);
- patients with clotting disorders who receive blood product concentrates (immunisation should be initiated at the time their specific clotting disorder is identified);
- individuals with chronic liver disease and/or hepatitis C virus (HCV) who are HBsAg negative, as the health of such individuals may be severely affected by a superimposed HBV infection; and
- people with intellectual impairment attending either long-term residential or acute care establishments.

Patients at risk of severe or complicated disease (immunocompromised people and those with pre-existing liver disease not related to HBV) and those in whom a poor response to HBV immunisation is expected (eg haemodialysis patients) should be tested for seroconversion to anti-HBV antibodies three months after the third dose of vaccine. Those who do not respond should be offered a further dose of vaccine as either a fourth double dose or a further set of three doses. Persistent nonresponders

should be informed about the need for HBV immunoglobulin (HBIG) within 72 hours of parenteral exposure to HBV with another dose in one month (NHMRC 2000).

Health care workers

HCWs will often encounter chronic carriers of HBV in health care establishments and specific provision should therefore be made to protect them. All HCWs should therefore be immunised against HBV using the schedule outlined in *The Australian Immunisation Handbook* (NHMRC 2000).

There are univalent and combination HBV vaccines approved for use in Australia. Before beginning employment, HCWs should be screened by personal medical history and tested if they are in any doubt about previous infection or immunisation. In accordance with NHMRC recommendations, nonimmune HCWs (including microbiology laboratory staff) should be offered HBV immunisation as soon as possible at the start of employment and should be tested for antibodies to HBsAg at three months after the third dose of vaccine. Those who do not respond should be offered a fourth double dose of vaccine or a further three doses. Persistent nonresponders should be informed about the need for HBIG within 72 hours of parenteral exposure to HBV with another dose in one month.

Following significant exposure (percutaneous, ocular or mucous membrane) to blood or potentially blood-contaminated body secretions, the source should be tested for HBsAg, and the recipient should be tested for antibodies to HBsAg and retested at three and six months postexposure.

If an HCW has not been immunised, is not known to be immune to HBV or is a persistent nonresponder to immunisation, then HBIG should be offered within 72 hours of significant exposure to blood or potentially blood-contaminated secretions from a known HBV carrier or an unknown source, with another dose within one month. HBV immunisation should be offered at the same time.

A clear protocol for management of HCWs involved in blood accidents should be available and its effectiveness regularly reviewed (see **Section 23**). HCWs who perform exposure-prone procedures have an ongoing responsibility to know their HBV infectious status.

Particular precautions apply to HCWs who are known to be acutely or chronically infected with HBV (see **Section 24**).

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.5 Hepatitis C

28.5.1 Disease description

Aetiology

Disease is caused by infection with hepatitis C virus (HCV). It was conclusively identified in 1989, and subsequent serological surveys have found that HCV is responsible for approximately 90% of all transfusion-related cases of non-A, non-B hepatitis (Mandell et al 1995)

Clinical manifestations

Although acute HCV infection is frequently asymptomatic, and fulminant HCV infection is rare, HCV causes chronic hepatitis in a high proportion of those infected. This may ultimately result in the development of chronic liver disease, cirrhosis and hepatocellular carcinoma (Ivatson et al 1995, Weimann et al 1995, Colombo and Corini 1995)

Occurrence

In Australia over 160,000 diagnoses of HCV were reported by the end of 2000, with a further 16,566 diagnoses made to the end of 2001.. The number of notifications over the period 1996 – 2000 has remained relatively stable in the range of 18,000 – 22,000 per year. Although there may be some duplicate reporting of hepatitis C it is likely that many people remain undiagnosed and therefore not reported.

Overall the male to female ratio of hepatitis C notifications remains stable at 1.7:1. Approximately equal numbers of male and female cases are reported in the 15 - 19 years age group. Most recent estimates suggest that the incidence of newly acquired hepatitis C infections in Australia is between 10,000 and 11,000 cases per year (National Centre in HIV Epidemiology and Clinical Research [NCHECR]2001. Annual Surveillance Report 2001).

Of the existing pool of past HCV infections, about 75% are thought to have a history of injecting drug use, with less than 20% having had a blood transfusion prior to mid-February 1990 (Strasser et al 1995) when screening was introduced. Occupational exposure and nonsterile tattooing practice account for a small proportion (Kaldor et al 1992).

28.5.2 Transmission

Source of infection

Acutely and chronically infected people are infectious. Infectivity is thought to be related to viral titre.

Mode of transmission

In the health care setting, HCV may be transmitted by parenteral exposure to blood or other body fluids. Perinatal transmission has been recorded with risk of transmission related to viral load.

Risk of acquisition

Patient-to-patient transmission of HCV has been associated with endoscopic procedures, including endoscopic sphincterotomy (Tennenbaum et al 1993, NHMRC 1997), routine upper gastrointestinal endoscopy (Crenn et al 1988) and colonoscopy (Bronowicki et al 1997). Failure to comply with recommended cleaning and disinfection protocols has been evident in the majority of adequately investigated transmissions (Tennenbaum 1993 et al, Bronowicki et al 1997, Cowen et al 1999).

28.5.3 Management

Patients

Standard precautions (see **Section 2.2**) are recommended as the principal means of preventing occupational spread of HCV. Adherence to standard precautions should provide adequate protection for HCWs.

Health care workers

Active immunisation is not available and there is no evidence that passive immunisation is effective.

HCWs who perform exposure-prone procedures have an ongoing responsibility to know their HCV infectious status, which is best determined by antibody testing and associated supplementary tests.

Assessment of any incident involving blood should include a review of the HCV status of the source individual and, if positive, the exposed person.

Further information on HCWs infected with HCV and other bloodborne viruses is given in **Section 24**.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.6 Herpes simplex virus infection

28.6.1 Disease description

Aetiology

Disease is caused by infection with herpes simplex virus (HSV), a herpesvirus. Two serotypes (HSV1 and HSV2) can be distinguished immunologically.

Clinical manifestations

Herpes simplex virus causes vesicular lesions of the oropharynx and of the genital area. It can occasionally cause lesions elsewhere (eg finger, buttock) and in neonates and immunocompromised patients it may cause a generalised vesicular rash.

Occurrence

The virus is widespread in the community with 50–90% of adults having antibodies to HSV1 (Chin 2000). Infection with HSV1 usually occurs in childhood before the age of five years, and HSV2 infection usually begins after the start of sexual activity (Chin 2000).

28.6.2 Transmission

Source of infection

The vesicular lesions contain infectious virus. Virus may also be present in saliva and in vaginal fluid even when vesicles are not present.

Mode of transmission

The virus can be transmitted by droplet spread, by direct contact and, indirectly, by fomites or by a third person.

Risk of acquisition

Susceptibility to primary infection is universal. Latent infection is common and may be reactivated by fever, intercurrent disease, trauma or physiological changes.

28.6.3 Management

Patients

Additional precautions (contact transmission) should be observed for patients with lesions that disseminate infectious virus.

HCWs should wear gloves whenever contact is made with any herpetic lesion or with a patient's mouth or genital area, or when handling a patient with a vesicular rash.

Mouth-to-mouth resuscitation should be replaced by mechanical ventilation with a bag and mask. Where there is a risk of saliva being sprayed from the mouth, as in dental procedures, goggles and mask should also be worn.

Health care workers

HCWs with herpetic lesions should wear gloves or some other effective occlusive dressing when the lesions are vesicular (virus is not shed from crusted lesions). Covered lesions present minimal risk. HCWs who perform exposure-prone procedures have an ongoing responsibility to know their HSV infectious status, which is best determined by antibody testing and associated confirmatory tests, and should avoid any invasive procedures while lesions are present.

HCWs with vesicles that cannot be covered (as in oral herpes) should not come into contact with newborn babies or immunocompromised patients, and should be excluded from operating rooms and delivery suites.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.7 Human immunodeficiency virus/acquired immunodeficiency syndrome

28.7.1 Disease description

Aetiology

Disease is caused by infection with human immunodeficiency virus (HIV), a retrovirus. Two serologically distinct types, HIV1 and HIV2, have been recognised.

Clinical manifestations

HIV can cause a severe, life-threatening condition known as acquired immunodeficiency syndrome (AIDS). This syndrome represents the late clinical stage of infection with HIV, which most often results in progressive damage to the immune system, resulting in opportunistic infections and malignancies and other organ damage. Between two weeks and several months following infection, seroconversion may result in an acute self-limited illness, similar to mononucleosis, lasting for a week or two. Infected people may then be free of symptoms or clinical signs for many months or years before other clinical manifestations, including opportunistic infections and malignancies and constitutional and neurological disorders, appear (Chin 2000).

The concentration of HIV in the bloodstream is very high in the early stages of infection, including the ‘window’ period between acquisition of HIV and the

seroconversion illness that typically occurs 2–4 weeks after contact (Ciesielski 1997). During this period the antibody test is negative, although tests for HIV DNA are positive. After the resolution of the seroconversion illness, HIV viral load decreases due to host immune responses and stabilises at a lower level. As immunodeficiency progresses and AIDS develops, the HIV viral load rises again. Viral load is also influenced by antiretroviral therapy. Most patients on combination antiretroviral therapy have a low HIV viral load.

Occurrence

During 2000, it was estimated that, after adjustment for reporting delay, there were 206 diagnosed cases of AIDS in Australia, and 123 deaths following AIDS. In addition, there were 723 new HIV diagnoses after adjustment for multiple reporting. Cumulatively to the end of 2000, there were 8564 diagnoses of AIDS, 6000 deaths following AIDS (adjusted for reporting delay) and 18171 diagnoses of HIV infection (adjusted for multiple reporting) (NCHECR 2001).

28.7.2 Transmission

Source of infection

Infectivity is believed to begin shortly after primary infection and continue throughout life, irrespective of whether the patient is symptomatic.

Mode of transmission

HIV is a bloodborne and sexually transmissible virus. HIV may be transmitted by direct contact with blood or other body fluids, through mucous membranes, nonintact skin or through percutaneous injury. The risk of HIV transmission ranges from close to 100% in the transfusion of an HIV-infected unit of blood, to 0.1–3.0% per act of unprotected receptive anal intercourse, and 0.1–0.2% per act of unprotected receptive vaginal intercourse.

Risk of acquisition

Patients

There has been one series (involving four patients) of patient-to-patient transmission of HIV in a surgical setting (Chant et al 1993). It is believed that a breakdown of standard infection control procedures was involved.

Health care workers

The risk to HCWs of acquiring HIV in the course of their employment is very small.

- In the occupational setting, blood is the single most important source of HIV infection so only those exposed to blood are significantly at risk.

- Exposure to blood through the percutaneous route is significantly more likely to result in transmission of HIV than is mucous membrane exposure.

Although a few episodes of HIV transmission after skin exposure have been documented, no HCWs enrolled in prospective studies have seroconverted after such an exposure. For an HCW, the average risk for HIV infection after a percutaneous needlestick injury with HIV-infected blood is estimated to be 0.3% (Bell 1997) and the risk associated with mucous membrane exposure is estimated to be about 0.09% (Ippolito et al 1993). The risk for transmission of HIV from patient to HCW clearly exceeds that of HCW to patient (Bell 1991). The risk to patients of contracting HIV through blood transfusion is exceedingly low; all blood for transfusion in Australia has been tested for HIV antibody since 1985, and there has been only one known case of transfusion-acquired HIV since that time (see **Section 23.1.1**).

At the time of writing, there have been no known cases of HIV transmission from HCW to patient in Australia. Internationally, there have been only two documented series of HIV transmission from HCW to patient. One occurred in the United States, where six patients became infected with HIV from a Florida dentist (Ciesielski 1991). This transmission was considered to be the result of a lapse in infection control procedures. More recently, HIV transmission occurred in one patient following prolonged orthopaedic surgery in France (Lot et al 1999). No further cases of transmission of HIV from HCW to patient have been detected, despite lookback studies of large numbers of patients who have been cared for by an HIV-infected HCW. Retrospective studies carried out for the (United States) Centers for Disease Control and Prevention (CDC) as of 1 January 1995, for patients of HIV-infected HCWs, indicate that of the 22,171 patients treated by 51 infected HCWs (29 dentists and dental students, 8 physicians and medical students, 13 surgeons or obstetricians and 1 podiatrist) no cases of transmission were documented from the infected HCW to the patient (Robert et al 1995).

A retrospective case–control study (Henry and Campbell 1995) of HIV seroconversion in HCWs after percutaneous exposure to HIV-infected blood, from January 1988 to August 1994, investigated factors that influence the risk of HIV infection. In this study, case HCWs had a documented occupational percutaneous exposure to HIV-infected blood, HIV seroconversion temporally associated with the exposure and no other concurrent exposure to HIV. Control HCWs had a documented occupational percutaneous exposure to HIV-infected blood, and were HIV seronegative at the time of exposure and at least six months later. Results indicated that for case HCWs, 94% of exposures were needlestick and 7% involved other sharp objects. For control-HCWs, 91% exposures were needlestick and 9% involved other sharp objects. The findings in this study indicate that an increased risk for HIV infection following percutaneous exposures to HIV-infected blood was associated with the following factors:

- a larger quantity of blood, indicated by visible contamination of the device; or
- a procedure using a hollow bore needle directly placed in a vein or artery, or a deep injury; or
- blood from a source with terminal illness.

28.7.3 Management

All health care establishments should implement standard precautions (see **Section 2.2**) as the primary basis for preventing HIV transmission.

Health care establishments should develop their own protocols for testing and preventing HIV transmission, based on the recommendations in these guidelines. The nature of the treatment provided, the health status of HCWs, especially in relation to skin conditions, and the consent and confidentiality rights of both patients and HCWs must all be taken into account.

Patients

Additional precautions for patients with HIV are required only for those patients with opportunistic infections such as infectious pulmonary tuberculosis.

Routine testing of patients for unidentified HIV is not recommended. Testing should be undertaken only on the basis of clinical assessment or where it is in the interests of both patients and HCWs. The provisions of confidentiality, privacy and consent for testing after counselling should be applied.

Health care workers

Health care establishments should provide HCWs with appropriate facilities and information about the risks of HIV transmission. Risk reduction strategies aimed at reducing exposure to blood and body fluids or contaminated sharps should be implemented.

Accident analysis should be included in occupational health programs. Such analysis can be a way of identifying risk exposure situations where special provisions can be applied (eg the use of special equipment).

Routine testing of HCWs for unidentified HIV is not recommended. Testing should be undertaken only on the basis of clinical assessment or where it is in the interests of both patients and HCWs. The provisions of confidentiality, privacy and consent for testing after counselling should be applied.

HCWs undertaking exposure-prone procedures have an ongoing responsibility to know their HIV status and, on the basis of confirmed test results, should not perform any procedure in which there is a risk of HIV transmission. Where there is any

uncertainty about the level of risk involved, individuals should be assessed by their registration board or an expert panel on a case-by-case basis to determine their continuing participation or modification of work practices (see **Section 24**).

The treatment provided to people involved in blood accidents (postexposure prophylaxis, or PEP) may also influence outcomes. In the case-control study described above, the use of zidovudine (ZDV) postexposure reduced the risk of HIV infection by approximately 79% (Henry and Campbell 1995). Simple measures such as washing blood out of eyes and mouth after accidental exposure may also reduce the risk of infection. It is now recommended that two or three antiretroviral drugs be administered as PEP to HCWs who have sustained a significant occupational exposure to HIV (CDC 1997a). On the basis of animal studies, it is generally considered that if ZDV is going to have maximal prophylactic benefit it should be given as soon as possible after the injury. Although animal studies suggest that PEP is probably not effective when started later than 24–36 hours postexposure, the interval after which there is no benefit in humans is unknown (CDC 1997a). All antiretroviral agents may cause side effects — mild, chiefly gastrointestinal, side effects are frequently reported by patients receiving PEP. More serious side effects such as nephrolithiasis, abnormal liver function and pancytopenia have been reported with the use of combination antiretroviral PEP. The decision to use antiretroviral PEP should be made promptly, in conjunction with a specialist HIV physician, and with the consent of the affected person.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.8 Influenza

28.8.1 Disease description

Aetiology

Disease is caused by infection with either influenza type A or type B virus.

Clinical manifestations

Clinical symptoms include abrupt onset of fever, headache, myalgia, sore throat and cough. Extreme malaise lasts several days, and the disease is usually self-limiting with full recovery within about seven days.

Occurrence

Influenza is an acute respiratory viral infection that occurs throughout the whole community, including HCWs. The disease may occur as isolated cases, localised

outbreaks, epidemics or pandemics. It is seasonal, with most cases reported from the middle of autumn to the end of winter each year.

28.8.2 Transmission

Source of infection

The period of communicability is believed to begin at the time of onset of symptoms, and continues for a period of 3–5 days in adults, and up to seven days in children.

Mode of transmission

Aerosolised respiratory secretions are the main source of transmission, but the virus can also be transmitted by direct contact with fomites, as it is relatively stable under conditions of low temperature and humidity.

Risk of acquisition

All people in contact with symptomatic influenza patients are at risk of the disease, unless they have been immunised with the current vaccine formulation. Influenza vaccine has an efficacy of about 70% (Palache et al 1993).

Those at particular risk from the complications of influenza include:

- adults with chronic debilitating disease, such as cardiac, pulmonary, renal and metabolic disorders;
- children with cyanotic congenital heart disease; people receiving immunosuppressive therapy;
- Aboriginal and Torres Strait Islander adults aged 50 years and over; and
- residents long-term care establishments.

28.8.3 Management

Details for the routine management of influenza in the health care setting are outlined below. However, at the time of a pandemic, the priority groups and the timing of immunisation may be quite different from those during interpandemic periods. In addition, the number of vaccine doses required to confer protection and the optimal time for immunisation may differ. The Australian Pandemic Planning Committee is developing guidelines for vaccine use and will advise health authorities regarding priority groups, dosing schedules and timing of immunisation should a pandemic occur (NHMRC 2000).

Patients

Additional precautions (droplet transmission) should be observed (see **Section 2.3**). Respiratory isolation practices should be implemented, and patients treated

symptomatically. Where possible, patients should be separated and the triage system implemented.

Influenza vaccine should be available to any healthy person to help minimise the incidence of influenza. Children as young as six months can be immunised. HCW should be aware that there is an increased risk of minor adverse events (following influenza vaccination) in children under five years of age (Gruber et al 1993, Belcher 1993).

Annual immunisation is recommended for:

- all adults aged 65 years and over;
- all Aboriginal and Torres Strait Islander adults 50 years and over;
- residents of long-term care establishments;
- children and teenagers (6 months to 18 years) on long-term aspirin therapy who therefore may be at risk of developing Reye syndrome after influenza;
- adults and children (6 months of age and over) with chronic disorders of the pulmonary or circulatory systems (including severe asthmatics, such as those requiring frequent hospitalisations, and children with congenital heart disease or cystic fibrosis); and
- adults and children (6 months of age and over) with other chronic illness requiring regular medical follow-up or hospitalisation in the preceding year, including diabetes mellitus (and other chronic metabolic diseases), renal dysfunction, haemoglobinopathies, or immunosuppression (including immunosuppression caused by medication).

Immunisation is also recommended for:

- all women who will be in the second or third trimester of pregnancy during the influenza season (CDC 1995) — women should be immunised before pregnancy so that they are protected for this period; and
- HIV-infected people, particularly those with minimal symptoms and high CD4 lymphocyte counts.

Health care workers

HCWs who contract the disease should take sick leave, or be deployed elsewhere to avoid patient contact, as appropriate.

To further protect patients, annual immunisation is also recommended for health care providers, including HCWs in long-term care establishments, and providers of home care to people at high risk (eg nurses, volunteer workers) (ATAGI 2000).

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.9 Measles

28.9.1 Disease description

Aetiology

Disease is caused by infection with measles virus, a morbillivirus of the Paramyxoviridae family.

Clinical manifestations

Measles is an acute, highly infectious disease characterised by fever, rash, conjunctivitis, coryza, cough and Koplik spots on the buccal mucosa. The rash sometimes results in desquamation. The disease is more severe in infants and adults than in children. Complications of measles include middle ear infections, pneumonia and encephalitis. A late complication, resulting from chronic infection with measles virus, is subacute sclerosing panencephalitis.

Occurrence

Before the introduction of an effective vaccine, measles was a common childhood disease. Measles immunisation programs have markedly decreased the incidence of the disease, although periodic outbreaks occur, mainly in nonimmunised people. At present, most disease occurs in children too young to be immunised, and those too old to have been immunised as children (Gidding et al 1999, Papania et al 1999, CDC 1999, Miller et al 1999).

28.9.2 Transmission

Source of infection

Patients are infectious from shortly before the onset of symptoms until about four days after appearance of the rash.

Mode of transmission

Measles virus is transmitted by aerosols or direct contact with nasopharyngeal secretions, or less commonly by items recently contaminated by infectious material.

Risk of acquisition

Susceptibility is universal in those who have never had the disease and who have not been immunised. Clinical measles or immunisation confers immunity, probably for life.

28.9.3 Management

The following information is based on the *Guidelines for the Control of Measles Outbreaks in Australia* (CDNANZ 2000), which should be consulted for further details.

Patients

Additional precautions (droplet transmission) should be observed (see **Section 2.3**). Susceptible people should wear a surgical mask when entering the room of a measles patient.

HCWs should be aware that an individual with measles can enter their health care establishment at any time and that there is a continuous risk of health care associated spread of measles. All staff should be familiar with isolation procedures to reduce measles exposure and should inform the establishment's infection control practitioner immediately measles is diagnosed. HCWs should consider the wider public health ramifications when diagnosing a case of suspected measles, and collaborate closely with the local public health unit (CDNANZ 2000).

HCWs should check the immunisation status of all children and young adults attending their health care establishment for any reason. If not fully immunised, the patient should be offered the appropriate immunisation if it is not contraindicated. This should be implemented at all immunisation clinics, doctors' rooms, public and private clinics, health centres and hospital emergency and outpatient wards (CDNANZ 2000). Consideration should be given to the use of the combined measles–mumps–rubella (MMR) vaccine. Pre-immunisation screening by history has been shown to be cost-effective (Ferson et al 1994).

Health care workers

HCWs with measles symptoms should be precluded from contact with susceptible persons until the results of appropriate tests to confirm measles are known. They may return to work if they have serological evidence of immunity (ie are IgG seropositive and immunoglobulin M (IgM) seronegative) or four days after appearance of the rash if they develop measles (CDNANZ 2000).

Susceptible HCWs are at significant risk since these diseases are often complicated in adults. Such HCWs should be identified by verbal medical screening for history of either infection or previous immunisation (Duclos et al 1999). Pre-immunisation screening by history has been shown to be cost-effective (Ferson et al 1994).

All HCWs who have not received two doses of a measles-containing vaccine or do not have adequate measles antibody titres at the time of employment and have no contraindications should be offered MMR immunisation (CDNANZ 2000). Tuberculin skin testing should not be carried out for at least one month after the MMR immunisation.

Susceptible HCWs exposed to measles should be offered a dose of MMR vaccine within 72 hours postexposure, or a dose of immunoglobulin if they were exposed between three and seven days earlier. Until the HCW receives either the MMR vaccine or immunoglobulin, or if they do not receive either of these within the specified timeframes, they should be precluded from contact with susceptible people until 14 days after their last exposure. Furthermore, if a susceptible HCW has not previously received any doses of a measles-containing vaccine, a second dose of MMR should be offered four weeks after the first dose.

Instruments and environment

Additional precautions (droplet transmission) should be observed in addition to routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**).

28.10 Parvovirus

28.10.1 Description

Aetiology

Disease is caused by infection with human parvovirus B19. Diagnosis is by serology and/or viral DNA detection.

Clinical manifestations

In children, human parvovirus B19 causes ‘fifth disease’ (erythema infectiosum), a rubella-like illness with a distinctive facial rash — the ‘slapped cheek’ syndrome. In adults, arthritis is often observed and may persist for weeks or even months. Both the rash and arthritis are due to circulating immune complexes of the virus and antibody. The incubation period is about 10–14 days.

The virus grows in the erythroid progenitor cells in the bone marrow. In patients with haemolytic anaemia, B19 infection causes aplastic anaemia, which may be severe but

resolves once the patient is convalescent. Immunosuppressed patients may be unable to clear the virus and persistent anaemia ensues. Administration of normal pooled immunoglobulin may assist the patient to eliminate the virus. Infection in the first half of pregnancy may affect the foetus, causing aplastic anaemia that later becomes manifest as midsemester hydrops foetalis (Gilbert 2000, Skjoldebrand-Sparre et al 2000). Foetal death occurs in less than 10% of cases (Yaegashi 2000). Intra-uterine transfusion has been used successfully in the management of this condition (Goodear et al 1998).

Occurrence

Community and school outbreaks occur at irregular intervals. A significant proportion of adult contacts are susceptible and may become infected. In temperate climates, epidemics tend to occur in winter and spring. Health care associated outbreaks of parvovirus B19 involving infection of patients and HCWs, including pregnant HCWs, have been reported.

28.10.2 Transmission

Source of infection

Most cases are believed to be infectious before the appearance of the rash, and probably not thereafter. Those with parvovirus-induced aplastic anaemia are infectious up to a week after onset of symptoms. Immunosuppressed patients with chronic infection may be infectious for some years (Broliden et al 1998).

Mode of transmission

Natural transmission is via the respiratory route.

Risk of acquisition

Susceptibility to infection is universal, and immunity is conferred by the development of antibodies. Those most at risk from the severe complications of infection are the immunocompromised, patients with haemolytic disease and women during the first half of pregnancy.

28.10.3 Management

Patients

Additional precautions (droplet transmission) should be observed for infected patients (see **Section 2.3**), and by those at high risk of the complications of infection. At present there is no vaccine.

Health care workers

HCWs with parvovirus B19 infection should be precluded from contact with susceptible persons while they are considered infectious (ie before the appearance of a rash). HCWs at high risk of the complications of infection should be rostered to avoid patients with parvovirus B19 infection. At present there is no vaccine.

Instruments and environment

The virus is very resistant in the environment and in biological materials such as blood or plasma. Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed (Schwarz 1994).

28.11 Respiratory syncytial virus (RSV) infection

28.11.1 Description

Aetiology

Disease is caused by respiratory syncytial virus (RSV), a paramyxovirus.

Clinical manifestations

In infants, up to 40% of cases present as lower respiratory tract infection, including bronchiolitis, pneumonia and tracheobronchitis. Low grade fever, accompanied by coughing and wheezing, is common. In more severe cases, profound respiratory distress can occur, resulting in hypoxia, cyanosis and apnoea.

Occurrence

RSV is a significant respiratory tract pathogen in young children and a major cause of lower respiratory infection in infants. The virus is widespread and causes seasonal outbreaks in temperate climates, with peak incidence usually in late autumn and winter.

28.11.2 Transmission

Source of infection

Patients are infectious from shortly before the onset of symptoms, and for the duration of the illness. In a small proportion of infants, shedding of the virus may occur for several weeks after resolution of symptoms.

Mode of transmission

RSV may be transmitted directly by oral contact, by exposure to aerosolised respiratory secretions or, indirectly, by contact with fomites, such as contaminated eating utensils, handkerchiefs, towels and toys (Hall 1987).

Risks of acquisition

The risk of acquisition is universal, and the risk of serious disease is greatest in infants (Bruckova et al 1979), children, the elderly, immunocompromised people (Englund 1991) and those with chronic heart or respiratory disease. Infection with RSV induces short-lived antibodies, and those who are reinfected generally have a milder illness.

28.11.3 Management

Patients

Additional precautions (contact and airborne transmission) should be observed (see **Section 2.3**). Patients should also be nursed in isolation from other at-risk individuals, such as infants, the elderly, the immunocompromised and those with chronic heart or respiratory disease. In situations where there are several patients with RSV, such as in hospital paediatric wards, patients can be cohort-managed.

Health care workers

HCWs with RSV should be precluded from contact with susceptible persons. HCWs at risk from the serious sequelae of RSV infection should not have contact with patients with this condition.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.12 Rotaviral enteritis

28.12.1 Description

Aetiology

Disease is caused by infection with rotavirus.

Clinical manifestations

The disease is seen mainly in children and is characterised by fever, vomiting and watery diarrhoea, although diarrhoea is uncommon in children less than three months

of age. In young children, severe dehydration and death may ensue if treatment is delayed.

Occurrence

Rotavirus infection presents as a gastrointestinal disease. The virus is widespread, and most children have been infected by the time they are three years old (Mrukowicz et al 1999). Most infections in the first month of life are asymptomatic. About one-third of infections after one month of age are associated with diarrhoea, with the peak incidence of clinical disease in the 6–24-month age group (Schumacher and Forster 1999, Murphy et al 1977). The virus will sometimes cause diarrhoea in adults, particularly the elderly (Marrie et al 1982, Dupuis et al 1995) and immunocompromised.

28.12.2 Transmission

Source of infection

Patients are infectious during the acute phase, and for up to eight days after recovery. Immunocompromised patients may excrete the virus for 30 days or more.

Mode of transmission

The most likely route of transmission is believed to be faecal-oral, although exposure to aerosolised respiratory secretions may be a secondary source of infection.

Risk of acquisition

Children aged 6–24 months, who have not been exposed to the virus, are most at risk from symptomatic disease. Immunocompromised people and the elderly are also at increased risk.

28.12.3 Management

Patients

Additional precautions (contact transmission) should be observed (see **Section 2.3**). Patients should be nursed in isolation from other at-risk patients. In paediatric settings, cross-infection occurs when several patients are hospitalised with rotavirus. Transmission between patients in the hospital setting can be prevented by giving hyperimmune bovine colostrum to all patients in the ward where there are cases of rota-virus.(Davidson et al 1989).

Health care workers

In addition to standard precautions, HCWs with rotavirus infection should either take sick leave or be rostered to avoid contact with at-risk patients.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.13 Rubella

28.13.1 Disease description

Aetiology

Disease is caused by infection with rubella virus, a togavirus.

Clinical manifestations

Rubella is a mild disease characterised by a low-grade fever and a maculopapular rash. Children generally have few symptoms, but adults frequently have fever, headache, lethargy, mild coryza and conjunctivitis and, occasionally, arthritis.

Occurrence

In general, women of child-bearing age are immune because of community immunisation programs, but males remain at risk. Rubella in males may cause significant debility (1–2 weeks away from work) and infected male HCWs can transmit infections to patients and other HCWs.

28.13.2 Transmission

Source of infection

Patients are infectious for about one week before, and for several days after, the onset of rash. Infants with congenital rubella syndrome may excrete the virus for several months after birth.

Mode of infection

Rubella infection is readily transmitted by droplets and through close contact with infected patients.

Risk of acquisition

All people who have not been immunised, or who have not had rubella, are susceptible. Infants infected in utero up to the 20th week of gestation are at highest risk of congenital rubella syndrome.

28.13.3 Management

Patients

Additional precautions (droplet transmission) should be observed (see **Section 2.3**).

Monovalent rubella vaccines and combination MMR vaccines are available for routine immunisation in Australia. All women found on antenatal screening to be susceptible to rubella should be immunised after delivery and screened before the next pregnancy. Either monovalent rubella vaccine or MMR can be used for this purpose (ATAGI 2000).

Health care workers

Due to the risk of congenital deformities in the foetus, nonimmune pregnant HCWs should be rostered to avoid contact with rubella-infected patients.

Monovalent rubella vaccines and MMR vaccines are available for routine immunisation in Australia (ATAGI 2000). Immunisation will reduce the likelihood of HCWs acquiring rubella. Pre-immunisation screening by history has been shown to be cost-effective (Ferson et al 1994). All male and female HCWs, including students, should be screened. Those without immunisation records, or who are seronegative, should be immunised both for their own protection and to avoid the risk of transmitting rubella to pregnant patients. Where necessary, those immunised can be tested for seroconversion two months after immunisation and be reimmunised if seronegative.

MMR should be offered to nonimmune HCWs. Women of child-bearing age given MMR should be advised not to become pregnant for two months after immunisation. Tuberculin skin testing should not be carried out for at least one month after MMR immunisation.

All HCWs born since 1970 should have either two documented doses of MMR vaccine or serologic evidence of immunity to measles, mumps and rubella.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.14 Varicella-zoster (chickenpox and shingles)

28.14.1 Disease description

Aetiology

Disease is caused by infection with varicella-zoster virus (VZV), a herpesvirus.

Clinical manifestations

Acute VZV infection in humans usually presents as chickenpox (varicella), which in adults can occasionally be a debilitating illness, particularly during pregnancy (see **Section 22.4.4**).

Infection of adults is generally more severe than infection of children (Chant et al 1998). There is also some evidence that the infection may be more severe in pregnant than in nonpregnant women (Pierre et al 1992, Enders et al 1994, Baren 1996).

Reactivation of VZV infection can occur as shingles (zoster), usually decades after the initial infection. Reactivation takes the form of a cluster of vesicles involving a single dermatome. Blister fluid from the vesicles is infectious and contact can result in primary varicella infection (chickenpox) in a nonimmune contact.

Occurrence

Acute VZV infection (chickenpox) occurs worldwide, with about 95% of people having been infected by early adulthood. With the introduction of VZV vaccine in some countries, the incidence of clinical chickenpox is expected to decline. Susceptible HCWs may acquire VZV (chickenpox) from patients who have either chickenpox or shingles. This occurs frequently in people with HIV infection or immunosuppression due to other causes (eg disseminated malignancies).

28.14.2 Transmission

Source of infection

Patients may be infectious for up to two days before the appearance of chickenpox lesions. Communicability persists for up to five days after vesicles first appear in acute infection, and patients with shingles should be regarded as infectious for up to a week after the rash appears. Immunocompromised people remain infectious for longer periods.

Mode of transmission

Acute VZV (chickenpox), is readily transmissible. Transmission occurs from person to person by direct contact, or by droplet or airborne spread of virus from either the

respiratory tract or vesicle fluid. Precautionary measures such as masks are only partially effective in preventing transmission to susceptible people.

Risk of acquisition

Susceptibility to VZV is universal in people who have not been previously infected or immunised. VZV is one of the most infectious of all communicable diseases. In the household setting, secondary attack rates range up to 90% in susceptible siblings.

28.14.3 Management

Patients

Additional precautions (airborne and contact transmission) should be observed for patients with chickenpox (see **Section 2.3**). Additional precautions (contact transmission) should be observed for patients with shingles. Masks are not completely effective in preventing transmission, so susceptible persons should avoid contact with patients with chickenpox.

The NHMRC has approved the use of VZV vaccine for children from 12 months of age (see ATAGI 2000).

Health care workers

HCWs (especially pregnant women) should not have direct contact with patients infected with VZV unless they have a definite history of previous chickenpox or serological evidence of previous infection. For high-risk situations (eg oncology, organ transplants), the VZV immune status of HCWs should be determined before rostering them in these areas. Screening by history is recommended. Immunodeficient HCWs should not be involved in the care of patients with VZV infection.

Before starting employment, HCWs should be screened by personal medical history and tested if in any doubt about previous infection or immunisation. An enzyme-linked immunosorbent assay (ELISA) is available that reliably detects the presence of serum antibodies to VZV after natural infection (but not after immunisation). Immunisation with VZV is recommended for nonimmune HCWs, particularly for nonimmune women before pregnancy and for nonimmune carers of immunosuppressed people. The vaccine should not be given during pregnancy and women who are immunised should not become pregnant for one month after immunisation (see ATAGI 2000). If a HCW has a history of clinical chickenpox, testing is not necessary since they will be immune. Further details on the prevention and management of VZV infection in pregnant HCWs is given in **Section 22.4.4**.

Before beginning employment or placement in paediatric wards, paediatric HCWs with patient contact should be asked if they remember having had VZV infection.

Those that have had the disease are considered immune but all other HCWs should have their immune status assessed by ELISA as soon as possible (Ferson et al 1990).

If susceptible HCWs are in contact with VZV, they should be assessed medically during the incubation period and precluded from contact with susceptible or immunocompromised patients. Zoster immunoglobulin (ZIG) prophylaxis should be considered in accordance with NHMRC guidelines (see ATAGI 2000). In such cases, use of high-titre ZIG, available from the Australian Red Cross Blood Transfusion Service on a restricted basis, should be considered for the prevention of varicella. ZIG must be given early in the incubation period (within 96 hours of exposure). Normal immunoglobulin (human) (NIGH) can be used for the prevention of varicella if ZIG is unavailable. ZIG should be given to pregnant women who are susceptible to varicella infection (they should have been tested for anti-VZV antibodies).

Treatment with acyclovir or related compounds may be indicated if lesions develop.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

28.15 Viral haemorrhagic fevers (VHFs)

28.15.1 Disease description

Aetiology

Viral haemorrhagic fevers (VHFs) are a group of viral diseases. The most clinically important viruses are:

- Lassa fever virus (an arenavirus);
- Marburg virus (a filovirus);
- Ebola virus (a filovirus); or
- Crimean-Congo haemorrhagic fever virus (a bunyavirus).

Clinical manifestations

VHFs usually present as febrile illness with headache, myalgia, sore throat, cough and vomiting. Some patients have a cough, chest pain, abdominal tenderness and skin rash. In severe cases, patients may suffer extensive haemorrhaging, accompanied by a purpuric rash and bleeding from almost any part of the body, including intestine, eyes, gums, nose, mouth, lungs and uterus. Encephalopathy and multiorgan failure are common in severe cases and the case mortality rate is high.

Occurrence

VHFs present a significant risk to Australia due to the ease of international travel. However, despite recent outbreaks in Africa, there have been no instances of confirmed infection with these viruses in Australia.

28.15.2 Transmission

Source of infection

Patients are infectious while they are symptomatic and until the virus has been cleared from blood and body fluids. Lassa fever virus has been found in respiratory secretions of a symptomatic patient and in urine during the convalescent phase. Sexual transmission of Ebola virus and Lassa fever virus has been recorded, and Ebola virus has been found in seminal fluid for up to two months after the onset of symptoms.

Mode of transmission

Recent evidence on the mode of transmission of these viruses indicates that the main risk of transmission in the health care settings is from mucosal or parenteral exposure to contaminated blood or other body fluids. Lassa fever virus may also be transmitted by exposure to aerosols of contaminated body fluids, particularly nasopharyngeal secretions and urine (Stephenson et al 1984).

VHFs are classified as dangerous biological agents (high individual and community risk; AS/ANZ 2243.3[1]). Transport and handling of specimens therefore requires special precautions.

Risk of acquisition

Susceptibility to these viruses is universal.

28.15.3 Management

Patients

Patients and their body fluids are highly infectious. Specific advice on management of suspected VHF infections should be sought from the chief quarantine officer in each State/Territory, who should be contacted immediately.

Lassa fever, Marburg haemorrhagic fever, Ebola haemorrhagic fever and Crimean-Congo haemorrhagic fever are quarantinable diseases.

All patients with suspected VHF and their specimens and bodily secretions should be handled at Physical Containment Level 4 (PC4) (AS/NZS 2243.3). All specimens

[1] AZ/NZS 2243.3 (1995) and Amendments 1 (1996) and 2 (1998) *Safety in laboratories - microbiology*

must be handled with appropriate safeguards. The specimens should not be sent through the normal courier mechanisms (human or other), to ensure that accidents do not occur as a consequence of mishandling or misplacement. The laboratory manager and infection control practitioner must be alerted immediately to ensure appropriate handling of specimens.

Health care workers

There are no vaccines available for VHFs. Additional precautions should also include rostering pregnant HCWs to avoid contact with a possible or confirmed VHF case.

Instruments and environment

PC4 containment (AS/NZS 2243.3) procedures should be used for waste or contaminated materials where a VHF is confirmed or suspected.

Contact State/Territory human quarantine officer to discuss waste containment and disposal requirements.

29 Bacterial diseases

Key points

- Common bacterial diseases of concern in the health care setting include gastrointestinal infections (mainly salmonellosis, campylobacteriosis, shigellosis. and *Clostridium difficile*-associated diarrhoea), legionellosis, listeriosis, meningococcal infection, whooping cough (pertussus), staphylococcal infection, streptococcal infection and tuberculosis.
- Most bacterial diseases are widespread in the community and are not significantly more common in the health care setting. However, without effective infection control, they may be readily transmitted from patient to patient and, to a much lesser extent, from patient to health care worker and vice versa. Some bacterial diseases are not common in the community (eg legionellosis and tuberculosis) but are nevertheless significant diseases.
- Susceptibility to bacterial infection frequently varies with age and with health status. Immunisation or naturally acquired immunity may confer protection in some instances (eg pertussis), but not in others (mainly enteric bacterial pathogens).
- In all instances of bacterial disease in the health care setting, standard precautions and work practices are required. However, in specific circumstances, additional precautions and work practices, which are related to the mode of transmission of the disease, are needed.

29.1 Gastroenteritis and enteric bacterial pathogens

29.1.1 Disease description

Aetiology

The more commonly diagnosed infectious agents include salmonella serotypes, *Campylobacter* spp, *Shigella* spp and *Clostridium difficile.*

Clinical manifestations

Abdominal pain, diarrhoea, nausea, vomiting and fever are common features of gastroenteritis.

Occurrence

Gastrointestinal infections are relatively common in the community, and there is no seasonality in incidence. Individuals may carry pathogens asymptomatically, sometimes for long periods.

However, not all diarrhoea occurring in health care establishments is infectious and not all gastrointestinal infections result in diarrhoea.

29.1.2 Transmission

Source of infection

Both symptomatic patients and asymptomatic carriers may be infectious. There are several pathogens that may be carried for long periods of time.

Mode of transmission

Gastrointestinal pathogens are transmitted by the faecal–oral route. The most likely sources of infection in health care establishments are other patients (especially paediatric patients) and food (see **Section 19.2**). Frequent screening of food handlers is not practicable. Asymptomatic excretors of gastrointestinal pathogens are unlikely to transmit disease if standards of hygiene are high and methods of food preparation and storage prevent incubation of pathogens.

Salmonella and campylobacter are present in 'normal' poultry and other animals. Possible contamination from both human and nonhuman sources must be considered when developing procedures for preparing and storing food. Education of health care workers (HCWs) who handle food is the most effective method of reducing the risk of foodborne infections in health care establishments.

Sporadic cases of health care associated diarrhoea due to organisms other than *Clostridium difficile* are unusual, and gut pathogens such as *Shigella* spp, *Salmonella* spp (including *Salmonella enterica*) and *Campylobacter* spp are unlikely to be transmitted to HCWs caring for patients with diarrhoea if standard precautions are practised (see **Section 2.2**).

Cross-infection with *Clostridium difficile* can occur with spread from patient to patient, both from the contaminated environment and via the hands of HCWs.

Risk of acquisition

All age groups are susceptible, with immunocompromised patients and those on long-term antibiotic therapy being at highest risk.

29.1.3 Management

Patients

Outbreaks of gastrointestinal infections should be investigated and any suspected cluster should be brought to the attention of an infection control practitioner immediately.

Sporadic diarrhoea occurring more than 48 hours after admission should initially be investigated only for *Clostridium difficile*.

Patients suffering from suspected or confirmed gastrointestinal infections (including *Clostridium difficile*) and who are continent should be nursed with standard precautions (see **Section 2.2**). If they are incontinent, a separate room with facilities (including toilet) that are not shared with other patients is advised. Adequate handwashing facilities for HCWs and patients are essential.

Health care workers

If HCWs caring for patients diagnosed with gastrointestinal infections become ill, they should be assessed for gut pathogens where appropriate, and infection control procedures should be re-examined.

HCWs with bacterial diarrhoea should not return to work until faecal cultures for the causative organism are negative. HCWs who handle food should not return to work until asymptomatic, and should not return to food-handling duties for another 48 hours after symptoms resolve. Known persistent carriers of salmonella should not handle food without assessment by infection control practitioners. Known carriers of salmonella should not work in food preparation areas without assessment of the premises and individual work practices.

Routine screening of HCWs for gastrointestinal pathogens is not recommended.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

29.2 Legionellosis

See also **Section 11** on design and maintenance of health care premises.

29.2.1 Disease description

Aetiology

Disease is caused by infection with *Legionella* spp, most commonly with *Legionella pneumophila*. In all, about 35 species of legionella are recognised.

Clinical manifestations

Legionellosis is an acute bacterial disease characterised initially by anorexia, myalgia, lethargy and headache, followed soon thereafter by fever commonly reaching 40.5°C. Cough, abdominal pain and diarrhoea occur frequently. Severe infections may lead to respiratory failure and death.

Occurrence

Legionellosis may occur as sporadic cases or outbreaks, and is more frequently reported in summer and autumn. The incidence of infection increases with increasing age, with most cases occurring in those over 50 years.

29.2.2 Transmission

Source of infection

The organism is found in many aqueous environments, including contaminated airconditioning cooling towers, hot water systems, humidifiers, spa baths and respiratory therapy devices.

Mode of transmission

Airborne transmission in water droplets is believed to be the major, if not sole, means of infection. Person-to-person transmission has not been demonstrated, and therefore, hospitalised patients with Legionellosis do not pose a risk for cross-infection.

Risk of acquisition

People over the age of 50 are at highest risk, particularly those who smoke or have chronic lung disease, renal disease, diabetes or a malignancy or who are immunocompromised.

29.2.3 Management

Patients

Standard precautions are adequate for patients with legionellosis (see **Section 2.2**).

Health care workers

Standard precautions provide adequate protection for HCWs (see **Section 2.2**).

Instruments and environment

Routine reprocessing of instruments and equipment should be employed (see **Sections 16 and 17**).

Special precautions for the environment include adequate maintenance of potential reservoirs of infection, such as hot water and airconditioning systems, spa baths (see **Section 11.5**), humidifiers and respiratory therapy equipment (see **Section 17.5**).

29.3 Listeriosis

29.3.1 Disease description

Aetiology

Disease is caused by infection with *Listeria monocytogenes*.

Clinical manifestations

Listeriosis is usually manifested as meningoencephalitis and/or septicaemia.

Occurrence

The disease primarily affects pregnant women, neonates, the elderly and immunocompromised individuals receiving radiation therapy, chemotherapy, haemodialysis and glucocorticosteroid medications.

29.3.2 Transmission

Source of infection

Listeria can be found on the surface of raw, unwashed vegetables and in certain processed foods, including soft cheeses (eg brie, camembert, fetta and ricotta), paté, some cold meats (eg cooked diced chicken and prepacked sliced meats) and packed salads (eg coleslaw). Listeria is only rarely transmitted by contact of open wounds with contaminated foods or sewage. Listeria is not unique to hospitals.

Mode of transmission

The disease is contracted by the consumption of contaminated foods (see Source of infection, above). Infants may contract the disease in utero or perinatally. Rare outbreaks have been associated with contaminated fomites or contact of wounds with contaminated sewage.

Risk of acquisition

Elderly and immunocompromised patients, and infants born to infected mothers, are at the highest risk of infection. Infection does not appear to confer subsequent immunity.

29.3.3 Management

Patients

Standard precautions (see **Section 2.2**) should be observed for patients with listeriosis. Pregnant women and immunocompromised people should avoid meals containing soft cheeses, diced chicken and cold processed meats.

Health care workers

General guidelines recommended for the prevention of listeriosis in a health care establishment are similar to those used to prevent other foodborne diseases:

- wash hands, knives and cutting boards after handling uncooked foods;
- keep uncooked meats separate from vegetables and from cooked and ready-to-eat foods;
- cook raw meats thoroughly;
    - wash raw vegetables thoroughly before eating; and
    - avoid serving pregnant women and immunocompromised people meals containing soft cheeses, diced chicken and cold processed meats.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

29.4 Meningococcal infection

Communicable Diseases Network of Australia (CDNA) published guidelines in October 2001 about meningococcal disease. This publication *Guidelines for the early clinical and public health management of meningococcal disease in Australia* (Meningococcal Guidelines) are available on the Department of Health and Ageing web site at: http://www.health.gov.au/pubhlth/cdi/pubs/mening.htm

The aims of the *Meningococcal Guidelines* are:

- to assist primary care practitioners with the emergency management of cases of suspected invasive meningococcal disease; and
- to assist public health practitioners with the prevention of further cases after a case of invasive meningococcal disease has been reported.

Topics covered in the *Meningococcal Guidelines* include:

- Emergency management of suspected invasive meningococcal disease in general practice;
- Early hospital management of suspected invasive meningococcal disease;
- Laboratory tests and their use;
- Public health management of sporadic cases of invasive meningococcal disease;
- Public health management of outbreaks of cases of invasive meningococcal disease; and
- Reporting and public health surveillance of meningococcal disease.

Key points

- Meningococcal septicaemia has considerably greater mortality than meningococcal meningitis and is often characterised by a rapidly evolving petechial or purpuric rash that does not blanch under pressure. The rash in its early stages may consist of a few haemorrhagic spots located in a place such as the groin or feet.
- Meningococcal disease may have clinical features not normally expected in children with acute systemic illnesses.
- Practitioners should ensure that a patient with a systemic febrile illness, particularly a child, can be promptly reassessed should the need arise.
- All general practitioners should have benzylpenicillin in their surgeries and emergency bags, and should be ready to administer it immediately to patients with a systemic febrile illness and a petechial or purpuric rash. The doses are: children aged < 1 year – 300 mg; children aged 1-9 years – 600 mg; adults or children aged 10 years or over – 1200 mg.
- The early administration of benzylpenicillin, followed by urgent transfer to hospital, can be life saving. Ceftriaxone is a suitable alternative if available.
- If clinical suspicion exists to warrant a referral for admission to hospital the patient should receive benzylpenicillin prior to transfer.
- A history of a rash following penicillin is not a contraindication for benzylpenicillin.
- The local public health unit should be notified immediately to enable an appropriate public health response.

29.4.1 Disease description

Aetiology

Disease is caused by infection with *Neisseria meningitidis*.

Clinical manifestations

Bacteraemia is an essential component of invasive meningococcal infection, which may present as meningitis, septicaemia or, more rarely, septic arthritis or chronic systemic infection.

Presentation may be as acute bacterial meningitis (fever, headache, vomiting, neck stiffness) with or without petechial haemorrhages or other skin lesions seen with meningococcal bacteraemia.

Meningococcaemia without meningitis may occur without a rash, but more usually with a petechial or grosser haemorrhagic rash. Progression to overwhelming shock can be rapid and this type of infection has a much higher death rate than uncomplicated meningococcal meningitis.

Occurrence

Meningococcal disease affects mainly younger children and adolescents, but can occur at any age. It can kill previously healthy children within several hours of onset. An increasing incidence of disease and of outbreaks has been associated with the spread of virulent clones of both serogroup B and serogroup C meningococci. In Australia, the incidence of meningococcal disease has been increasing over the past decade.

29.4.2 Transmission

Source

Nasopharyngeal carriers may be sources of infection. Patients with meningococcal septicaemia or meningitis usually become noninfectious within 24 hours of institution of appropriate therapy.

Mode

Neisseria meningitidis is spread by direct contact, including by respiratory droplets from the nose and throat of infected people.

Risk of acquisition

Meningococcal infection has sometimes been a concern to hospital HCWs in contact with these cases. The risk of acquisition of infection by hospital HCWs is extremely low, unless they are in prolonged direct contact with the patient or they undertake mouth-to-mouth resuscitation of infected patients. This situation is unlikely to arise

in a hospital after a patient is diagnosed and treated. Once treatment is initiated in acute meningococcal infection, infectivity appears to decrease rapidly, despite the fact that penicillin is not effective in clearing nasal meningococci in carriers. The *Meningococcal Guidelines* recommend the use of rifampicin following parenteral penicillin, where that antibiotic has been used to treat meningococcal infection (CDNA, 2001).

29.4.3 Management

Patients

Additional precautions (droplet transmission) should be observed for 24 hours after the initiation of specific therapy (see **Section 2.3**).

It is vital that all cases of meningococcal disease are notified, so that outbreaks can be identified. HCWs should be guided in the management of outbreaks by State/Territory health authorities. Close contacts who have become colonised with a virulent strain may develop invasive meningococcal disease: the risk is greatest in the first week after contact but may persist for many months. Those at risk include household members and contacts in day care centres, who may have been exposed to the carrier who infected the index case in the 10 days preceding onset of illness in that case. People exposed to oral secretions (eg by kissing or by mouth-to-mouth resuscitation) are also at risk. All those at risk should receive chemoprophylaxis.

The *Meningococcal Guidelines* should be consulted on the recommended chemoprophylaxis (CDNA, 2001). No chemoprophylactic strategy is 100% effective. The most important aspect of prophylaxis is the need for immediate medical attention for any contact who develops a febrile illness within days or weeks of contact with a person with invasive meningococcal infection. In any such situation, depending upon the clinical circumstances, it will often be appropriate to culture a blood sample and start treatment without delay as for invasive meningococcal infection.

An outbreak of meningococcal disease in an institutional or community setting is a public health emergency needing a rapid response from both clinicians and public health practitioners. The decision to control an outbreak with an immunisation program will depend on identifying a well-defined population at risk, and estimating the magnitude of ongoing risk. The *Meningococcal Guidelines* should be consulted when conducting such immunisation programs for the control of outbreaks of meningococcal disease (CDNA, 2001).

Health care workers

Postexposure prophylaxis is not recommended for HCWs unless they have carried out mouth-to-mouth resuscitation on an infected person. For information on PEP for

meningococcal disease, the NHMRC guidelines should be consulted (Guidelines for the control of meningococcal disease in Australia – 1996, ISBN 0 644 47585 4) (

Routine immunisation of staff with current meningococcal vaccines is not recommended, as the risk of meningococcal disease in Australia is relatively low. Immunisation is, however, recommended for microbiology laboratory staff who may be exposed to meningococcus and people with inherited defects of properdin or complement, or functional or anatomical asplenia (see NHMRC, 2000).

Instruments and environment

Additional precautions (droplet transmission) should be observed (see **Section 2.3**).

29.5 Pertussis (whooping cough)

29.5.1 Disease description

Aetiology

Disease is caused by infection with the gram-negative coccobacillus *Bordetella pertussis*.

Clinical manifestations

Pertussis (whooping cough) is a serious, sometimes fatal, respiratory infection. The cough becomes paroxysmal usually within 1–2 weeks and often lasts 1–2 months or longer. Patients frequently expel clear, thick mucous and vomiting is common. Infected adults may have a persistent cough, but without the paroxysms seen in children.

Occurrence

Pertussis is endemic in Australians of all ages. Outbreaks occur periodically but the incidence is low in communities with high immunisation rates.

29.5.2 Transmission

Source

Humans are thought to be the only natural reservoir. Children may be infected by a sibling or an infected adult.

Mode

Pertussis is a highly infectious disease, spread by respiratory droplets. The incubation period is usually 7–10 days. Individuals may be infectious from seven days after exposure to three weeks after the onset of typical paroxysms. The initial catarrhal stage of the illness has an insidious onset and is the most infectious period.

Risk of acquisition

Risk of infection decreases after administration of appropriate antibiotics but treated patients may be infectious for up to five days. Nonimmunised or partially immunised children are at risk of infection. Immunity has been shown to wane in adults so teenagers and adults are also at risk. HCWs involved in the care of nonimmunised children should be aware that adult pertussis does occur.

29.5.3 Management

Patients

Additional precautions (droplet transmission) should be observed (see **Section 2.3**). Known cases should be accommodated in a single room for at least five days after starting appropriate antibiotic treatment. Suspected cases should be isolated from young children and infants, particularly those not immunised. If there has been inadvertent exposure of patients to an infectious individual with pertussis in the previous 10 days, then erythromycin prophylaxis should be offered.

Infants in Australia are immunised with acellular pertussis vaccine, given together with diphtheria and tetanus as DTPa vaccine or with diphtheria, tetanus and hepatitis B virus as DTPa-hepB (see NHMRC 2000).

Health care workers

HCWs diagnosed with pertussis infection should be treated and rostered to avoid contact with susceptible patients until five days after the start of effective antibiotic therapy. HCWs with persistent cough should be tested for pertussis, and similarly excluded from patient contact until the result of the test is known.

It is not currently recommended that pertussis vaccines be used after eight years of age, although the use of acellular pertussis vaccines in adults is currently being tested. If there has been inadvertent exposure of HCWs to an infectious individual with pertussis in the previous 10 days, then erythromycin prophylaxis should be offered. Chemoprophylaxis is not routinely recommended for HCWs caring for infected children.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

29.6 Staphylococcal infection

29.6.1 Disease description

Aetiology

Disease is caused by infection with coagulase-positive strains of *Staphylococcus aureus* and less commonly coagulase-negative *Staphylococcus epidermidis*.

Clinical manifestations

Staphylococcus aureus commonly causes cellulitis and wound infections. It may also cause more serious conditions such as osteomyelitis and bacteraemia. Enterotoxin-producing staphylococci may also cause food poisoning.

Occurrence

Staphylococcus aureus is present on the skin and in the nose of approximately 30–50% of the general population, and may be higher in HCWs.

29.6.2 Transmission

Source

Usually an asymptomatic carrier, or a patient with a purulent staphylococcal lesion, is the source of infection.

Mode

S. Aureus is transmitted by direct contact with a colonised or infected person. Airborne transmission also occurs, but to a lesser extent. Nasal secretions contain large numbers of bacteria that will contaminate the hands. Staphylococci can penetrate into the deeper layers of the skin, where they live and multiply in the pores and hair follicles. Hands colonised in this way may be washed and scrubbed without removing the organisms. Antiseptic lotions may help to reduce the skin carriage of staphylococci.

Methicillin-resistant *Staphylococcus aureus* is discussed in **Section 30.2**.

Risk of acquisition

The risk of transmitting organisms from HCW to patient depends on the underlying medical condition of the patient, on the extent of skin shedding by the HCW and on the extent of contact between the two. These infections are relatively common among patients, who may themselves sometimes be carriers and heavy shedders of these microorganisms.

HCWs with exfoliative skin conditions are at increased risk of both acquiring and transmitting infection. HCW carriers, including asymptomatic nasal carriers, who maintain high standards of hygiene, implement standard precautions, and do not have either an exfoliative skin condition or overt sepsis (eg paronychia) are unlikely to transmit significant numbers of staphylococci. Sinusitis is a particular infection that may be associated with heavy shedding.

29.6.3 Management

Patients

Standard precautions should be observed (see **Section 2.2**).

Identification by clinical assessment of those patients with presumptive staphylococcal sepsis should be made. Routine laboratory screening for colonisation is not warranted.

If a patient is excreting large numbers of *Staphylococcus aureus* (eg from an infected wound), they should be accommodated in a single room with its own toilet and bathing facilities. Standard precautions must be maintained (see **Section 2.2**).

If a patient has a *Staphylococcus aureus* respiratory tract infection and is dispersing the organism into the air (eg by cough), then the patient should preferably be accommodated in a respiratory isolation room with negative pressure ventilation (see **Section 11.5.4**).

Measures to protect patients from staphylococcal infections are best directed at identifying heavy shedders.

Contamination of food with enterotoxin-producing *Staphylococcus aureus* can cause food poisoning. Staphylococcal sepsis on the hands of HCWs preparing or handling food is the most likely source.

Health care workers

Identification (by verbal medical history and examination) of HCWs with conditions which predispose them to heavy shedding should be made. The degree of shedding should be assessed by culturing sites of potential carriage (eg skin lesions, anterior nares, axilla and groin) but routine laboratory screening for colonisation is not warranted. If an outbreak occurs, selective screening may be necessary.

Provision of a roster system and/or treatment program for heavy shedders should be made. Heavy shedders should not be rostered to work in high-risk areas, but should be suitably redeployed.

Preclude people with skin lesions from clinical contact and food preparation unless lesions can be fully covered.

HCWs with predisposing conditions (eg dermatitis) should be rostered away from patients known to be infected with *S. aureus*.

Gloves must be worn when contact is made with infected lesions (ie standard precautions).

Hands must be thoroughly washed before and after significant patient contact.

Instruments and environment

Routine reprocessing for instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

29.7 Streptococcal infection

29.7.1 Description

Aetiology

Disease is caused by infection with group A (beta haemolytic) *Streptococcus pyogenes*.

Clinical manifestations

Streptococcus pyogenes is a common cause of pharyngitis, skin infections such as cellulitis and wound infections. It is also a cause of scarlet fever and rheumatic fever and can contribute to more serious conditions, such as necrotising fasciitis and bacteraemia. Streptococcal infections are sensitive to penicillin, although the response can be slow in invasive infections (eg bacteraemia).

Antibiotic therapy relatively quickly decreases the numbers of bacteria present in wounds and rapidly lowers the risk of cross-infection.

Occurrence

Streptococcal pharyngitis occurs more frequently in temperate climates than tropical zones. The age/frequency distribution is unimodal, with a peak at 6–12 years of age. It is uncommon in children less than three years of age. Cases occur throughout the year, but peak in late winter and early spring.

Streptococcal impetigo occurs throughout the year — most frequently in young children in late summer and autumn. Erysipelas and scarlet fever occur sporadically, with seasonal and geographic distributions similar to streptococcal pharyngitis.

29.7.2 Transmission

Source of infection

Outbreaks of health care associated infection have been traced to asymptomatic carriers of the organism. Pharyngeal, nasal, skin, anal and vaginal carriers have been implicated. Patients with overt disease, such as impetigo and pharyngitis, are also infectious. Outbreaks of pharyngeal infections have followed ingestion of contaminated foods, particularly milk, eggs and their products.

Mode of transmission

Aerosol transmission by expelled respiratory secretions from symptomatic patients or asymptomatic carriers is common. Patients with purulent discharges are generally infectious for up to 24 hours after the start of appropriate therapy. Infection may sometimes occur through direct contact with contaminated fomites.

Risk of acquisition

Most people are generally susceptible to streptococcal pharyngitis or scarlet fever, but some have developed immunity due to inapparent infection.

29.7.3 Management

Patients

Acute septic lesions (impetigo, cellulitis, paronychia) and acute pharyngitis should be assessed for pathogenic streptococci.

If a patient is excreting large numbers of these organisms from an infected wound, they should be accommodated in a single room with its own toilet and bathing facilities. Standard precautions (ie gloves when wounds are dressed or examined) must be used when attending these patients (see **Section 2.2**).

If a patient has a group A streptococcal respiratory tract infection, and is dispersing this organism into the air (eg by cough) then additional precautions (droplet transmission) should be implemented in addition to standard precautions for at least the first 24 hours of effective antibiotic treatment (see **Section 2.3**). The patient should preferably be accommodated in a respiratory isolation room with negative pressure ventilation (see **Section 11.5.4**).

Health care workers

Acute septic lesions (impetigo, cellulitis, paronychia) and acute pharyngitis should be assessed for pathogenic streptococci. Clinical contact staff with streptococcal lesions should cover those lesions and be given systemic and local treatment. Similarly,

HCWs with acute streptococcal pharyngitis should receive antibiotic treatment and should be precluded from direct patient contact for at least the first 24 hours.

Instruments and environment

Routine reprocessing of instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

29.8 Tuberculosis (TB)

29.8.1 Disease description

Aetiology

Tuberculosis (TB) is caused by infection with *Mycobacterium tuberculosis*-complex spp, predominantly *M. tuberculosis*. Disease due to *M. bovis* or *M. africanum* is only occasionally reported in Australia. See also **Section 30.4** on multidrug-resistant tuberculosis.

Clinical manifestations

Many initial infections with *M. tuberculosis* or related species are asymptomatic. Approximately 90–95% of those who have the bacterium become latent carriers who have a lifelong risk of developing clinical (active) disease. Approximately 10% of infected adults will develop such clinical disease in their lifetime, about half of these in the first five years after infection (but predominantly in the first year) and the other half later in life. The risk of developing disease is much greater in infants and young children, and in those with impaired immune function.

Early clinical symptoms include fatigue, weight loss, fever and night sweats. In more advanced disease, hoarseness, cough with blood-stained sputum and chest pain are common.

Occurrence

There are approximately 1000 new cases of TB notified each year in Australia, of which 60–70% are pulmonary TB. About 75% of notified cases are bacteriologically confirmed, with less than 50% of bacteriologically confirmed cases being sputum-smear positive for acid fast bacilli (ie the most important form of TB in terms of transmission of infection).

Within this relatively low incidence of TB, subsegments of the population (eg indigenous Australians, migrants from high TB-risk countries) have a higher TB burden. In particular, some young immigrants are more prone to rapid progressive disease following TB infection. Immunocompromised patients are at high risk of developing active TB if they become infected with *M. tuberculosis*.

TB is usually a pulmonary disease. Extrapulmonary TB is much less common, but infection may occur in any organ or tissue, including meninges, lymph nodes, pleura, pericardium, kidneys, bones, joints, larynx, skin, peritoneum, intestines and eyes. Miliary TB may also occur.

29.8.2 Transmission

Source of infection

Symptomatic or asymptomatic people with viable bacilli in their sputum may be infectious. Untreated or inadequately treated patients may be sputum-positive intermittently for many years, although children with primary TB are generally not infectious. Patients usually become noninfectious within a few weeks of beginning appropriate therapy.

Mode of transmission

TB is usually transmitted by exposure to airborne droplet nuclei produced by people with pulmonary or laryngeal disease, during expiratory efforts such as coughing and sneezing. Prolonged close contact with such patients increases the risk of transmission.

The aerosol droplets of less than 5 µm in diameter produced by TB patients contain acide-fast bacilli. These droplets can remain afloat and viable in the environment unless they are removed by planned infection control procedures. When inhaled, the acid-fast bacilli can settle in the lungs, where they may result in TB infection and may remain viable for the lifetime of the new host. People with TB infection of this nature without evidence of clinical disease are not infectious and are asymptomatic. Not all of those who have progressed to active pulmonary TB have respiratory symptoms capable of producing droplet nuclei into the environment and onto new hosts. It should be emphasised that HCWs can also be exposed during procedures such as cough induction, bronchoscopy, intubation and autopsy, particularly when these involve a patient with undiagnosed TB. Other respiratory tract sites (eg in laryngeal TB) are also a significant source of organism transmission. Infection by direct contact with mucous membranes or skin lesions is very rare.

Bovine TB may result from drinking unpasteurised infected milk or by aerosol transmission from infected animals to farmers or animal handlers.

Risk of acquisition

The risk of acquisition is related to the degree of exposure to the infectious agent. The greatest risk of disease occurs from 6–12 months after exposure. For people with latent infection, susceptibility to reactivation is increased in those with immunosuppression, or debilitating diseases such as diabetes, cancer and renal failure,

and in those who engage in substance abuse or who are malnourished. Reactivation of latent infection accounts for a large proportion of cases in elderly people.

29.8.3 Management

There is a hierarchy of individual risk for HCWs, patients and visitors to health care establishments, as well as a hierarchy of potential for transmission of TB in different established.

TB control measures should reflect the order of risk to those in health care settings. Thus, in the hierarchy of TB control, the most important aim is to decrease the risk of exposure of both HCWs and patients to infectious cases of TB. Since it is the undiagnosed TB patient who presents the most risk, infection control protocols should ensure rapid detection, isolation, diagnosis and treatment of TB. Next in the hierarchy are those measures that reduce the risk of infection from infectious droplet nuclei, followed by measures based on HCW screening.

At one extreme, small hospitals only rarely catering for active TB may maintain minimal TB infection control measures against transmission. At the other extreme, major hospitals should have, documented and operational, most of the requirements of TB infection control in place. In between these two extremes, variable degrees of TB infection control protocols are required and should be devised based on local epidemiology and assessment of risks.

Each health care establishment should develop its own TB infection control policy appropriate for its estimated risk of health care associated infection.

Patients

Additional precautions (airborne transmission) should be observed (see **Section 2.3**). People (HCWs and visitors) should wear a P2 particulate respirator (see **Section 13.3**) when entering a TB patient's room until effective treatment has been verified, or where normal treatment measures are not likely to be effective (eg disease due to drug-resistant strains of *M. tuberculosis*). Care should be taken to ensure that all people who use these masks are instructed in the correct fit and wearing of the masks. When the patient is required to leave a TB isolation room (eg for chest X-ray), then the patient should wear the mask if their TB is considered infectious. TB patients should be educated to cover their mouths and noses while coughing or sneezing, and to dispose of used tissue in a closed container for incineration.

Medical procedures that present a particular risk of cross-contamination from an infectious patient include bronchoscopy (**Sections 11.5.5 and 17.3**) and the use of respiratory and anaesthetic apparatus (**Section 17.5**).

Bacille-Calmette Guerlin (BCG) immunisation is recommended for neonates born to patients with leprosy or TB. In the case of neonates born to patients with TB, BCG should be given after completion of isoniazid prophylaxis, as isoniazid will inactivate BCG. BCG immunisation and protective preventive treatment (usually with isoniazid) have often been inappropriately compared with each other in providing protection against TB. Although BCG immunisation in the general population and in adults is no longer considered to be indirectly effective against transmission of TB, its benefit in preventing complicated TB, particularly in children, is well documented (NHMRC 2000).

If active TB occurs during pregnancy, standard antituberculosis therapy (ie isoniazid, rifampicin and ethambutol) can be used safely (Brost and Newman 1997).

Immunocompromised patients should not be accommodated in the same area of the establishment as known or suspected TB cases.

Health care workers

HCWs working in TB-risk areas (medical wards, chest clinics, bronchoscopy units, radiology units, TB laboratories, HIV-dedicated wards and autopsy rooms) are at greatest risk of occupational exposure.

At the start of employment, all HCWs should be screened by personal medical history for previous infection or immunisation and should undergo an initial two-step tuberculin skin test (see also **Section 22.5.1**). HCWs working in high-risk areas (eg microbiology laboratories and respiratory wards) should be retested yearly if their initial skin test is negative. Other Mantoux-negative HCWs should be regularly retested (the frequency depending on their level of risk). HCWs that test positive should be followed up with a chest X-ray and clinical review.

When designing HCW screening protocols, special attention should be given to:

- minimising the risk of an HCW with active TB working in a setting involving patients with increased risk of disease when infected (eg neonates, immunocompromised patients); and
- minimising the risk of exposure to TB of HCWs at particularly high risk of developing disease if infected (eg immunocompromised HCWs).

Immunodeficient HCWs should not be involved in the care of patients with tuberculosis.

Whenever a patient is diagnosed with active pulmonary TB, HCWs with a high risk of exposure should be investigated. Their tuberculin skin test status, nature of exposure and other factors associated with active infection should be assessed.

BCG immunisation is of uncertain value, but can be offered to tuberculin skin test-negative HCWs at high risk from TB. However, BCG immunisation is not recommended for immunodeficient HCWs. The decision to undertake a program of BCG immunisation is often a matter for staff health authorities who should follow the guidelines as set down by their State/Territory TB control unit. These authorities should arrange for periodic surveillance of tuberculin reactivity, or should initiate special surveys after accidental exposure in keeping with the policy of their State/Territory. BCG vaccine may also be useful to prevent infection of HCWs by multidrug-resistant TB, and would certainly be more effective than offering complicated preventive therapy.

Instruments and environment

Routine reprocessing for instruments and equipment (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

30 Antibiotic-resistant bacteria

Key points

- The most important antibiotic-resistant bacteria are: methicillin-resistant (or multiresistant) *Staphylococcus aureus* (MRSA); vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* (VRE); multiresistant gram-negative bacteria; and multidrug-resistant tuberculosis.
- These bacteria are amplified by the use of broad-spectrum antibiotics and are more common in hospitals than in the wider community. Although they are not generally more virulent than their antibiotic-sensitive counterparts, their resistance patterns make them more difficult to treat and they may readily colonise patients and, less frequently, HCWs.

30.1 Introduction

Organisms with acquired resistance to multiple antibiotics are common in many hospitals. Currently, the important multiresistant bacteria are:

- methicillin-resistant (or multiresistant) *Staphylococcus aureus* (MRSA);
- vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* (VRE) (other naturally vancomycin-resistant enterococcal species are not a cross-infection problem);
- multiresistant gram-negative bacteria , including extended spectrum beta-lactamase enzyme producers (ESBLs); and
- multidrug-resistant tuberculosis (MDR-TB).

Of these, MRSA is the most prevalent. Additional precautions are recommended for all patients colonised or infected with MRSA or VRE.

Many of these bacteria are amplified by the use of broad-spectrum antibiotics, and may colonise patients and sometimes health care workers (HCWs). These organisms do not appear to be more virulent than the antibiotic-sensitive strains but, because of their resistance patterns, are more difficult to treat if infection occurs.

30.2 Methicillin-resistant *Staphylococcus aureus* (MRSA)

30.2.1 Disease description

Aetiology

Disease is caused by infection with coagulase-positive *S. aureus* with acquired resistance for methicillin and commonly one or more other antibiotic classes. There are currently three main types of MRSA circulating within Australia (Turnidge and Bell 2000):

- classical methicillin-resistant MRSA, also termed eastern Australia (EA) MRSA (resistant to beta-lactams, erythromycin, gentamicin and trimethoprim–sulfamethoxazole);
- community MRSA, also termed Western Australia (WA) MRSA or Kimberley MRSA (resistant to methicillin and beta-lactams, generally sensitive to gentamicin); and
- community MRSA different from WA MRSA, but similar to community strains in New Zealand and other south Pacific islands.

Clinical manifestations

As with other strains of *S. aureus*, MRSA may cause skin lesions (impetigo, folliculitis) and systemic infections such as abscesses, pneumonia, osteomyelitis, sepsis, endocarditis and meningitis.

Occurrence

EA MRSA is common in many hospitals, and has a high propensity to become endemic (ie present at all times within a health care establishment). Additional precautions (contact transmission) are recommended for all patients colonised or infected with MRSA.

Despite vigorous attempts at eradication over the last 20 years, MRSA continues to be the major health care associated pathogen in Australian acute care institutions.

MRSA is endemic in the majority of Australian teaching hospitals. Occasional episodic outbreaks occur, especially in intensive care units. There is a high patient morbidity and mortality in association with health care associated MRSA especially in:

- intensive care units;

- infected vascular and orthopaedic prostheses;
- surgical wound infection; and
- cases where septicaemia and pneumonia develop.

Community strains of MRSA are currently most prevalent in Western Australia, but are being seen more often in South Australia and the Northern Territory as well (Turnidge and Bell 2000). It has recently been reported that a different type of community strain has been identified in the eastern states, which appears to be similar to a community strain seen in New Zealand (Nimmo et al 2000). While these types of MRSA appear more frequently in the community, they are capable of causing health care associated infections and outbreaks if introduced into a health care setting.

Intermediate glycopeptide-resistant MRSA have recently been detected in other countries, and health care establishments need to be aware that glycopeptide resistance is possible in MRSA.

30.2.2 Transmission

Source of infection

MRSA colonisation precedes infection. Infected and colonised hospital patients are the major primary reservoirs. People with purulent discharges or draining lesions are the most common sources during epidemics within health care establishments. Colonisation of hospital patients depends upon:

- length of hospital stay;
- nutritional status of patient;
- severity of underlying disease;
- presence of invasive devices;
- recurrent or recent antibiotic treatment; and
- presence of wounds.

Community reservoirs are less important and include:

- patients recently discharged from hospital;
- chronic leg ulcer patients;
- residents of long-term care establishments (eg aged care facilities, hostels);
- intravenous drug users;
- patients with dermatological disease (eg eczema); and
- insulin-dependent diabetics.

Carriage by HCWs is usually transient, but some may harbour MRSA in the nose or on the hands (contact dermatitis or eczema), and may act as primary reservoirs.

The level of MRSA infection is usually indicative of the overall infection rate of the health care establishment. It may reflect:

- overcrowding of wards;
- heavy nursing load and understaffing;
- increased use of agency nursing staff unfamiliar with local infection control procedures; and
- higher concentrations of sicker patients.

As the rate of MRSA infection rises, the global rate of health care associated infection rises within a health care establishment. Tackling the MRSA problem often reduces the overall burden of health care associated infections.

Mode of transmission

The major route of transmission of MRSA within health care establishments is from patient to patient via the hands of HCWs who acquire the organism after direct patient contact or after handling contaminated materials. This is usually associated with inadequate handwashing. Unfortunately it has been shown that HCWs, particularly physicians, frequently fail to wash their hands between patients.

Other forms of transmission, such as from colonised HCWs or from air or environmental surfaces, are usually less important. Certain body sites that are more resistant to eradication of MRSA include:

- tracheostomy sites;
- chronic leg ulcers;
- wounds; and
- rectal and perineal regions.

Risk of acquisition

Infants and chronically ill people are at most risk from infection. The elderly and debilitated in acute care settings, those with congenital or acquired immunodeficiency or those being treated with steroids or antineoplastic drugs are particularly susceptible. The vulnerability of patients is largely determined by the presence of indwelling devices (peripheral intravascular lines, central lines, urinary catheters, surgical drains, endotracheal tubes) and treatment or prophylaxis with selective antibiotics. Areas known to accommodate vulnerable patients, and in which multiresistant organisms can become common, include intensive care areas (medical, surgical, general, neonatal), renal units and certain surgical units, especially cardiothoracic, orthopaedic, vascular and urology.

Residents of long-term care establishments may be at risk of becoming colonised with MRSA if there are other residents who are colonised with MRSA in the facility. This may then become a potential source of MRSA if patients are transferred to an acute

care establishment that cares for patients at risk of infection with MRSA. However, the risk of active infection in residents appears to be no greater than for the general public, unless those residents require treatment within an acute care facility (see **Section 38**).

30.2.3 Management

Patients

Additional precautions (contact transmission) should be observed.

Management of these organisms depends upon two factors according to strain and endemicity: the endemicity of the resistant organism in the health care establishment, and the vulnerability of the patients in the wards where they occur. Where the organisms are not endemic to the establishment, rigorous application of additional precautions has been shown to be effective in containing or eliminating the problem, although this can be expensive and its cost-effectiveness is unclear (BSAC et al 1998). These measures should be implemented where there is a clear risk to patients from active infection with MRSA, rather than colonisation alone.

The objectives of infection control may differ depending on endemicity. In health care establishments where the organisms are nonendemic, the object should be elimination, while in establishments were they are endemic, the object should be minimisation of further transmission. Application of additional precautions is useful in both settings.

Elimination involves confining the organisms to the individual(s) who are first identified as colonised or infected and detecting other patients to whom the infection may have been transmitted (as for outbreak screening). Elimination is usually achieved by discharging colonised/infected patients. An alert system for readmission of these patients is required to make this fully effective, because carriage can be very prolonged. The role of broader screening of risk groups on a routine basis is less clear, and costs can be considerable.

Minimisation involves ensuring that further transmission to new patients is minimised. Segregation of known colonised and infected patients still plays a useful role. In high-risk patients and clinical areas (eg intensive care units), some form of ongoing screening program may be of benefit in identifying new admissions who are colonised, but this is not recommended as a routine procedure.

There are no universally agreed standards for infection control of multiresistant organisms. One approach is suggested in **Table 30.1**. Detailed recommendations on the control of MRSA are given by Humphreys and Duckworth (1997). For further discussion of management of MRSA in long-term care settings (see **Section 38**).

Additional precautions for MRSA include the following.

- A proper monitoring system should be in place. If it becomes apparent that the rate of MRSA is disproportionately high, then specific and locally appropriate preventive measures need to be developed. In this context, medical practitioners would be wise to collaborate with an infectious diseases physician, clinical microbiologist and/or infection control consultant to devise the most effective plan.
- Identify infecting organisms by bacterial culture.
- Assign patient to a single room with its own bathroom facilities or cohort patients with presumed or known same strain of the organism (see **Section 11**).
- Wear a clean, nonsterile gown and gloves when entering room (see **Section 13**).
- Remove gown and gloves before leaving room and wash hands with antiseptic liquid handwash or alcohol-based hand rub. Ensure gown and gloves do not contact environmental surfaces before disposal.
- Use mask if patient has colonised respiratory secretions (see **Section 13.4**).
- Use dedicated equipment — stethoscope, sphygmomanometer, thermometer. Clean and disinfect before reuse.
- Use disposable equipment whenever possible.
- Instruments used for dressing changes should not be transferred from patient to patient but should remain by the patient's bedside.
- Consider the surfaces and furniture within the rooms to be contaminated as well as the patients themselves.

The optimal requirements for discontinuation of additional precautions for antibiotic-resistant organisms are unclear, and should be chosen in consultation with an infectious diseases physician, clinical microbiologist and infection control practitioner.

Table 30.1 Suggested approach to multiresistant organisms, based on endemicity of the pathogen and patient vulnerability

		Endemicity	
		Not endemic	Endemic
Patient vulnerability	Low	Single room	If practical, room with patients with known same strains (cohort managed), I
	High	Additional precautions for multiresistant organisms in nonendemic settings Temporary screening program as for outbreak	Additional precautions for multiresistant organisms in endemic settings Consider permanent screening program

Health care workers

MRSA poses a minimal health risk to HCWs. Additional precautions (contact transmission) should be observed. HCWs with skin conditions that predispose them to shedding should not care for patients with MRSA (see **Section 22.2.2**). There is no vaccine for MRSA.

Additional precautions for multiresistant organisms include:

- using a mask if the patient has respiratory secretions colonised with the organisms; and
- considering the surfaces and furniture within the rooms to be contaminated, as well as the patients themselves.

Instruments and environment

Routine reprocessing for instruments (see **Sections 16 and 17**) including meticulous cleaning of all patient care items (including stethoscopes, blood glucose monitors, etc) before use on other patients, and routine cleaning of the environment (see **Section 18**) should be employed. Particular attention should be paid to cleaning horizontal surfaces (to remove dust) and miscellaneous cleaning equipment.

30.3 Vancomycin-resistant *Enterococcus faecium* and *E. faecalis*

30.3.1 Disease description

Aetiology

Disease is caused by infection with *Enterococcus faecium* or *Enterococcus faecalis* with the *vanA* or *vanB* resistance gene to the antibiotic vancomycin.

Clinical manifestations

Enterococci may be cultured from surgical wound infections, liver and intra-abdominal abscesses, and foot ulcers in diabetic patients.

Occurrence

E. faecium and *E. faecalis* are commensal bacteria in the gastrointestinal tract of healthy individuals. VRE has a high propensity to become endemic. Additional precautions (contact transmission) are recommended for all patients colonised or infected with VRE.

Many of these bacteria are amplified by the use of broad-spectrum antibiotics and may colonise patients and sometimes HCWs. These organisms do not generally appear to be more virulent than sensitive strains but, because of their resistance patterns, are more difficult to treat if infection occurs.

30.3.2 Transmission

Source of infection

VRE readily colonises the bowel without causing symptoms of infection and VRE is not a cause of diarrhoea. If a patient with diarrhoea has VRE cultured from a faecal specimen without any other signs of systemic infection, they should be considered to be colonised.

Certain groups of patients are at increased risk for VRE colonisation or infection, such as patients who:

- are critically ill (eg in intensive care units);
- are immunosuppressed (eg oncology or transplant patients);
- have had intra-abdominal or cardiothoracic procedures;
- have a central venous catheter;
- have a prolonged hospital stay; and

- have had recent broad-spectrum antibiotic therapy, or who have received oral or intravenous vancomycin.

Most patients with VRE in Australia are colonised rather than infected, and become a potential reservoir of VRE.

There are no data on the epidemiology of VRE in long-term aged care establishments in Australia. However, overseas data suggest infection caused by VRE and transmission of VRE in these settings is rare.

Mode of transmission

A major route of transmission of VRE within health care establishments is from patient to patient via the hands of HCWs who acquire the organism after direct patient contact or after handling contaminated materials. This is usually associated with inadequate handwashing. Unfortunately it has been shown that HCWs, particularly physicians, frequently fail to wash their hands between patients.

Risk of acquisition

Vulnerability of patients is largely determined by the presence of indwelling devices (peripheral intravascular lines, central lines, urinary catheters, surgical drains, endotracheal tubes) and treatment or prophylaxis with selective antibiotics, rather than immunological impairment, although the latter can play an enhancing role. Areas known to accommodate vulnerable patients, and in which multiresistant organisms can become common, include intensive care areas (medical, surgical, general, neonatal), renal units and certain surgical units, especially cardiothoracic, orthopaedic, vascular, urology, haematology and oncology units.

30.3.3 Management

Patients

Additional precautions (contact transmission) should be observed (see **Section 30.2.3**).

There are no universally agreed standards for infection control of multiresistant organisms. One approach is suggested in **Table 30.1**. Detailed recommendations on the control of VRE have been published by HICPAC (1995).

Health care workers

No additional precautions are required for HCWs colonised with VRE. Staff should adhere to standard precautions, particularly with respect to handwashing and disinfection.

Instruments and environment

Enterococci persist in the environment. Disinfection with a hospital-grade disinfectant should be undertaken in addition to standard cleaning. Cleaning cloths and equipment should be appropriately reprocessed before use in other areas.

Standard sterilisation procedures for instruments should be employed.

30.4 Multiresistant gram-negative bacteria

30.4.1 Disease description

Aetiology

There is currently no agreed definition for multiresistant gram-negative bacteria. Multiresistant gram-negative bacteria are defined for the purpose of these guidelines as those gram-negative bacteria with resistance to two or more antibiotic classes to which they would usually be sensitive, including those which have extended beta-lactamase enzymes (ESBLs) and organisms known to express inducible beta-lactamase resistance (ESCAPPMs, or *Enterobacter* spp, *Serratia* spp, *Citrobacter freundii*, *Acinetobacter* spp, *Proteus vulgaris* and *Proteus penneri*, *Providencia* spp, *Morganella morganii*).

Clinical manifestations

As with other gram-negative bacteria, multiresistant strains may cause local wound infections and systemic infections such as abscesses, pneumonia, osteomyelitis, sepsis, endocarditis and meningitis.

Occurrence

Multiresistant gram-negative bacteria occur more often in acute care establishments, especially intensive care units. Patients with indwelling invasive devices (eg central venous catheters, urethral catheters) are more likely to be infected.

The organisms may also be seen in patients with long-term indwelling catheters, especially those who have had frequent antibiotic treatment or long-term antibiotic prophylaxis. Often these patients have bladder colonisation rather than infection, but they remain a source of infection both for themselves and for others via HCWs' hands

30.4.2 Transmission

A major route of transmission of multiresistant gram-negative bacteria within health care establishments is from patient to patient on the hands of HCWs who acquire the organism by direct patient contact or by handling contaminated materials. This is usually associated with inadequate handwashing. Unfortunately it has been shown

that HCWs, particularly physicians, frequently fail to wash their hands between patients.

Transmission from patients with bladder colonisation may occur when HCWs manipulate urethral catheters or drainage bags.

30.4.3 Management

Patients

Additional precautions (contact transmission) are recommended in areas where other at-risk patients (eg those with invasive devices) are cared for.

Where there are two or more patients in any health care establishment with the same multiresistant gram-negative bacteria, then an investigation should be undertaken for potential common sources (see **Section 21.3**).

In long-term care establishments, care should be taken in handling catheters and drainage bags where residents are known to be colonised. If possible, patients who have indwelling devices should not share rooms.

Health care workers

No additional precautions are required for HCWs colonised with multiresistant gram-negative bacteria. Staff should adhere to standard precautions, particularly with respect to handwashing and disinfection.

Instruments and environment

Routine reprocessing of instruments (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

30.5 Multidrug-resistant tuberculosis

30.5.1 Disease description

Aetiology

Multidrug-resistant tuberculosis (MDR-TB) is caused by infection with *Mycobacterium tuberculosis*-complex spp, predominantly *M. tuberculosis*, with resistance to a range of antibiotics.

Clinical manifestations

See **Section 29.8.1**.

Occurrence

About 2% of cases of notified cases of TB are classified as multidrug resistant, being resistant to both isoniazid and rifampicin (see **Section 29.8.1** for details about the occurrence of TB in Australia).

30.5.2 Transmission

See **Section 29.8.2**

30.5.3 Management

Patients

The management of patients with TB is described in **Section 29.8.3**.

It is preferable that cases of MTR-TB be managed at establishments with expertise in this infection. Respiratory isolation precautions must be used (see **Section 11.5.4**), and their movement around the establishment should be minimal. A particulate filter mask (see **Section 13.4**) should be worn in all circumstances where the patient is considered to be infectious, regardless of personal risk reduction measures or engineering controls.

Health care workers

The management of HCWs caring for patients with TB is described in **Section 29.8.3**.

HCWs should observe additional precautions (airborne transmission). In particular, the recommendations for mask use must be strictly followed as this is a situation in which normal risk-reduction measures are not completely effective.

Instruments and environment

Routine reprocessing of instruments (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

31 Creutzfeldt–Jakob disease

31.1 Preface

This section provides recommendations for infection control management procedures to minimise the risk of transmission of classical forms of Creutzfeldt-Jakob disease (CJD) in health care settings. CJD is an infectious disease, the aetiological agent of which is relatively resistant to inactivation, and which therefore requires special additional precautions outlined in this chapter. At the time of writing variant CJD (vCJD) has not been reported in Australia. It has been determined that the risk of transmitting vCJD in Australia in the course of health care delivery is extremely remote, and does not warrant additional precautions beyond standard precautions. The recommendations provided in this document specifically address cCJD, and provide a firm foundation for additional recommendations that may be necessary for the control of vCJD in the future.

The identification of persons "at risk" of developing CJD and persons with CJD raises serious ethical and professional responsibilities in regard to appropriate care of these persons and their families and in regard to how HCWs and health care establishments respond to these responsibilities. Discussion of the principles involved are found in Section 10 **Ethical and legal issues** and 31.11 **Ethical Issues.**

An expanded version of this chapter can be found in Appendix 9. Please note that the numbering in this section is unconventional and has been maintained as it relates to the expanded version. The numbering will be amended during the final editing process, and this and the previous sentence will be deleted. Please also note that for brevity and convenience of HCWs, most of the research references related to this section only appear in the expanded version.

31.2 Disease description

31.2.1 Introduction

The transmissible spongiform encephalopathies (TSEs) are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans. TSEs are a unique class of infectious agent, as they can be both inheritable and transmissible.

The first authenticated case of what is now called classical Creutzfeldt–Jakob disease (cCJD) was described in the early 1920s. Other related conditions include kuru,

Gerstmann–Sträussler–Scheinker disease (GSS) and fatal familial insomnia (FFI). Most cases of cCJD appear to develop sporadically i.e. with no identifiable source of transmission. However, as incubation periods of 10 years or more have been observed in cases of health care associated CJD, a proportion of the so-called "sporadic" cases may have resulted from undetected or subclinical case-to-case transmissions many years earlier. Approximately 5 – 10% of cCJD cases present as familial disorders with an autosomal dominant pattern of inheritance.

vCJD was first identified in the United Kingdom in 1996 and approximately 130 cases have been reported to date (August 2002) in the UK, France, Ireland, Italy and Canada. It is believed that vCJD was acquired through the consumption of beef infected with the agent of bovine spongiform encephalopathy (BSE).

31.3 Infectious Agent

Refer to Appendix 9.

31.4 Clinical manifestations

CJD presents in several forms, including;

- Sporadic CJD
- Familial CJD
- Health care associated (iatrogenic) CJD
- Gerstmann-Straussler-Scheinker Disease (GSS)
- Kuru
- Fatal familial insomnia (FFI)
- variant CJD

For simplicity, the term classical CJD (cCJD) is used to describe all forms of human CJD except vCJD. These diseases are characterised by a subacute progressive dementia with widespread neurological impairment. This occurs over a period of months, inevitably leading to death. The nature of the brain damage is unusual; there is no detectable immune response and the disease process is confined to the CNS (Johnson and Gibbs, 1998). The term "spongiform encephalopathy" describes the appearance of microscopic holes or vacuoles that occur with variable distribution in the grey matter of the brain.

31.5 Occurrence

The incidence of cCJD in Australia is 1.5 cases per million, per year. The basic epidemiological features of cCJD have been reviewed elsewhere. On a global basis, approximately 10% of all patients show a family history of the disease (this includes GSS and FFI). In most of these familial cases, a disease-related mutation of the PrP

gene can be identified; such mutations code for a prion protein which is more susceptible to folding into an abnormal form (see Appendix 9 for detail).

In Australia, approximately 3% of CJD cases reported to date are health care associated (iatrogenic). These were recipients of either cadaver derived human pituitary hormones or dura mater grafts.

31.6 Diagnosis

If an individual acquires the infectious agent of cCJD through a health care associated procedure or other means, there may be an incubation period ranging from about 18 months to more than 40 years before the onset of disease. During this time, the infectious agent does not cause an immune or inflammatory response. At the time of writing, there is no test available to detect infection before the onset of symptoms.

Diagnosis of cCJD is by clinical and neuropathological examination. Currently, the only method for obtaining a definitive diagnosis is by examination of brain tissue by biopsy or autopsy. However, brain biopsy is not recommended as a routine procedure to confirm the clinical suspicion of CJD (WHO, 1998b). Rather, its use should be to exclude other causes of treatable dementia, such as vasculitis.

31.6.3 Genetic testing

Whenever possible, all newly identified cases of CJD should be evaluated for possible familial CJD. The reader should refer to the expanded version of this section for further information and **Section 10** and **Section 31.11** for Ethical and legal issues pertaining to genetic testing and patient consent.

31.7 Transmission

31.7.1 Sources of infection

For most cases of cCJD, a thorough analysis of the patient's medical and occupational histories fails to disclose clear evidence of an external source or point of infection, and they are therefore considered to be sporadic CJD. However, in a small number of patients there has been a clear instance of health care associated transmission through neurosurgical instruments contaminated with CNS tissue and through tissue implants or products (dura mater grafts, corneal grafts, pituitary products). There is no evidence that the disease can be transmitted through normal social or sexual contact. There is also no evidence of vertical transmission (see 31.7.4) or transmission to humans through blood or blood products.

Although transmission of CJD is rare, health care workers (HCWs) should be aware of the potential for health care associated transmission by contaminated instruments or transfer of contaminated tissues or agents.

31.7.2 Modes of Transmission

Refer to Appendix 9

31.7.3 Infectivity of human tissues (cCJD)

Table 31.7.3 is a guide to the predicted infectivity of body tissues and fluids of symptomatic and asymptomatic patients with cCJD. This information is largely based on studies of experimentally transmitted cCJD in non-human primates and other animals.

High infectivity tissues

Brain, spinal cord, eye (retina and optic nerve), pituitary and dura mater tissues have demonstrable infectivity (see Table 31.7.3). In areas of the brain affected by spongiform change, the CNS may contain levels of infectivity of more than 10^5 infectious units/g (Brown et al, 1994).

As the highest risk of health care associated transmission occurs when the CNS of a CJD patient is exposed, particular care should be exercised in the management of instruments used in neurosurgery, ophthalmic surgery, neurology (lumbar punctures) and laboratory procedures when brain tissue is manipulated, see **Section 31.12**.

Low infectivity tissues

- **Cornea** - The precise distribution of infectivity in the eye remains uncertain. While corneal transplantation has been associated with a few cases of health care associated (iatrogenic) cCJD, it is possible that the cornea was contaminated during harvesting through contact with instruments used to remove the eye after death. There is increasing evidence that the CJD agent accumulates in the retina and optic nerve which are direct extensions of the CNS

- **Cerebrospinal fluid (CSF)** - Although CSF has been included as a lower infectivity secretion (Table 31.7.3), its reported infectivity has varied in different studies (WHO, 1998b).

A number of other tissues (dorsal root ganglia, kidney, liver, lung, lymph nodes/spleen, maxillofacial neurovascular tissue, placenta, uterus, see Table 31.7.3) have been shown to be infectious in some animal studies, but the results are not conclusive (WHO, 1998b) and for this reason these tissues are regarded as low infectivity.

No known human infectivity

- **Blood** - There is still uncertainty as to whether blood components carry the infectious agent in humans. Some investigators have reported infectivity and abnormal forms of the PrP molecule in the blood of experimental animals. However, there is no human epidemiological evidence that blood transfusion is a risk factor for cCJD.

- **Other body fluids/secretions** - Tears, saliva, sputum, faeces, milk, semen and other bodily secretions have not been shown to transmit the infectious agent using currently available tests (See Table 31.7.3). Most external bodily secretions have not shown infectivity either in humans or in milk-producing experimental animals (WHO, 1998b).

  There is one report of urine of a single patient with cCJD being infectious in mice. There is also a recent, as yet unconfirmed report that the abnormal isoform of the prion protein (PrP^{Sc}) has been found in the urine of patients with CJD, in bovines with BSE and hamsters with scrapie.

- **Skin** - There is no evidence to suggest that CJD can be spread by contact with intact skin. Therefore, standard infection control procedures should be adequate for the most routine nursing or social interactions. Additional infection control procedures are unnecessary when open wounds (such as bedsores, abrasions or weeping rashes) are present in higher risk or lower risk patients.

Other tissues - The infectious agent has not been detected in heart or skeletal muscle, cartilage, connective tissue, adipose tissue or testes. However, additional infection control precautions apply for procedures involving the exposure of these tissues in higher risk patients, due to the involvement of blood or lymphoid tissue in such procedures.

Table 31.7.3 Demonstrated or predicted infectivity of human body tissues and fluids for cCJD

Infectivity category	Tissues	Secretions and excretions
"High infectivity" sites (Demonstrated or predicted to be consistently infectious)	Brain Pituitary gland Spinal cord Eye (retina and optic nerve)	
"Low infectivity" sites (Demonstrated or predicted to be infectious, but not consistently)	Eye (cornea and anterior chamber) Dorsal root ganglia Kidney Liver Lung Lymph nodes/spleen Placenta Trigeminal ganglia Uterus	CSF
"No infectivity" (Have not been demonstrated to be infectious).	Adipose tissue Adrenal gland Blood Bone marrow Gingival tissue Heart muscle Intestine Peripheral nerve Prostate Skeletal muscle Testes Thyroid gland	Faeces Milk Nasal mucous Saliva Semen Serous exudate Sweat Tears Urine

Source: Modified from WHO 1998b (Table 9, p46)

31.7.4 Vertical transmission

Studies of kuru indicate that vertical (mother to child) transmission does not occur, although one study suggests that the human placenta may be infectious for the CJD agent. These findings and other animal data suggest the theoretical possibility of postpartum transmissibility to the infant.

31.7.5 Health care associated (iatrogenic) transmission

CJD can be transmitted from person to person when tissue (usually brain tissue) infected with CJD is transferred to a recipient via a contaminated instrument, during a surgical procedure. Experience to date indicates that the highest risk of health care associated transmission occurs when the CNS is exposed in a patient with CJD.

31.7.6 Occupational transmission

There have been reports of cCJD in health care workers, and in farmers who were exposed to cattle with bovine spongiform encephalopathy (BSE), a bovine TSE. It remains unclear whether there is any statistically significant association between occupational exposure and cCJD.

31.8 Basic infection control measures

The reprocessing procedures required for items potentially contaminated with CJD agents are detailed in Section 31.14. Refer to Section 16 for general principles of reprocessing.

31.8.3 Tracking and traceability of equipment

Systems should be in place to track "high infectivity" site reusable items of equipment, especially for procedures where transmission of infection has been known to occur. Instruments that have been in contact with neural or ocular tissue such as brain, spinal cord, retina, optic nerve and pituitary should not only be tracked but also handled in such a way as to avoid cross contamination of any other instruments, e.g. maintaining a one way flow of instruments during surgical procedures and separating instruments potentially contaminated with CJD infectious agents from other instruments.

31.8.4 Disinfectants and sterilants

The only chemicals that have any effective activity against the TSE agents are hypochlorites, iodine and harsh acids and alkalis (see Table 31.8.4). Section 31.14 details the procedures required for disinfection and sterilisation of items potentially contaminated with CJD agents.

Table 31.8.4 Activity against TSE infectious agents by the active chemical substances used to formulate disinfectants and antiseptics

Disinfectant group	Activity against TSEs	**Other properties/comments**
Hypochlorites	Partially effective	• May be used at 20,000 ppm available chlorine (2%) for 1 hour if more stringent procedures are not suitable for higher risk CJD spills/contamination (see Table 31.14.1)
Iodine preparations	Variable/partially effective	• May be inactivated by organic matter • May corrode metals (eg aluminium) • Useful as a skin disinfectant but some preparations may cause skin reactions (povidone–iodine is much less irritant than iodine itself) • May only be used on instruments if labelled as an instrument grade disinfectant
Sodium dichloroisocyanurate (SDIC) granules	Ineffective	—
Acids (formic)	Restricted use for CJD see 12.2.1	• Corrosive/caustic • Use only with special care
Alkalis (sodium hydroxide)	Restricted use for CJD (see Table 31.14.1	• Corrosive/caustic • Use only with special care
Alcohols	Ineffective	—
Aldehydes	Ineffective	—
Chlorhexidine and biguanide polymers	Ineffective	—
Peracetic acid and other peroxide compounds	Ineffective	—
Phenolics	Ineffective	—

31.9 Identifying and managing the risk

The recommended approach (WHO, 1998b) for managing the risk of health care associated transmission of CJD is to identify individuals who pose a risk in the health care environment and manage them under conditions that prevent disease transmission.

The standard method of preventing CJD transmission in health care environments is to destroy all instruments and fomites (materials capable of harbouring infectious agents) that have come into contact with infected tissue. Using this approach is not

only expensive and resource-intensive but it may lead to discrimination against people in recognised risk groups for CJD by limiting their access to health care services.

An alternative method of minimising disease transmission that is cost effective and efficacious can be achieved by universally applying more stringent methods of instrument processing and using less invasive clinical procedures for all patients when they are available. Taking these factors into account, it is international convention to define two risk categories that reflect the theoretical and demonstrable risks of transmitting CJD:

- higher risk — people who represent a definite risk of CJD transmission; and
- lower risk —people who represent a potential risk of CJD transmission.

These risk categories are described in more detail below. Infection control procedures and recommendations are adjusted according to the risk category of the individual and the nature of the procedure.

31.9.1 Higher risk individuals

The only certain method of diagnosing cCJD is by neuropathological examination of brain tissue.

An individual is diagnosed as "higher risk" when they present with symptoms (of cCJD) coupled with results of medical investigations that are usually associated with cCJD. These individuals, who are highly likely to have cCJD but have not had a confirmatory brain biopsy, are classified according to WHO case definitions as "definite".

Individuals diagnosed as "definite", "probable" and "possible" are all regarded as highly likely to harbour prions that can be transmitted during invasive procedures. These individuals are classified as "higher-risk" individuals.

In the WHO Manual for Strengthening Diagnosis and Surveillance of Creutzfeldt-Jakob Disease (WHO 1998b), the higher risk category includes individuals fulfilling the WHO recommended case definitions for cCJD subtypes:

- definite
- probable
- possible

Each of these higher risk categories is defined below for the Australian health care setting. An additional group has also been included in these guidelines and defined as *other higher risk individuals* (see Table 31.9.1). This group includes carriers of a pathogenic mutation and those with two or more first-degree relatives who have been

diagnosed with cCJD. The definition of "probable" cases has been extended to include the results of the assay for 14-3-3 protein in CSF. It should be noted that the sub-type of a case can change as more diagnostic information becomes available.

Table 31.9.1 Individuals in the higher risk category for CJD

Higher risk individuals	
Definite	Individuals with a confirmed clinical diagnosis of cCJD as determined by the combination of progressive dementia, myoclonus and multifocal neurological dysfunction associated with a characteristic periodic EEG and/or Individuals with a diagnosis of cCJD as determined by standard neuropathological examination
Probable	Individuals with high probability of cCJD as determined by a combination of • progressive dementia • **AND** at least two of the following four clinical features: – myoclonus – visual or cerebellar disturbance – pyramidal/extra pyramidal dysfunction – akinetic mutism • **AND** – an atypical EEG during an illness of any duration; **or** – a positive 14-3-3 CSF assay and a neurological illness of less than 2 years duration • **AND** routine investigations which do not suggest an alternative diagnosis
Possible	Individuals suspected to have cCJD as determined by a combination of • progressive dementia • **AND** at least two of the following four clinical features: – myoclonus – visual or cerebellar disturbance – pyramidal/extra pyramidal dysfunction – akinetic mutism • **AND** – no EEG or an atypical EEG • **AND** – a clinical illness of less than 2 years duration **NOTE:** Most human pituitary hormone related cases and up to 40% of sporadic cases do not demonstrate characteristic EEG appearances
Other	The following people are also classified as being at higher risk: • carriers of disease-linked mutations of the PrP gene; and • persons in whom the PrP gene has not been sequenced but who have two or more first-degree relatives with cCJD (including GSS or FFI)

31.9.2 Lower risk individuals

The following groups are defined as being at lower risk:

- Any person with a progressive neurological illness of less than one year's duration, with or without dementia. These people should have a competent and complete neurological assessment at the earliest possible opportunity to determine whether they should be moved into the *higher risk* category or moved out of the

risk categories altogether (i.e. at no risk for the purposes of CJD management). Persons for whom a determination cannot be made following competent professional review to assess the parameters for higher risk people (as specified above) should remain in the *lower risk* category.

- Any person with progressive neurological illness of less than one year's duration, with or without dementia, who is waiting the outcome of assessments as specified above.

- Patients who are subject to neurosurgical investigations. During the investigation, instruments should be regarded as potentially contaminated until the patient's risk status is confirmed. Where possible use disposable instruments or apply the reprocessing and quarantining procedures detailed in Section 31.12.4 for this group of individuals where CJD cannot be ruled out on clinical grounds. These recommendations apply to –

  (a) Patients undergoing a diagnostic biopsy for progressive brain disease; or

  (b) Patients undergoing neurosurgical investigations (including brain biopsy) for a progressive disorder that includes dementia e.g. possible normal pressure hydrocephalus.

- All genetically related members of a family in which there is a strong family history (two or more first-degree relatives) of dementia or neurological illness, in which affected individuals have not been competently and completely assessed neurologically, specifically for cCJD.

- Recipients of cadaver derived human pituitary hormones (growth hormone and gonadotrophins) before 1986 (Allars, 1994).

  In Australia, five persons have developed cCJD as a result of exposure to contaminated human pituitary hormones. This is from an estimated exposed population of 2000 persons. No new cases have occurred since 1990 and it appears that the risk of further cases in this exposed population is extremely small. In contrast, the exposure of individuals of small stature to contaminated products in France and the UK has resulted in a larger number of cases per capita. New cases are still occurring in this group and this factor should be considered when a patient from UK or Europe presents for assessment.

- Recipients of dura mater homografts or transdural neurosurgery before 1990, and neurosurgical patients for whom the use of dura mater homografts cannot be excluded by reference to patient records.

  In Australia, five persons have developed CJD as a result of exposure through dura mater grafts. New cases of dura mater–associated CJD are continuing to

occur (the last occurred in 2000). Worldwide, significant numbers of cases also continue to occur (particularly in Japan where the dura mater product was used extensively). An estimation of the relative risks between dura mater-exposed population and pituitary hormone-exposed population would therefore indicate diligent approaches to identification.

- Although corneal graft recipients are not accepted as blood donors under the ARCBS blood donor deferral policy, this group does not present a risk in the health care environment and therefore have not been included in the lower risk category for CJD.

31.10 Responsibilities

Health care establishments, HCWs and patients all have specific responsibilities for infection control management that are described in Section 5. One specific aspect that applies to CJD is that HCWs should fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting (see Section 31.7). The awkward situations that have occurred in the past have generally been resolved by providing adequate education to HCWs about the real and perceived risks of transmitting CJD during medical or surgical procedures.

31.10.1 Health care establishments

General education and training responsibilities are discussed in detail in Section 9 ICG. The following key points should be included in an education program designed to equip HCWs to care for patients in either risk category for CJD.

- HCWs should fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting (see Section 31.7).

- Principals should ensure that HCWs are appropriately trained and adequate facilities are available to practise medical procedures to minimise the risk of health care associated transmission of CJD.

- Principals should ensure HCWs are aware of privacy legislation as it relates to their particular work area and are trained to understand the importance of collecting adequate medical histories from individuals or their carers and ensuring that appropriate information from the medical history is provided to other HCWs involved in the individual's treatment and care. This approach should ensure that all infection control issues are resolved before patients are prepared for medical or surgical procedures and avoid potential embarrassment, stress or inconvenience to patients.

- Principals and HCWs should maintain confidentiality in relation to the identity of people who may be in a risk group for CJD, including those people who may be genetically at risk of developing the disease.

- HCWs should implement additional precautions for the use and reprocessing of instruments to minimise the risk of health care associated transmission of CJD (see Section 31.12 and 31.14).

- HCWs should implement and maintain procedures for tracking instruments as appropriate to minimise the risk of health care associated transmission of CJD (see Section 31.12).

31.10.2 Patients, HCWs and carers

Individuals who have, or are likely to have, CJD have a moral obligation to avoid any activity that could knowingly lead to the transmission of infection to others. Patients (or their carers) should notify HCWs about anything that may affect infection control procedures. This obligation will, in practice, be constrained by the extent to which people are aware of their status. As recognition of that status is likely to become evident, in the first instance, to their medical attendants, people should be offered sensitive counselling as discussed in Section 31.11.

Current epidemiological evidence indicates that health care associated transmission of CJD may occur during some surgical procedures. Therefore, people in a *higher risk* or *lower risk* category for CJD have an obligation to advise HCWs of their status in the interest of public health. Carers also have a moral obligation to disclose the status of their patient during hospital admission procedures (see Section 31.9).

31.11 Ethical issues

Major ethical and legal considerations arise in the implementation of guidelines for the prevention of transmission of infectious disease in health care settings. Broadly, ethical issues relate to consideration of the rights of infected individuals and the responsibilities of health care workers (HCWs) to do no harm to their patients. Legal issues arise in relation to the duty of care of health care establishments to protect both patients and HCWs from infection and in relation to various State/Territory legislation concerning infectious diseases. Please refer to Section 10 of these guidelines for comprehensive information about -

- Developing and implementing policy and procedures around ethical considerations
- Isolation policies
- Duty of care — emergency care
- Referring patients to another practitioner

- Patient decision making and consent
- Preoperative testing
- Patient testing for hospital admissions
- Privacy and confidentiality
- Antidiscrimination

31.11.1 Patient decision making and consent and genetic testing

Informed and voluntary consent must be obtained before taking a clinical specimen to test for any purpose. (For further information see **Section 10.6)**. For example, screening for PrP mutations without the patient or carer's consent is unethical. Specific consent should be obtained for each blood or DNA test. In addition, the patient and the patient's family must be provided with relevant information concerning the purpose of a blood, DNA or other specific test recommended.

If family members are to be asked to undertake genetic testing for CJD, careful thought needs to be given to the ethical issues involved and to the practical consequences of being tested or of refusing to be tested. Pre and post test counselling must be offered and should be provided, preferably by a knowledgeable professional who is aware of the skills needed and the matters that should be covered, and who is prepared for the issues that might arise during counselling. Additional ethical considerations arise if parents are being asked to provide consent for their children to be tested. (For a detailed discussion of counselling for genetic tests, see NHMRC publication *Ethical Aspects of Human Genetic Testing; An Information Paper, 2000*).

The need for pre and post test counselling is based on ethical considerations relating to good patient care, there being no legal requirement for the provision of counselling for testing for this infectious disease. Special care is needed in counselling if there are barriers to communication (such as the need for an interpreter) or to comprehension. A uniform level of comprehension about the consequences of testing cannot be assumed. Pre-test counselling for genetic testing implies (among many things) that the possible consequences of any result for other family members be discussed. As this is also an infectious disease, counselling will need to cover other outcomes of a positive result, such as the requirement to notify authorities, which could lead to restrictions on the patient, or to a change in the manner in which health care is provided. Refer to section 10.6 for further information.

31.11.2 Patient competency

In obtaining consent for testing, treatment or other procedures, other than in an emergency, the treating medical practitioner must assure him/herself that the patient is an adult and has the cognitive capacity to understand what is being proposed. In

general, the more complex or risky the procedure , the higher the level of understanding will be required.

Thus obtaining consent which is ethically acceptable and legally valid can be problematic when caring for a patient whose mental competence may be fluctuating or deteriorating due to CJD.

The commonly accepted ethical goal of a consent process is to reach a decision that expresses and implements the patient's own choice, made for reasons that are most important for her or him. The expression "authentic" is sometimes used to describe a decision that so expresses an individual's well considered choice. It is implicit that the decision should not be influenced by other people's preferences or wishes.

Legally speaking, while it is customary to converse with and obtain informal consent from relatives for very minor aspects of medical and nursing care, health care workers need to be aware that a relative cannot legally give consent on behalf of a patient unless that person has been officially appointed as a decision maker, eg as guardian.

Health care workers therefore need to be conversant with the relevant guardianship or health decision legislation in their state or territory and if in doubt should not hesitate to contact the local Guardianship Board which in most jurisdictions provide a 24 hour advice service.

31.12 Patient management

31.12.1 Triage policy

When individuals are being admitted to hospital or presenting at an outpatient/emergency unit or health care waiting room a detailed medical history should be collected from an individual or their carer. Triage staff should use a "checklist" to assess patients for conditions that require additional precautions, as well as prioritising those who may require urgent attention or immediate treatment. Using a triage "checklist" may also reveal a patient with a medical history relating to CJD, for example:

- a pre-existing neurological disease that requires further evaluation;
- a family history of two or more first degree relatives with CJD or other undiagnosed neurological illness;
- a history of receiving human pituitary derived gonadotrophin (for infertility) or growth hormone (for short stature); or
- a dura mater graft in a neurosurgical or other surgical procedure before 1990.

Principals should ensure HCWs are trained to understand the importance of collecting adequate medical histories from patients or their carers and ensuring that appropriate

information from the medical history is provided to other HCWs involved in the patient's treatment and care. This approach should ensure that all infection control issues are resolved before patients are prepared for medical or surgical procedures and avoid embarrassment, stress or inconvenience to patients. Some awkward situations that have occurred previously have generally been resolved by providing adequate education to HCWs about the real and perceived risks of transmitting CJD during medical or surgical procedures and disseminating information about patients' medical histories in an appropriate manner.

31.12.2 Standard and additional precautions

Standard precautions should apply to the routine management of all patients. Additional precautions that apply to the handling and reprocessing of surgical instruments and diagnostic equipment are shown in Table 31.12.5. These and other additional precautions necessary in the care of patients in a CJD risk category (see Section 31.9) are described in Sections 31.12.6 to 31.12.10, below.

31.12.3 Disposal of Single Use Instruments

Single use instruments potentially contaminated with the infectious agent for CJD should be disposed of according to NHMRC National Guidelines for Waste Management in the Health Care Industry (see Section 15).

31.12.4 Reprocessing and quarantining instruments

Instruments used for neurosurgery, neuroradiology or ophthalmic surgery (see Table 31.12.5) should be manually cleaned and sterilised using routine methods then labelled and quarantined either -

- until the patient's CJD risk status is clarified (at which time the instruments should be destroyed if CJD is confirmed or they may be put back into circulation if there is no risk); **or**
- for the future exclusive use of that individual patient in the higher or lower risk category for CJD for the duration of the course of their therapy then disposed of by incineration (see Section 31.14.3).

31.12.5 Reprocessing instruments using additional levels of heat or chemical sterilisation

This option refers to patients in the higher risk category and only applies to instruments used for "low infectivity sites" and "no infectivity sites" (see Table 31.7.3). This option must only be used for instruments that are approved by TGA as multiple use instruments that are also capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods as detailed in Table 31.14.1.

A routine practice in many neurosurgical units is to sterilise all instruments, used in procedures involving high risk tissues, at higher temperatures and longer holding times (see table 31.14.1). This practice is encouraged for patients who are not in a risk group for CJD as a preparation for a development of procedures that can routinely be applied to
risk tissues. However, there is insufficient evidence at present to confirm that this is a safe "standard practice" for patients in CJD risk groups. All instruments used on 'high infectivity' tissues in higher or lower risk patients should be destroyed.

The TGA's advice about reprocessing "single use" instruments is as follows – *Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use" should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and that this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices, but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.*

Table 31.12.5 Additional precautions required for handling instruments and equipment for patients in the higher or lower risk categories for CJD[a]

Patient risk category	Neurosurgery, neuroradiology or ophthalmic (posterior segment) surgery	Other surgery or diagnostic procedures including ophthalmic (anterior segment) surgery
Higher risk patient[a]	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess and quarantine instruments pending determination of risk status (then destroy or put back into circulation if there is no risk) OR keep for the exclusive use of an individual patient involved in a course of therapy (then destroy)[c]	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess instruments that are approved by TGA as multiple use and can withstand additional heat or chemical sterilisation methods. These instruments may only be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1). Consideration could be given to offering alternative procedures if available and provided patient care is not compromised
Lower risk patient	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess and quarantine instruments pending determination of risk status (then destroy if there is a CJD risk, or put back into circulation if there is no risk) or keep for the exclusive use of an individual patient involved in a course of therapy (then destroy)[c]	Routine reprocessing.

[a]See Section 31.9 for a description of definite, probable and possible higher risk CJD patients.

[b]See Section 31.12.3.

[c]See Section 31.12.4

31.12.6 Surgical procedures at CJD "high infectivity" sites

Neurosurgery, neuroradiology and ophthalmology

When the brain, spinal cord, eye (retina, optic nerve), or pituitary are penetrated or exposed, maximum containment and cleaning and disinfection procedures should be used for the whole area, including surfaces, for patients in both CJD risk groups (see Table 31.12.6).

The performance of neurological, interventional neuroradiological or ophthalmological procedures (retina, optic nerve) on either higher or lower risk patients is not

contraindicated, but additional precautions are required as shown in Tables 31.12.5 and 31.12.6.

- All surgical procedures involving "high infectivity" sites in patients in the higher and lower risk categories should be undertaken at centres with appropriate neurological facilities and staff who fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting.

- All instruments and equipment exposed to CJD "high infectivity" sites (brain, spinal cord, CSF, retina or optic nerve) of higher or lower risk CJD patients should be immediately destroyed; or

- reprocessed and quarantined for the exclusive reuse by an individual patient involved in a course of therapy (and then destroyed).

- A one way flow of instruments should be maintained during surgical procedures. Instruments potentially contaminated with CJD infectious agents should be separated from other instruments until they are destroyed or reprocessed. In the latter case, surgical instruments and equipment should be manually cleaned, reprocessed using routine methods, labelled and quarantined pending subsequent treatment on the same patient. Packs of instruments should be maintained together as integral units. During reprocessing, potentially contaminated instruments should not be processed with other instruments that are destined for general re-use.

- Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should also be single use equipment.

Worldwide, only a handful of cases of iatrogenic CJD have been associated with corneal transplantation; none has occurred in Australia. Given this low risk and because of the current uncertainty of the potential infectivity present in the anterior segments of the eye (cornea, sclera, lens, etc.), instruments used in procedures in this region may be reprocessed after use in lower risk patients. Such re-use should not be allowed for instruments contacting the optic nerve or posterior segments of the eye.

Table 31.12.6 Additional precautions for neurosurgery, neuroradiology ophthalmology and other procedures on higher or lower risk CJD patients[a]

Procedure	Recommendations	
	Higher risk patient[a]	**Lower risk patient[a]**
Use of instruments	HCWs should maintain a one-way flow of instruments for all procedures and instrument potentially contaminated with CJD infectious agents should be separated from other instruments. Equipment should be single-use.	HCWs should maintain a one-way flow of instruments for all procedures and instrument potentially contaminated with CJD infectious agents should be separated from other instruments.. Equipment should be single-use.
Reusable equipment	See Table 31.12.5	See Table 31.12 5
Tonometers	Non-contact air or puff tonometers that do not contact the cornea should be used. Tonometers that come into direct contact with corneas should be discarded after use, or reprocessed using additional heat or chemical sterilisation methods (see Table 31.14.1). If non-contact tonometers are not available, disposable plastic tonometer covers should be used and discarded immediately after use.	Non-contact air or puff tonometers that do not contact the cornea are recommended. If non-contact tonometers are not available, disposable plastic tonometer covers should be used and discarded immediately after use.
Anaesthetic equipment	Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should be single use equipment.	Routine precautions should be applied.
Scheduling of patients	Operations or procedures should be scheduled at the end of the day to allow appropriate cleaning of facilities.	Operations or procedures should be scheduled at the end of the day to allow appropriate cleaning of facilities.
Training for HCWs	HCWs should be trained to understand CJD risk and be trained and tested in appropriate infection control procedures. The minimum number of HCWs should participate in the operation/procedure.	HCWs should be trained to understand CJD risks and trained and tested in appropriate infection control procedures.
Personal protective equipment (PPE)	HCWs should wear single-use PPE at all times.	HCWs should wear PPE at all times. Single-use PPE is recommended.
Surgical drapes	Surgical drapes should be single use and disposed of by incineration.	Surgical drapes should be single use and disposed of by incineration.

HCW = health care worker; CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective equipment

[a]See Section 31.9 for patient risk categories

[b]Seal items in yellow clinical waste bags with international biohazard symbol and the words " clinical waste" and dispose of by incineration. See Table 15.1.

Table 31.12.6 Continued

Procedure	Recommendations	
	Higher risk patient[a]	Lower risk patient[a]
Disposal or laundering of contaminated personal protective equipment and drapes[b]	Single-use gowns, other PPE and drapes should be incinerated after use.	Single-use gowns, other PPE and drapes should be incinerated after use. Non-disposable gowns or other PPE soiled with brain or CNS tissue should be incinerated. Normal laundering and steam sterilising is suitable for non-disposable gowns that are soiled with other tissues including blood and CSF.
Collection of specimens	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.
Disposal of specimens[b]	All spent specimens should be disposed of by incineration.	Brain, CNS tissue and CSF samples should be incinerated. Standard infection control procedures and environmental landfill recommendations should be followed for disposal of other spent specimens.
Other articles used in procedures[b]	Reusable articles should not be reused. All swabs, dressings, linen, etc used during operations should be disposed of by incineration. Needles and other sharps should be placed in appropriate containers for disposal by incineration (in accordance with AS 4031[c]).	All articles that contact brain, CNS tissue or CSF during a procedure should be disposed of by incineration. Standard infection control procedures and environmental landfill recommendations should be followed for disposal of other waste materials.

HCW = health care worker; CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective clothing

[a]See Section 31.9 for patient risk categories

[b]Seal items in yellow clinical waste bags with international biohazard symbol and the words "clinical waste" and dispose of by incineration. See Table 31.15.

[c]AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas.*

31.12.7 Neurology services

Neurologists often have the primary responsibility for the initial diagnosis and management of patients with CJD. Consequently, there is an increased likelihood of contamination of neurological instruments. Particular attention should be given to electromyography (EMG) needles, sensory testing pins and lumbar puncture needles.

For patients in both risk groups, contaminated instruments should be treated in the same way as for neurosurgical instruments (see Section 31.12.4 and Table 31.12.5).

31.12.8 Interventional radiology, general surgery, anaesthesia and obstetrics

The additional precautions required for interventional radiology, general surgery and anaesthesia are shown in Table 31.12.8. For higher-risk patients, surgical instruments in contact with tissues outside the "high infectivity" CNS sites described in Section 31.12.6 still carry a risk of CJD contamination (see Table 31.7.3) and single-use instruments should be used where possible. If reusable equipment is used, it should be either destroyed or reprocessed and quarantined for possible future exclusive use of an individual patient (see Table 31.12.5), as described in Section 31.12.6.

For other surgery in higher risk patients where instruments are not exposed to "high infectivity" tissues the instruments may be reprocessed if they comply with TGA regulations as described in Section 31.12.5 using additional levels of steam and/or chemical sterilisation as detailed in Table 31.14.1.

Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should be single use.

Additional CJD precautions should be taken when dealing with the placenta and amniotic fluid from a person with higher risk CJD (see Table 31.12.5)

Table 31.12.8 Procedures for interventional radiology, general surgery and anaesthetics for higher risk CJD patients[a]

Procedure	Recommendations
Surgical instruments	Use single-use equipment wherever possible. All instruments that have been in contact with brain, spinal cord or CSF should be destroyed. Instruments that have been in contact with blood or other tissues should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1). This only applies to instruments as detailed in Section 31.12.5.
Reusable equipment (ie, equipment not normally regarded as single-use instruments)	Avoid using endoscopes, bronchoscopes, other fibre-optic scopes and diagnostic ultrasound probes, wherever possible. (see Section 31.14.6 for further information on special instruments).
Anaesthetic equipment	Anaesthetic equipment including tubing and masks that has direct mucosal contact with patients should be single-use equipment.
Scheduling of patients	Operations or procedures should be scheduled at end of day to allow adequate cleaning of facilities.
Training and HCWs	HCWs should be trained to understand CJD risk management and be trained and tested in appropriate infection control procedures. The minimum number of people should participate in the operation/procedure.
Personal protective equipment (PPE)	HCWs should wear single-use PPE (eg gowns, caps) at all times.
Surgical drapes	Single-use surgical drapes should be used.
Disposal or laundering of contaminated PPE and drapes[b]	Single-use gowns, other disposable PPE and drapes should be incinerated. Non-disposable PPE that has been soiled with brain tissue, or CNS tissue should be incinerated. Normal laundering and steam sterilising is suitable for non-disposable PPE that are soiled with other tissues including blood and CSF.
Collection of specimens	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.
Disposal of specimens[b]	Dispose of all specimens according to NHMRC National Guidelines for Waste Management in the Health Care Industry.
Other articles used in procedures[b]	Reusable articles should not be reused. Dispose of swabs, dressings, linen etc used during operations by incineration. Needles and other sharps should be placed in appropriate containers for disposal by incineration (in accordance with AS 4031[c]).

CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective equipment

[a] Additional precautions conditions are not required for patients in the lower risk category (see Table 31.12.5)

[b] Seal items for disposal in yellow clinical waste bags with international biohazard symbol and the words "clinical waste" and dispose of by incineration. See Table 31.15.

[c] AS 4031 (1992) and Amendment 1 (1996) Non-reusable containers for the collection of sharp medical items used in health care areas.

31.12.9 Dentistry

There is no epidemiological evidence that dentistry is a risk factor for cCJD although some experimental studies suggest that it is possible to transmit a TSE through the dental route. Standard precautions apply for routine dental procedures on lower risk individuals. Additional precautionary recommendations for maxillofacial surgery and endodontic procedures are shown in Table 31.12.9. As for all procedures involving body fluids, standard precautions should also apply. Single-use items, clothing and equipment, including dental syringes should be used wherever possible.

Dentists and other HCWs should wear masks, protective eyewear, single-use gloves and gowns during all dental procedures.

Dentists should take an appropriate medical history of all patients.

Dental work on higher risk patients involving maxillofacial surgery or endodontic procedures should be carried out at a central referral facility designated by the relevant State/Territory Health authority (such as a specialist dental hospital or a dental unit in a major hospital) and by HCWs who are familiar with CJD infection control procedures.

A separate isolated water supply and separate isolated suction should be used for all patients in the higher and lower risk group involved in maxillofacial surgery and endodontic procedures.

A separate isolated water supply and separate isolated suction should be used for all patients in the higher risk group involved in all other operative dental procedures.

Table 31.12.9 shows the additional precautions necessary for dentistry on patients in a risk category for CJD.

Table 31.12.9 Additional precautions for dentistry on patients in CJD risk categories[a]

Patient risk category	Maxillofacial surgery and endodontic procedures	Other procedures
Higher risk patient	Patients should be treated in a specialised facility. A separate isolated water supply and suction should be used. Disposable handpieces should be used. All burs, broaches, reamers, files, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks.[b] All other instruments should be destroyed OR provided that OH&S concerns are satisfied all other instruments should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of an individual patient involved in a course of therapy and then destroyed.	A separate isolated water supply and suction should be used. Disposable handpieces should be used OR Hand pieces should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of a patient involved in a course of therapy. All burs, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks. [b] All other instruments should be destroyed OR provided that OH&S concerns are satisfied all other instrument should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of an individual patient involved in a course of therapy and then destroyed.
Lower risk patient	A separate isolated water supply and suction should be used. All burs, broaches, reamers, files, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks. [b] Provided that OH&S concerns are satisfied, all other instruments should be reprocessed using additional levels of steam and/or chemical sterilisation (see table 31.14.1).	Routine infection control procedures should be applied. • Anti-retraction (non-return) valves in water lines should be checked and functioning. • All burs, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks. [b]

[a]See Section 31.9 for patient risk categories

[b]Items should be sealed in yellow clinical waste bags marked with the international biohazard symbol and the words "clinical waste" and collected for disposal by incineration.

31.12.10 Routine hospital, long-term residential or community care

Routine contact with people in either risk group does not represent a risk, as there is a low potential for transmitting CJD via non-parenteral routes. Standard precautions apply and no additional precuations are required for the routine care of patients/residents. For more detail see an expanded version of this section in Appendix 9.

31.13 Health care worker responsibilities

All HCWs and other people, who are responsible for caring for patients with CJD, should be trained in appropriate infection control and risk management procedures relating to CJD that may affect personal safety.

31.13.1 Needlestick or other body fluid exposure

There are no special requirements following a needlestick or other body fluid exposure from an individual with CJD or an individual in the higher or lower risk category for CJD. If a needlestick or other exposure to blood or body fluids from a person in a CJD risk category occurs refer to Section 23.6 for standard wound cleansing procedures, and if applicable, post exposure prophylaxis (PEP).

31.13.2 Laboratory staff

In the clinical pathology laboratory, specimens from both higher and lower risk individuals should be treated according to standard precautions. However, in the anatomical/surgical pathology laboratory, appropriate containment and cleaning procedures are necessary when handling brain tissue and other surgical specimens from patients in either the higher or lower risk groups.

Cut-up/blocking of tissue samples from either risk category should be performed in a biohazard hood, preferably located in a circumscribed area that can be easily cleaned. Because of the known resistance of CJD infectivity to aldehydes and alcohols, the safest manner in which to handle biopsy material is by fixation of small blocks of tissue, followed by immersion in formic acid for one hour. After washing, these blocks can then be processed routinely for histology. Procedures for CJD infection control in laboratories are shown in Table 31.13.

31.13.3 Postmortem examinations

Guidelines relating to the conduct of postmortem examination in CJD have been reported and should follow the same protocols established for other infectious diseases such as HIV and tuberculosis.

In general, it is recommended that at least one centre in each Australian capital city be designated as a referral centre with expertise in the conduct of such an autopsy. Removal of the brain should be performed with sufficient containment to avoid aerosol contamination with the electric bone saw. Alternatively, a handsaw may be used.

After immersion-fixation of the brain in formalin, blocks can be taken and treated in formic acid as described for laboratory specimens (Table 31.13). If frozen tissue is to be retained for genetic testing, diagnosis or research, appropriately labelled containers should be used. Dedicated sets of instruments should be used for autopsies when CJD is suspected. All instruments in the autopsy room that contact CJD infectious tissue should be destroyed to avoid cross contamination of instruments that are used to harvest tissue for donation.

31.13.4 Mortuaries and funeral industry workers

Cleaning and reprocessing of instruments and surfaces in the mortuary should follow the guidelines set out in Tables 31.13 and 31.14.1.

Funeral industry workers employed in mortuaries should clean working surfaces and instruments according to the guidelines in Table 31.13 and Section 31.14 when working with the bodies of higher risk patients.

Embalming of bodies from higher risk patients should be avoided. No special precautions are required when transporting bodies.

Table 31.13 Infection control procedures in the laboratory setting for tissues from patients in the higher or lower risk groups for CJD

Procedure	Minimum safety requirements for laboratories
Standard precautions	Standard precautions apply at all times.
Steam-sterilising facilities	Facilities for steam sterilising and/or chemical cleaning of instruments and surfaces should be available in proximity to the cut-up area and mortuary.
Personal protective equipment (PPE)	Single-use gloves should be worn for all procedures involving contact with body fluids or tissues. Impermeable gowns (preferably single-use), masks and protective eyewear should be worn, particularly where splashing of blood, tissue and other body fluid may occur. All other linen (including linen soiled with blood) should be laundered as usual. Gowns contaminated with CNS tissue from CJD patients or patients in the higher or lower risk groups should be destroyed by incineration[a]. Gowns contaminated with blood or other tissues may be laundered normally.
Cleaning of contaminated surfaces (eg bench tops, floors)	Single-use absorbent bench-coats or other bench coverings should be used wherever possible and disposed of by incineration. Spills of CNS tissue or CSF should be absorbed onto paper towels and disposed of by incineration. The surface should then be soaked with 1 molar sodium hydroxide or 2.0–2.5% sodium hypochlorite, left for 1 hour and cleaned again with paper towels that are disposed of by incineration. Spills of blood or other body fluids and tissues should be cleaned using standard spills management procedures. Gloves used for protection when cleaning contaminated surfaces should be incinerated after use.
Specimen preparation and handling	Blood, tissue or CSF specimens should be collected into sealable containers and labelled clearly with the patient details, including CJD risk status. Special safety precautions should be applied when handling brain tissue and other surgical specimens from both higher and lower risk patients in anatomical/surgical pathology laboratories. A separate area with a biohazard hood should be available for cut-up/blocking of tissue samples from higher and lower risk patients. Because of the known resistance of infectivity to aldehydes and alcohols, biopsy material should be fixed in 4% formaldehyde solution (10% formol–saline), followed by immersion in formic acid (>96%) for one hour. For machine processing, tissues should be rewashed in formalin, as formic acid may damage plastic containers. Where tissues are processed by hand they should be transferred directly from formic acid into ascending alcohol solutions. Cryostat microtome should be cleaned and disinfected when frozen sections are prepared. All "high infectivity" site specimens should be treated as potentially infectious for CJD until proved otherwise. Waste tissue should be disposed of by incineration. Note: Do not steam sterilise formaldehyde solutions.
Cadavers for teaching purposes	Cadavers from either higher or lower risk patients should not be used for teaching purposes.

[a] See Section 31.9 for patient risk categorisation

31.14 Instruments and equipment

This section describes the basic principles of cleaning and reprocessing. Information about disinfectants and sterilants is given in Section 31.8.4.

Contaminated objects and surfaces, which cannot be discarded, should be disinfected with heat and/or chemicals. The following reprocessing procedures may not completely inactivate the infectious agent:

- normal steam sterilising (121°C at 15 psi or 101 kPa);
- dry heat sterilisation;
- ultraviolet or gamma irradiation;
- boiling;
- ethylene oxide;
- low-temperature hydrogen peroxide plasma and peracetic acid systems;
- glutaraldehyde and other aldehydes; and
- acetone, alcohols and most other chemical disinfectants (see Table 31.8.4).

Although there is not currently a method that guarantees complete sterilisation (Taylor and McConnell, 1988; Brown et al, 1990), the methods believed to be most effective in reducing the level of infectivity are presented in Table 31.14.1.

Table 31.14.1 Additional instrument reprocessing or disposal methods.

Note: Some instruments and devices, eg power drills, may not withstand some sterilisation methods intended for reusable items. In such cases, the manufacturer should be consulted to determine the most appropriate course of action. Additional methods are detailed in WHO, 2000.

Instruments for which additional reprocessing methods are indicated (see Tables 31.12.5 and 31.12.9) should be kept immersed in a dedicated container in an anionic detergent solution, at ambient temperature, until they are manually cleaned and reprocessed using the methods shown in the following table. Contaminated instruments from each patient should be cleaned and reprocessed in separate batches, and not mixed with other surgical instruments at any stage of the reprocessing cycle. Ultrasonic cleaners and automatic washing appliances should not be used in the preparatory cleaning process. Instruments should not be exposed to instrument-grade disinfectants or sterilants prior to the above manual cleaning procedures.

NB HCWs should adhere to State/Territory OH&S requirements at all times	
Method of Reprocessing.	**Application**
A. Incineration Soiled articles should be immediately placed into the correct container (yellow infectious waste bag with international biohazard symbol and the words " clinical waste") for disposal by incineration (see Section 14.2). Needles, blades and other sharp articles should be placed in containers (in accordance with AS 4031[a]) and disposed of by incineration.	All tissues, disposable instruments and wastes including: swabs, wound dressings, needles, catheter tubing, single-use personal protective equipment (PPE) and other single-use equipment from surgical or other procedures involving treatment of higher risk patients. Also suitable for linen soiled with CSF from higher risk patients and for disposing of contaminated organs and tissue sections. This is the preferred method for instruments exposed to tissues from higher risk patients and suitable for hospital and office practice.
B. Reprocessing alternatives for heat-resistant instruments involving steam or chemical sterilisation ***Method 1.*** Autoclave at 134°C for 18 minutes. ***Method 2.*** Immerse in 2% sodium hypochlorite solution[d] (20,000 ppm available chlorine) or 1M NaOH at ambient temperature for 1 hour. Clean, rinse in water and subject to routine sterilisation. Methods involving NaOH are not suitable for instruments containing metals that are corroded by this compound (eg aluminium alloys). 1M NaOH is very caustic, ensure adequate ventilation, avoid contact with eyes and mucous membranes and adhere to State/Territory OH&S requirements. Instruments should be completely submerged in NaOH and sodium hypochlorite solutions. Instruments should be scrubbed by hand to remove any adherent material before sterilisation. Items used to clean instruments should be either destroyed or adequately sterilised.	
C. Reprocessing alternatives for heat-sensitive instruments and surfaces ***Method 1.*** Flood with 1M NaOH or 5% sodium hypochlorite; let stand for 1 hour; mop up and rinse with water. ***Method 2.*** Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefit may be derived from the use of one or another of the partially effective methods listed in Table 7.1.	Instruments should be completely submerged in sodium hypochlorite or NaOH solution. Surfaces, eg benchtops and floors, should be thoroughly soaked in the solution for a full hour.

[a]AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas*

Source: WHO (2000)

[b] Unless otherwise specified, the recommended concentration is 1M. 1M NaOH is readily inactivated by air, forming Na_2CO_3. 1M NaOH solutions should be prepared fresh from dry NaOH or by dilution of a stock solution of 10M NaOH.

[c] Sodium hypochlorite (bleach). Efficacy depends on the concentration of available chlorine, that (unless otherwise stated) should be 20,000 ppm (2 %). Chlorine is evolved continuously by hypochlorite solutions that affects both the concentration in solution and the concentration in the environment (which is a potential health hazard). Working stocks should be prepared freshly.

Source: WHO (2000)

31.14.1 Reprocessing of reusable instruments and devices

HCWs and other people working with patients diagnosed with CJD or individuals in the higher or lower risk category should be appropriately trained and tested in the special requirements and infection control procedures necessary for personal and public safety. Education and general training requirements are discussed in the Section 9.

31.14.2 Single-use instruments and equipment

Single-use sterile instruments and equipment should be used wherever possible for procedures involving interventional radiology, general surgery and anaesthetics for higher risk patients and whenever the instruments or equipment may contact CJD contaminated neurological tissues.

The Therapeutic Goods Administration's (TGA) advice about reprocessing "single use" instruments is as follows –

Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use", should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.

This option only applies to instruments and equipment that are also capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods as detailed in Table 31.14.1

31.14.3 Reusable instruments and equipment

Additional precautions apply for handling instruments and equipment possibly contaminated with CJD. These procedures are described in Section 31.12, and Tables 31.12.5 and 31.12.6 of these guidelines.

High infectivity tissue: Higher risk patients - When an instrument contacts "high infectivity" tissue (brain, spinal cord, retina, optic nerve or pituitary; see Table 31.7.3) of patients identified in the higher risk CJD category, that instrument should be either destroyed or subjected to reprocessing and quarantined for the exclusive use of an individual patient involved in a course of therapy, and then destroyed (see Section 31.12.4, Table 31.12.5 for more detail).

Other surgery: Higher risk patients - Instruments used for other surgery on higher risk patients should be either single use or destroyed. If the instruments have been approved by TGA as multiple use and can withstand additional heat or chemical sterilisation methods (see Section 31.12.6 to 31.12.10, Tables 31.12.5 and 31.14.1) then these instruments may be reprocessed using these additional sterilisation methods.

High infectivity tissue: Lower risk patients - When an instrument contacts "high infectivity" tissue (brain, spinal cord, retina, optic nerve or pituitary; see Table 31.7.3) of patients in the lower risk CJD category, that instrument should be destroyed, or if a re-useable instrument, may be subjected to reprocessing and quarantined for the exclusive use of an individual patient involved in a course of therapy, and then destroyed (see Section 31.12.6 to 31.12.10, Table 31.12.5 for more detail).

Other surgery: Lower risk patients – **Reusable instruments used on lower risk patients may be subjected to routine reprocessing (see Section 31.12.6 to 31.12.10 and Table 31.12.5).**

31.14.4 Manual cleaning procedures

CJD infectivity may be stabilised by drying on metal surfaces and become more difficult to inactivate. Therefore instruments potentially contaminated with CJD agents should be kept immersed in a dedicated container in an anionic detergent solution, at ambient temperature, until they are manually cleaned and reprocessed using the methods shown in Table 31.14.1. Contaminated instruments from each patient should be cleaned and reprocessed in separate batches, and not mixed with other surgical instruments at any stage of the reprocessing cycle. Ultrasonic cleaners and automatic washing appliances should not be used in the preparatory cleaning process. Instruments should not be exposed to instrument-grade disinfectants or sterilants prior to the above manual cleaning procedures.

31.14.5 Disinfection and sterilisation

Most routine methods are not suitable for reprocessing items contaminated with the infectious agents of CJD (see Section 31.14). Suitable methods for inactivating these agents are described in Table 31.14.1.

31.14.6 Instruments that cannot be adequately reprocessed

There are several instruments, due to the equipment design and/or current technology available for reprocessing that cannot be cleaned and reprocessed adequately in respect of the agents of CJD and related diseases. These include, for example, endoscopes, bronchoscopes, cystoscopes, other fibreoptic scopes (e.g. laparoscopes), diagnostic ultrasound transducers, and certain ophthalmic and optometric equipment. Diagnostic or therapeutic procedures using these instruments on patients in the higher risk category for CJD should be avoided when possible.

If instruments have been in contact with “high infectivity” tissue (see Table 31.7.3) and have been reused (after use on a patient who has been subsequently diagnosed with CJD), a lookback investigation may be necessary to identify at-risk patients (see Section 31.16).

Alternative approaches to diagnosis and management of routine health conditions in patients at risk of CJD should be considered, if available, provided the care of the patient is not compromised. Best quality health care should be provided without incurring unnecessary discrimination or expense for infection containment.
For example, Radiological investigations may substitute for endoscopy in some situations.

In some cases, however, the treating medical practitioner may consider it essential to perform a procedure where an instrument which can not be adequately reprocessed in respect of CJD, comes into contact with "low infectivity tissue". In that situation, instruments should be handled as follows in respect of the patient groups described below.

Patient group A. Higher risk patients as defined in Table 31.9.1, and symptomatic patients in the lower risk group as defined in Section 31.9.2. All parts of instruments which cannot be adequately reprocessed and which come into contact with "low infectivity tissue" should be destroyed. This would include, for example, bronchoscopes, endoscopes and colonoscopes, and instruments which come into contact with the anterior components of the eye.

Patient group B. Asymptomatic patients in the lower risk group as defined in Section 31.9.2. Instruments should be kept immersed in an anionic detergent before being manually cleaned in accordance with the procedures outlined in Section 31.14.4, followed by routine reprocessing.

Patient group C. Patients for whom there is no identified risk of CJD. Instruments should be kept immersed in an anionic detergent before being manually cleaned in accordance with the procedures outlined in Section 31.14.4, followed by routine reprocessing.

> It should be noted that while these guidelines have been endorsed by the Communicable Diseases Network Australia and the National Public Health Partnership, not all members of these committees agreed with the recommended action for instruments used on Group A patients. This is due to the very limited data available to assess the possible level of risk of transmission of infectious material from "low infectivity tissue". Some health authorities may place a different interpretation on the data, and have policies which vary from these guidelines. Therefore, before undertaking procedures of this type in Group A patients, the treating medical practitioner should seek advice from the relevant State or Territory health authority.

Where a patient in Group B or Group C has undergone a procedure of this type, and is subsequently diagnosed with CJD or a related TSE, a lookback may be considered (See Section 31.16). In this situation, an instrument which has come into contact with low infectivity tissue in the patient, and has been re-used ten or fewer times before diagnosis of the patient, should be taken out of circulation. If it has been re-used more than ten times before diagnosis, it may continue to be used.

31.15 Waste management, spills and linen

See Section 15 for the guidelines on the collection and management of clinical and related wastes .

31.15.1 Spills

Spills of brain or CSF from a higher risk CJD patient on a bench top or the floor should be cleaned with sodium hydroxide (see Table 31.14.1). Spills of blood, other body fluids and tissues from patients in either the lower or higher risk CJD categories

should be cleaned using standard spills management procedures as described in Section 18.

31.15.2 Cleaning equipment (spills kit)

A sodium hydroxide spills kits (that includes OH&S recommendations) for higher risk CJD spills should be available in areas of increased risk, such as neurosurgery units, mortuaries and laboratories.

31.15.3 Linen and laundry

Disposable linen and PPE should be used when neurosurgery, ophthalmological surgery or interventional neuroradiology is carried out on higher risk CJD patients and disposed of by incineration. Re-useable linen and PPE contaminated with brain from higher or lower risk CJD patients should be disposed of by incineration.

Re-useable linen and PPE contaminated with blood, other body fluids or tissues should be laundered normally (see Section 19).

31.16 Surveillance and "lookback" investigations

State and Territory health authorities are responsible for the surveillance and control of all communicable diseases that affect the Australian population, including CJD. Nationally notifiable diseases and some selected non-notifiable infectious diseases of public health importance are regularly reported to the Commonwealth Department of Health and Ageing as part of the National Notifiable Diseases Surveillance Scheme (NNDSS). Although CJD is not currently a notifiable disease in Australia, health care establishments have a responsibility to contact local public health authorities or State/Territory Chief Health Officers directly about any incident related to possible CJD exposure. Timely notification will be especially important if look-back studies are required and/or if the media is involved (see Section 21.5).

31.16.1 Australian National CJD Registry

The Registry records the occurrence of CJD through regular contact with neurologists and anatomical pathologists. The registry also reviews death certificates and discharge diagnoses from hospitals. Upon notification of a suspected or confirmed CJD case, a registry neurologist, neuropathologist and research nurse assess the clinical and pathological information. The Registry contacts relatives of an individual with a confirmed case of CJD and request they complete a questionnaire designed to identify known or suspected risk factors. The contact details are:

Australian National CJD Registry

Department of Pathology
The University of Melbourne
PARKVILLE VIC 3052
Telephone: 03 8344 5868
Facsimile: 03 8344 4004

E-mail: ANCJD-REG@unimelb.edu.au

31.16.2 Lookback investigations

It is possible that patients or HCW may have been inadvertently exposed to CJD in the past, before the implementation of these guidelines, or that there may be future exposures resulting from infection control breach incidents. If such exposures are suspected by a medical practitioner or other HCW, or by a health care establishment, there is an ethical obligation to investigate the incident, to "lookback" and trace the individuals concerned, and to notify and counsel them about the level of risk and its potential implications. HCWs associated with suspected exposure incidents should also be informed.

The health care establishment, in consultation with the State or Territory Health Authority, is responsible for tracing individuals suspected of exposure to CJD. Health care establishments should develop a "lookback" contingency plan that can be activated in the event that an exposure is suspected. The plan should allow for tracing of potentially exposed individuals, assessment of their potential exposure to risk and consider ethical and legal issues and counselling requirements. The contingency plan should also ensure that a lookback investigation is initiated only after the level of risk is fully assessed and the need for lookback warranted.

In determining the need for a lookback study, consideration should be given to the benefit of informing individuals of a hypothetical risk of CJD and their "right to know" against the real risk of psychiatric injury and their right "not to know" about the risk of developing a disease that has no treatment or cure. Psychiatric injury is well documented after notification of increased CJD risk among some recipients of human pituitary hormones. Because of the ethical and legal implications, every effort must be made by health authorities to protect the confidentiality of the individuals concerned and to avoid publicity and media involvement in the "lookback" unless it is strictly necessary to locate those affected.

The level of risk may be considered substantial where, for example, instruments contaminated with proven CJD-affected CNS tissues have been mistakenly re-used after inadequate cleaning and reprocessing. In contrast, the level of risk may be considered minimal or theoretical in situations, for example, where endoscopy equipment has been reprocessed and re-used many times after use on an individual who is retrospectively diagnosed as having had CJD at the time of their procedure.

Where a patient has undergone a procedure such as endoscopy or bronchoscopy where the instrument can not be adequately reprocessed for CJD, and the patient is subsequently diagnosed with CJD or a related TSE, lookback is not routinely indicated. This question should be considered on a case by case basis. A decision as to whether a lookback is to be undertaken should be made in accordance with the principles outlined in these Guidelines, and in compliance with the policies of the State or Territory health authority in which the procedure was performed. Issues to be considered in assessing the appropriateness of a lookback would include, for example; the invasiveness, and hence the relative risk of the procedure, the number of times the instrument has been reprocessed since it was used on the patient (and hence the extent of diminished risk to subsequent patients), the public health implications of not conducting a lookback, and the personal health benefits, or otherwise, of notifying patients possibly at risk.An important consideration will be the degree to which the establishment can identify those exposed to the risk. In some circumstances it may not be possible to identify those exposed by direct tracing and notification. In this circumstance, the use of a community announcement may be required for lookback. The establishment must also be responsible for remedying any situation that results in a breakdown of infection control procedures.

Any medical practitioner or organisation proposing to initiate a look-back investigation for CJD should in the first instance notify their regional health authority of the circumstances and proposed look-back method and obtain appropriate advice.

31.17 Blood and blood products for transfusion

31.17.1 Donor selection

Universal policies are in place to exclude donors at risk of developing CJD. This is done more on the basis that blood should be collected from healthy individuals than because of any perceived risk of CJD transmission by blood. The ARCBS donor deferral policy is consistent with international practice and permanently defers donors with -

- a diagnosis or family history of two or more first degree relatives with TSE, including CJD, FFI and GSS;
- donors with possible exposure through treatment with cadaveric human hormones, including growth hormone and gonadotrophins prior to 1986; and
- recipients of dura mater before 1990; and
- corneal graft recipients (ARCBS, 1998).

31.17.2 Recall policies for CJD

In Australia, including a blood donation from a high-risk cCJD individual in a pool used for the manufacture of plasma products is not in itself grounds for a product recall. However fresh components should be recalled if the products are still "in-date".

In the USA the FDA's original policy required recall of both plasma products and fresh components (CBER, 1996). This was modified (CBER, 1998) to restrict plasma product recall to cases where a donor is diagnosed with vCJD (see below), but the recall provision for "in-date" fresh components was maintained. This mandatory recall of any fresh components is limited to "in-date" whole blood and "in-date" cellular products when a blood donor is identified as being at high risk of cCJD.

Modifying the policy for plasma products brought the FDA into line with European guidelines as stated by the European Medicines Evaluation Agency (EMEA), which has never required recall of plasma products because of CJD (CPMP, 1995). Given that the impact on the blood supply of such a recall is significantly less than a recall of plasma products, this policy is reasonable. Never the less, certain European authorities have elected to recall plasma products when a donor at risk of CJD (or diagnosed with CJD) contributed to the pool, despite the EMEA policy.

ARCBS and most individual national health authorities in Europe follow a similar recall policy for fresh components. This recall policy is also reflected in WHO consensus statements.

31.18 Organs and tissues for transplantation

Organs and tissues are transplanted in several situations. Solid organs such as kidneys, livers and lungs are transplanted immediately after donor death, tissues such as corneas, heart valves and skin are stored in a tissue 'bank' prior to implantation, and materials are sometimes collected for the preparation of therapeutic or diagnostic products.

In all situations the following should be excluded from the routine donation of organs and tissues:

- people in the higher and lower risk groups (see Section 31.9);
- people who die in psychiatric hospitals, with the exception of those in whom CJD has been specifically excluded; and
- people who die with any obscure undiagnosed neurological disorder, including dementia.

Agencies that are responsible for recruiting organ/tissue donors and for the banking of tissues (eg corneas, heart valves, skin) should be aware of the public health implications of CJD and should have exclusion criteria and procedures in place.

When tissues are collected at autopsy for storage in a 'bank', the brain of the cadaveric donor should be assessed by a pathologist and the paraffin blocks archived for future reference. The stored tissue should not be transplanted until examination of the autopsy material has been completed.

Particular attention should be paid by eye banks that harvest corneas. These should be obtained using procedures that prevent contamination of the cornea from instruments that are used to remove the eye and hence have come into contact with optic nerve and/or retina.

Material from patient groups at risk of transmitting CJD and related TSEs should not be used for the preparation of any therapeutic products or laboratory reagents (eg thromboplastin or Kveim test material).

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32 Other diseases

Key points

- The most significant other diseases of concern in the health care setting are scabies (caused by infestation with the mite *Sarcoptes scabiei*) and pediculosis (caused by infestation with head lice, *Pediculosis humanus capitis*). These organisms are readily transmitted through human contact.
- Additional precautions should be observed where cases of scabies or head lice have been identified.

32.1 Scabies

32.1.1 Disease description

Aetiology

Disease is caused by infestation with the mite *Sarcoptes scabiei*.

Occurrence

Scabies is a parasitic skin infestation that occurs globally. There is no seasonality in its incidence.

Clinical manifestations

The mite burrows under the skin, causing intense itching, especially in bed at night or after a hot bath or shower.

Clinical symptoms may be different or even absent in the frail elderly or those with recent corticosteroid use, making diagnosis difficult during outbreaks in long-term care establishments.

32.1.2 Transmission

Source of infection

Human beings are the only source of infection and any person infested with either mites or eggs should be regarded as infectious. Patients with hyperinfestation (Norwegian scabies) are highly infectious due to shedding large numbers of mites in skin scales.

Mode of transmission

Transmission of scabies is by direct skin-to-skin contact. In health care establishments, they are mainly transmitted by intimate direct contact with an infested person, even when high levels of personal hygiene are maintained (Danchaivijitr et al 1995, Gooch et al 1978). Transmission to health care workers (HCWs) has occurred during activities such as sponge-bathing patients or applying body lotions. Transmission between patients may also be possible when patients are ambulatory. Transmission via inanimate objects, such as clothing and bedding, is uncommon, and only occurs if the objects are contaminated immediately before contact with the new host as the mites do not survive very long out of contact with human skin.

Risk of acquisition

Susceptibility is universal. Rarely, some people may suffer hyperinfestation (Norwegian scabies), and these individuals are highly contagious.

Residents and HCWs in long-term care establishments that house patients with scabies may be more at risk of infestation than HCWs and patients in acute care establishments, mainly due to the type and frequency of skin-to-skin contact during care (eg hands within bed for prolonged periods).

32.1.3 Management

Patients

Additional precautions (contact transmission) should be observed. for at least 24 hours after appropriate treatment is initiated. Consideration should be given, in consultation with an infectious disease specialist, to extending this period in the case of immunocompromised or heavily infested patients. Patients coming from communities with endemic scabies should be considered for treatment on admission (Danchaivijitr et al 1995, Gooch et al 1978, Jimenez-Lucho et al 1995)

Health care workers

HCWs with scabies should be rostered to avoid patient contact for 24 hours after the commencement of appropriate treatment..

Instruments and environment

Routine reprocessing of instruments (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

32.2 Pediculosis (head lice)

32.2.1 Disease description

Aetiology

Disease is caused by infestation with *Pediculosis humanus capitis* (head lice).

Occurrence

Head lice are a worldwide phenomenon, occurring mainly in schoolchildren and in other institutional settings. Head lice infestation is a social problem more than an infectious disease hazard, as head lice do not transmit any diseases. Head lice can infest any person regardless of socioeconomic status or cleanliness.

Clinical manifestations

Infestation may occur in the hair, eyebrows and eyelashes. The lice cause pruritic lesions on the scalp, neck and shoulders, which may lead to crusting and matting of hair. In extreme cases, the lesions may lead to the development of secondary bacterial infections.

32.2.2 Transmission

Source of infection

Humans are the only source of infestation. Any person infested with either lice or eggs (nits) is infectious.

Mode of transmission

Transmission occurs either by direct head-to-head contact, or via hair care articles such as combs, brushes and hair accessories. Transmission to HCWs during provision of care is not highly likely unless direct head-to-head contact occurs.

Risk of acquisition

Susceptibility is universal. Head lice leave a febrile host; fever can increase the risk of transmission.

32.2.3 Management

Patients

Additional precautions (contact transmission) should be observed for at least 24 hours after appropriate treatment is initiated. There are a number of effective treatments available, but lice can become resistant to specific treatments, so advice should be sought from public health departments about suitable preparations when eradication is

difficult. Due to differences in product formulations, the manufacturer's directions for use should always be followed.

Health care workers

HCWs with head lice do not pose a risk to others unless direct head-to-head contact is likely to occur (eg during patient handling procedures). This type of contact should be avoided until no lice or eggs are visible.

Instruments and environment

Routine reprocessing of instruments (see **Sections 16 and 17**) and routine cleaning of the environment (see **Section 18**) should be employed.

Part 5

Infection control in specific health care settings

33 Operating theatres and day surgery units

Key points

- Each health care establishment undertaking surgery must have a specific protocol for operating room procedures, including specific requirements for surgical handwashing routines and handling of sharps.
- Prior to hospital admission a detailed medical history should be collected from an individual or their carer to identify conditions that may require additional precautions when individuals are being admitted to hospital or presenting at an emergency unit.
- All articles used in an operation must be sterile.
- The principles of sterile aseptic technique (see **Section 6.1**) must be applied to all operating room procedures. The principle of 'confine and contain' must be applied at all times for all patients.
- Sterile drapes must be used for the patient and sterile full operating room personal protective clothing for all health care workers.
- Patients should inform their doctor of their infectious status. Preoperative testing of patients should be on clinical indication.
- All HCWs in the surgical team should be vaccinated against hepatitis B. Surgical HCWs should not perform exposure-prone procedures if they are considered actively infectious with human immunodeficiency virus, hepatitis B virus or hepatitis C virus (see **Section 25**).
- HCWs with dermatitis or skin wounds should be excluded from the operating team.
- Operating lists should allow sufficient time for adequate infection control activities including routine cleaning and the appropriate disposal of clinical waste.
- The operating room should be cleaned as soon as practicable after surgery, including the correct handling of sharps, disposal of clinical waste and cleaning of all surfaces.

> Reusable instruments should be immersed in warm water and detergent as soon as possible after use and must then be thoroughly cleaned in a designated clean-up area before sterilisation.

33.1 Introduction

This section has been modified from the *Infection Control in Surgery* published by the Royal Australian College of Surgeons (RACS 1998).

The principles of sterile surgical technique, which is the prevention of access of microorganisms to an operative field (see **Section 6.1**), must be used for all operating room procedures. This is achieved by methods that destroy bacteria and viruses (sterilisation) or that prevent them from contaminating objects that come into contact with the surgical field (use of sterile drapes and personal protective clothing).

Modern surgery is aseptic in the use of sterile instruments, sutures and dressings and in the wearing of sterile gowns and gloves by the operating team. When the concept of the 'sterile field' is used, everything within a defined radius must be sterilised. All articles used in an operation must be sterile. All members of the operating team who are 'sterile' must touch only sterile articles; persons who are 'unsterile' must touch only unsterile articles.

Precautions should be taken to reduce microbiological risks (including the risk of transmission of hepatitis and human immunodeficiency virus (HIV) to patients and health care workers (HCWs) during all procedures in the operating room. To achieve this, the principle of 'confine and contain' applies at all times for all patients. Each patient and each operation should be considered as a potential source of contamination/infection. Therefore, it is essential that operating room HCWs demonstrate their knowledge of potential risks by ensuring that a 'confine and contain' approach is implemented for every procedure.

The surgeon in charge of the patient, the anaesthetist and the registered nurse in charge of the room should be responsible for ensuring that all members of the operating team know the operating room procedures and current infection control precautions that are to be taken, including any additional precautions that may be required. Staff involved in cleaning and sterilising instruments and equipment used in the operating rooms should also be informed of the need for any additional precautions.

Transmission of bloodborne viruses from health care worker to patient

In July 1990, the CDC reported the transmission of HIV to five patients by an infected Florida dentist during invasive dental surgery (Clesielski et al 1994). A French surgeon transmitted HIV to a patient during a long orthopaedic operation (Dorozynski 1997)

Hepatitis B virus (HBV) is considerably more infectious than HIV; at least 25% of susceptible individuals exposed to needlestick injury with hepatitis B 'e' antigen (HBeAg)-positive blood develop hepatitis. However, transmission to patients should now be rare because effective immunisation is well established, and post-exposure prophylaxis is available for individuals who have not responded to vaccination.

All HCWs in the surgical team should be vaccinated against HBV (see **Section 22**). Since the introduction of sereologic testing for HBV infection in the early 1970s there have been published reports of 20 clusters of over 300 patients who were infected with hepatitus B in association with treatment by an HBV-infected health care worker. These clusters have been linked to general practitioners, cardiopulmonary bypass pump technicians, obstetricans, gynaecologists, and cardiothoracic, abdominal, colorectal and oral surgeons.

Seven of the HCWs linked to published clusters were allowed to perform invasive procedures, following modification of techniques (eg double gloves and restriction of high risk procedures). In two instances involving an obstetrician and an oral surgeon, hepatitis was transferred to patients after techniques had been modified.

It has been estimated that about 1% of surgeons are infected with HBV, and although transmission from surgeons to patients is uncommon, a recent study indicated a surgeon who was HBeAg-positive, with a high serum HBV DNA concentration, infected 19 of 144 susceptible patients whilst performing surgery between July 1991 to July 1992, despite apparent compliance with infection control practices (Harpaz et al 1996).

There has been a reported case of a cardiac patient in the United Kingdom who developed HCV infection following surgery. The probable source was an infected cardiac surgeon (PHLS Communicable Diseases Surveillance Centre 1995). In another study, a Barcelona cardiac surgeon with chronic hepatitis C virus (HCV) may have transmitted HCV to five of his patients during open-heart surgery between 1988 and 1993 (Esteban et al 1996).

33.2 Protocol for operating room procedures

Each health care establishment undertaking surgery should have a specific protocol for operating room procedures. This should include specific requirements for surgical handwashing routines.

33.2.1 Preoperative procedures

- Patients should inform their doctor of their infectious status, particularly with regard to bloodborne diseases and any complicating factors, to ensure that

appropriate care and treatment is provided, and so that the need for any additional precautions can be identified.

- Preoperative testing of a patient for infectious agents should be on the basis of clinical indication, and medical practitioners should exercise their professional judgment in ordering any clinically relevant test, with the patient's consent. In the case of elective surgery, any testing considered relevant should be completed before admission.

- Discretion and patient confidentiality must be maintained in all circumstances.

- Surgery lists should be scheduled on the basis of clinical urgency, and in such a way as to allow ample time for adequate infection control procedures to take place. The patient's infectious or immune status should be considered in determining the patient's order on the operating list to allow appropriate clinical management that may include the need for additional precautions. Operating room and anaesthetic HCWs who may be exposed to infectious material in the course of their duty should be informed of the patient's infectious status before surgery.

- Preoperative shaving should be avoided. Clipping should be used as the standard process for hair removal in the operating room immediately before surgery. If hair is to be removed from the operative site, it can be clipped in the operating rooms without significantly increasing the wound infection rate, provided the clipper head is sterile (Alexander et al 1983, Masterton et al 1984). Shaving hair from the operative site, whether on the evening before operation or immediately before wound incision can increase the risk of wound infection (Seropian et al 1971, Alexander et al 1983, Bird et al 1984). Depilatory creams are not recommended because they can cause serious skin irritation and rashes in a significant number of patients, which may lead to wound infection (Hamilton et al 1997).

33.2.2 Requirements for health care workers

- Surgical HCWs should not perform exposure-prone procedures if they are actively infectious with HIV, HBV or HCV (see **Section 24**).

- HCWs with skin abrasions, dermatitis or wounds of the skin should be excluded from the operating team. Definitive diagnosis and treatment is needed for HCWs with dermatitis or other skin irritations (eg due to latex allergy).

33.2.3 Personal protective clothing and drapes

- Outside clothing must be changed for clean, laundered operating room attire of closely woven material.

- An impermeable, cuffed-wrist, sterile gown should be worn by HCWs. Operating room gowns should be made of waterproof fabric with ability to 'breathe', should be comfortable to wear and should be of sufficient length to overlap with protective footwear.

- Open footwear must never be worn in the operating room. Calf length, waterproof overboots should be worn where gross contamination is likely.

- Double sterile gloving, ie a double glove with the larger size glove on the inside, is recommended for all surgeons involved in operating room procedures. A prospective randomised study in which the hands and fingers of surgeons and first assistants were closely observed after surgical procedures found that when a single layer of gloves was worn, penetration of the skin occurred in 51% of cases but when a double layer was worn the rate of penetration was 7% (Hamilton et al 1997).

- If a glove is torn or a needlestick or other injury occurs, the gloves should be removed and hands washed when safety permits and new gloves should be put on promptly. The needle or instrument involved in the incident must also be removed from the sterile field. Needlestick and mucous membrane exposures are to be attended to immediately as safety permits, and reported to appropriate authorities.

- Head and facial hair should be fully covered with a cap or balaclava.

- Eye protection and face shields (see **Section 13.4**) are essential to avoid body fluid splashes to the conjunctiva. Masks with a fluid shield (attached plastic shield for eye protection), protective goggles, glasses, full-face shield or surgical helmet systems should always be worn during procedures. A surgical (fluid repellent) mask should be worn. It should be tied securely to cover the nose and mouth, and should be changed frequently.

- Full, ventilated total body suits (stretcher suits) may be used where there is a high level of risk of exposure to infectious aerosols.

- In the event of any 'strike through' of operating room clothing by body fluids, the surgeon or nurse concerned should remove the contaminated clothing, shower and redress. The clothing should then be disposed of as described for contaminated linen.

- HCWs who attend the patient should not leave the operating room until their outer gown, gloves, masks and protective face-shields are removed.

- Operating room clothing should not be worn outside the operating room environs.

- Sterile drapes used in the operating rooms should be impervious. Drapes should incorporate systems for the containment of blood and irrigation fluids.

DISCUSSION POINT

Surgical masks — do they really help?

Surgical face masks have become a tradition because of the assumption that exhaled droplets would contaminate the surgical wound and cause infection. A tracer study has shown that although masks effectively prevent large droplets from escaping, smaller droplets can escape around the periphery of the mask, not through the fabric, and still gain access to the wound (Ha'eri and Wiley 1980).

In another study, (Orr 1981) no masks were worn during operations for 6 months and the infection rate was then compared with a similar six months period during the preceding four years. It was found that during the period masks were not worn, the infection rate was significantly lower.

Masks should protect the operating team from aerosolised fluids. Researchers have shown that for ideal protection, a mask should be fluid-capture efficient and air resistant (Chen and Willeke 1992). At present, the wearing of a fluid-repellent deflector face mask is recommended mainly to protect the surgical team from blood splatter and aerosolised fluids. This function may be better served by a face shield. However, this possibility has not yet been tested (Quebbeman 1997).

33.2.4 Operating room procedures and surgical techniques

Surgical team

The surgical team should be limited to essential members, but with sufficient supporters to tend to the patient's needs without cross-contaminating the operating team. The roles of 'circulating nurses' and operating room HCWs should be clarified to prevent contact between potentially contaminated items and the surgical team. The number of students allowed to attend the operation should be limited.

Surgical handwashing

Surgical handwashing routines should be specified. Hands, nails and forearms should be washed thoroughly. The first wash for the day should be for a minimum period of five minutes and subsequent washes for three minutes. Hands should be dried carefully using sterile towels. Care should be taken to ensure there is no hand contact with any nonsterile object. An appropriate skin disinfectant should be used during the scrub (see also **Section 12.3**)

An appropriate skin disinfectant should be applied at least two and preferably five minutes before starting aseptic or surgical procedures. The user should check the

manufacturer's label for the specific contact time for each antiseptic (see also **Section 13.3**)

Anaesthetic team

Whenever procedures are done by anaesthetists where gloved hands are placed into a patient's mouth, there is the potential to pass on bloodborne viruses if the patient has had a procedure where the mucosal surfaces might have been compromised e.g. laryngeal mask insertion. This method of cross contamination can occur if the anaesthetist does not treat the immediate environment as an aseptic field, and decontaminate all that may be touched when handling successive patients. The environment should be treated as that of a dentist performing exposure prone procedures, or gloves changed on each occasion that the anaesthetist's hands enter the patient's mouth (Perceval, 1994).

Handling of sharps and avoidance of sharps injuries

- Health care establishments in which operative procedures are performed should develop and implement policies on the handling of sharps within surgical procedures.
- Before any surgical or operative procedure, the surgeon and scrub nurse should decide on the routine for passage of sharp instruments during the procedure. This may entail the designation of a 'neutral zone'.
- Sharp instruments (see **Section 6.4**) should not be passed by hand. A specified puncture-resistant sharps tray must be used for the transfer of all sharp instruments. Only one sharp must be in the tray at one time. If two surgeons are operating simultaneously, for example, varicose veins operation on both legs, each surgeon needs his/her own sharps tray.
- All operating room HCWs, including surgeons, must be responsible for safe handling of sharp instruments.
- Hand-held straight needles should not be used.
- Needles must never be picked up with the fingers, nor the fingers used to expose and increase access for the passage of a suture in deep tissues. When suturing, forceps or a needle holder should be used to pick up the needle and draw it through the tissue.
- Surgeons may use a sterile thimble on the index finger of the less dexterous hand for protection when suturing.

- Where practical, suture needles should be cut off before knots are tied to prevent needlestick injury. The sharp point of the needle should be sheathed in the jaws of the needle holder before being cut off.

- Hands of assisting HCWs must not be used to retract the wound on viscera during surgery. Self-retaining retractors should be used, or a swab on a stick, instead of fingers.

- Certain instruments should be avoided unless essential to the procedure; for example, sharp wound retractors such as rake retractors and skin hooks.

- Wire sutures should be avoided where possible because of the high injury rate to the surgeon. Following a surgical procedure, the skin should be closed with staples whenever possible.

- Blunt needles should be used to close the abdomen.

- The surgeon must avoid placing his/her less dexterous hand in potential danger.

- The diathermy and suction should be placed on the opposite side of the table to the surgeon, thereby ensuring the assistant does not reach across the table between the surgeon and nurse.

- Where appropriate, wound dressings with an impervious outer covering that will contain wound exudate should be used.

- Closed wound drainage systems should be used, inlcuding single-use articles

- Care should be taken that blood soaked sponges and swabs are kept in a sterile bowl on the surgical set-up and are carefully counted into a plastic bag when five have accumulated.

- All blood should be cleaned from the patient's skin after the operation using an aqueous solution of 0.05% w/v chlorhexidine or 0.5% cetrimide.

Laser therapy and dermabrasion

- The generation of a potentially infected aerosol plume during laser therapy requires purpose-designed plume suction that must be safely vented. The plume extractor must be as close as possible to the area of skin being worked on.

- The generation of airborne particulate matter and blood spray during dermabrasion requires the use of shielding to cover the entire face of all HCWs in the work area. Caps to protect the hair from such debris must be worn by all HCWs. As much as possible of the area in the vicinity of the procedure should be covered with either disposable or sterilisable drapes.

Instruments and equipment

- Reusable instruments and equipment used on sterile sites must be sterile and should be processed accordingly (see **Sections 16 and 17**).

Cleaning of the operating room and instruments

- In order to minimise the risk of spread of infection to other patients, adequate time must be allowed at the end of each case to allow for appropriate cleaning of the operating theatre and the appropriate disposal of clinical waste. For further details see the current Australian College of Operating Room Nurses ACORN Standards.

- Instruments for reuse should, as soon as possible after use, be immersed in warm water and detergent to prevent congealing or solidifying of blood and fatty materials, and must be thoroughly cleaned in the designated clean-up area before sterilisation. Where practicable, used instruments should be washed mechanically rather than by hand (see **Section 16.3**)

- Scalpel blades, needles and all other nonreusable sharps should be placed in a designated puncture-proof sharps container (disposable containers must comply with AS 4031[1], while reusable containers must comply with AS/NZS 4261[2]). The container should be sealed and removed from the operating room for appropriate disposal.

- Clinical waste (excluding sharps) should be placed into an appropriate leak-resistant bag, sealed and removed from the operating room. Disposal of infectious waste must comply with State/Territory regulations (see also **Section 15**).

- Linen should be handled in accordance with the establishment's linen service policy, with State/Territory health department guidelines and with Standards Australia guidelines for correct laundry practice (AS/NZS 4146[3]).

- Between cases, all surfaces (operating table, instrument table, equipment used and the floor) should be carefully cleaned using warm water and detergent.

- Blood and other body fluid spills should be cleaned up immediately, using absorbent material such as paper towelling that should then be discarded into the infectious waste bag. Gloves must be worn. The area should then be cleaned with warm water and detergent. The area may be treated with sodium hypochlorite (1% or 10,000 ppm available chlorine) or other appropriate disinfectant, in accordance with the establishment's spills management protocol. Disinfectant solutions

[1] AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas*
[2] AS/NZS 4261 (1994) and Amendment 1 (1997) *Reusable containers for the collection of sharp itemsused in human and animal medical applications*
[3] AS/NZS 4146 (2000) *Laundry practice*

should not be allowed to pool or remain on surfaces for longer than is required to effect disinfection, usually 10 minutes (see **Section 18**). Surfaces should be cleaned and dried after applying disinfectants.

- At the end of the day, after spot cleaning, the operating lights, all the furniture and equipment, including diathermy, suction, anaesthetic equipment and the operating table should be cleaned with warm water and detergent and dried thoroughly. The floor should be mopped with warm water and detergent and left dry.
- See also **Sections 15 and 18**, and ACORN Standards 2000.

33.3 Additional operating room precautions

Additional precautions are required where the transmission of infection might not be contained by standard precautions; for example:

- where pulmonary tuberculosis (or any aerosolised pathogens), or pathogens that can be spread via environmental surfaces such as methicillin-resistant *Staphylococcus aureus* (MRSA) are involved;
- where there is an established risk of transmission regardless of the nature of the procedure being undertaken; or
- where the procedure itself carries an established risk of blood accident or HCW/patient injury.

The exact nature of additional precautions that are implemented depend upon the mode of transmission (such as via aerosols), the type of microorganisms (eg Creutzfeldt–Jakob disease compared with *Staphylococcus*) and the procedure itself (eg where this carries an established risk of accidental injury).

Additional precautions may include the use of experienced surgeons and operating room HCWs to minimise the likelihood of accidents and complications, the use of special protective equipment (eg full-face visors), and the appropriate scheduling of patients on operating lists to ensure that the required additional precautions can be efficiently applied and infection of following patients avoided.

Where additional precautions are required, and in order to minimise surface contamination from aerosolised infectious material, patients may be anaesthetised in the operating room rather than the anaesthetic room.

Where additional precautions are required, and where it is possible, single-use equipment should be used (eg suction tips, bottles, tubing, drapes, gowns and sigmoidoscopes).

34 Office practice (general)

Key points

- Office practice health care establishments include general practitioner rooms, dentist rooms, specialist consulting rooms, infant welfare clinics, immunisation clinics, sports medicine clinics, acupuncture clinics, physiotherapist rooms, podiatrist rooms and so on.
- The general principles of infection control that apply to large health care settings also apply to office practices, including for surgical procedures. Each individual practice should develop a manual of protocols to be carried out during all procedures.
- Sterilisation by steam under pressure is the preferred method of sterilisation in office practice. Health care workers should be trained in the use of the steam steriliser and the manufacturer's instructions should be followed. Items must be thoroughly cleaned before sterilising.

34.1 Introduction

Office practice includes:

- general practitioner rooms;
- dentists rooms;
- specialists consulting rooms/clinics;
- infant welfare clinics;
- immunisation clinics;
- sports medicine clinics;
- acupuncture clinics;
- alternative therapists; and
- physiotherapists, chiropracters, podiatrists, etc.

Office spaces and facilities will vary. Each practice should develop a manual of the protocols required for all procedures. These should be based on the principles, work practices and procedures covered in **Parts 1 to 4** of these guidelines. The manual should be developed cooperatively with all the health care workers (HCWs) involved in the delivery of the service, and should demonstrate clearly to HCWs, patients and regulatory bodies that the principles of infection control are understood and practised.

Most dentistry, and a range of minor surgery, is carried out in office practice. The principles of infection control apply equally for surgical procedures in both the hospital and office situation, as well as for mobile medical and dental clinics.

The protocol should be drawn-up by reference to the various sections of this manual and tailor recommendations to the particular practice. In addition, an office infection control protocol or manual should include:

- methods of handwashing (routine and surgical);
- personal protective equipment requirements;
- the setting up of the treatment area in preparation for a patient visit;
- the defined areas of contamination that require protective barriers and cleaning between patients;
- change-over procedures between patients;
- management of blood or body fluid spills;
- handling and disposal of sharps;
- waste disposal;
- management of blood or body fluid exposure;
- processing of reusable items — cleaning, packaging, sterilisation, disinfection, storage;
- processing of radiographs;
- quality control mechanisms, including documentation of maintenance and monitoring programs for equipment;
- staff immunisation requirements;
- single-use items;
- solo operators (those professionals who do not have an assistant present during direct patient contact);
- continuing education;
- recording of information during patient treatment;
- use of computers and computer-run equipment during patient treatment; and
- management of water lines which have direct patient contact.

34.2 Sterilisation in office practice

Sterilisation by steam under pressure is the preferred method of sterilisation in office practice. It is described in detail in **Section 16.5.2**. Dry heat sterilisers with fan-assisted mechanical air convection (see AS 2487[4]) have had limited application (see **Section 16.5.3**) and are not recommended for office practices.

[4] AS 2487 (1981) *Dry heat sterilizers (hot air type)*

When purchasing a steam steriliser (autoclave) for use in office-based practice, consideration must be given to HCW training, quality control (see AS/ANZ 4815[5]) and running costs. Such ongoing expenditure may make the use of an external service (other office practice, hospital or commercial facility), or disposable single-use items, practical and cost-effective alternatives for smaller practices.

Sterilisers must be used in accordance with the manufacturer's instructions. It may be necessary to contact relevant State/Territory occupational health and safety authorities regarding registration and inspection of steam sterilisers.

Items must be thoroughly cleaned before sterilising. If the steriliser has a built-in drying unit, the items should also be packaged or wrapped (see **Section 16.5** for details of these procedures).

For group practices, the greater volume of instruments required may justify the use of larger, more sophisticated steam sterilisers. These larger sterilisers should conform to AS 1410 and/or AS 2192.[6]

34.2.1 Cryotherapy, electrocautery and related devices

Instruments and devices used in the treatment of skin and mucosal lesions such as warts, and which come into direct contact with the lesions must be single use, disposable or cleaned and re-sterilised after each patient. This applies to cryotherapy tips, electro cautery tips and other devices that apply treatment to skin and mucosal lesions. These tips should be processed as for other surgical instruments according to the manufacturer's recommendations either by steam or gas sterilisation.

34.3 Special precautions for CJD

Information on disposal, quarantine and reprocessing of instruments contaminated with Creutzfeldt–Jakob disease (CJD) is given in **Section 31**.

[5] AS/NZS 4815 (2001) *Office-based health care facilities not involved in complex patient procedures and processes — Cleaning, disinfecting and sterilizing reusable and surgical instruments and equipment*

[6] AS 1410 (1987) and Amendments 1 and 2 (1987) *Sterilizers – Steam – Prevacuum*
AS 2192 (1991) *Sterilizers – Steam – Downward displacement*

35 Dental practice

Key points

- All instruments and equipment (including dental burs, reamers and files) used in the mouth of patients should either be disposable (single use) or sterilised between cases*.
- HCWs should wear personal protective equipment (PPE), including eye and face protection, where aerosols are likely to be generated. Patients should be provided with protective eye equipment.
- The integrity of the operating field should be maintained during each case. The formation of droplets, splatter and aerosols should be minimised during treatment. Barrier draping, using either plastic wrap, sterile drape or preformed plastic covers, should be used where appropriate. Sterile drapes should be used for surgical procedures.
- All articles within the operating field should be considered contaminated by the case in progress and must be removed for reprocessing before the next case begins.
- Materials, equipment and instruments must be kept bagged, covered with an impermeable material in closed drawers or in dedicated covered containers until use, to protect them from contamination by aerosols created in the dental environment. Instruments that penetrate normally sterile tissue must be sterile at time of use and must be kept bagged until use. Bagging should be checked for damage before use; instruments stored in bags found to be damaged should resterilised before use.
- All environmental surfaces outside of the operating field should be maintained in a clean and hygienic condition at all times.
- Dental lasers and air abrasion devices create particular bioaerosol hazards and extra control measures are required during their use.
- All materials transported to and from dental laboratories should be firstly cleaned, disinfected as appropriate and placed in a sealed container. Standard precautions should apply when receiving, handling and working on dental materials.

In addition to the general requirements for office practice (**Section 34**), there are some special considerations and requirements for dental practice.

*In Section 35 (Dental Practice) the term "case" should be read as –

treatment provided by a dental HCW, to a patient during one session.

35.1 Liability

Nonregistered practice owners have obligations to provide facilities, health care workers (HCWs) and equipment necessary to ensure that the practice and its employee HCWs can comply with current infection control guidelines. Whilst the liability for adequate infection control procedures lies with the registered HCW, in some States/Territories the nonregistered owner shares this liability.

35.2 Personal protective equipment

Personal protective clothing and equipment is discussed in **Section 13**.

Adequate eye and face protection should be worn where aerosols are likely to be generated.

Gloves should be worn by dental HCWs for all procedures where contact with patient secretions or tissue is possible. Gloves do not need to be sterile for most general dental procedures. However, gloves should be sterile when invasive procedures (eg incision into soft tissue or surgical procedures) are carried out. In dental practice gloves should be worn for most procedures and in these circumstances allergy or sensitivity can become significant issues.

Patients should be provided with protective eye equipment.

35.3 Operative field

The integrity of the operative field should be maintained during dental procedures. Appropriate use of dental dams, high-volume evacuation and proper patient positioning should minimise the formation of droplets, splatter and aerosols during treatment.

The following equipment should be cleaned or barrier protected after each patient use:

- any hand-operated control in the operating field, the operating light handle, the X-ray head, the suction tubing and the cradles they rest in;

- any intraoral light source eg fibreoptic illuminators, intraoral cameras, the polymerising light and the handle of its light shield; and
- the bracket table and its handle.

Protective covering using either plastic wraps, sterile drape or preformed plastic covers may be applied to surfaces which have been cleaned at the beginning of each day. Protective coverings should be disposed of after each case.

Materials should be routinely pre-dispensed. However, if retrieval of additional instruments and materials from outside the operative area is required the following procedures should be followed:

- gloves must be removed and hands washed to dispense materials from their containers into the field or, alternatively, overgloves can be used;
- drawers must be opened by elbow touch, degloving or a suitable no-touch technique (eg use of transfer tweezers or single-use barriers on handles);
- retrieval of instruments or materials from drawers must be by transfer tweezers that are kept separate from the other instruments;
- transfer tweezers may be handled with gloved or ungloved hands during a case and should be sterilised at the end of each case;
- precut supplies of some materials (eg floss, cellulose acetate strips, gingival retraction cord and articulating paper) can be stored in the drawers and predispensed before procedures or retrieved with transfer tweezers.

All articles within the operative field should be deemed contaminated by the case in progress, and must be removed, cleaned, and disinfected or sterilised before the next case can begin (CDC 1991).

All instruments and equiment used in the mouth must be sterilised after each use.

35.4 Intraoral dental handpieces

All dental handpieces should be cleaned according to the manufacturer's instructions and sterilised after each patient use.

The manufacturer's instructions regarding the choice of lubricants should be followed, and care taken to choose a lubricant that does not compromise the sterilisation process. If the handpiece is relubricated after sterilising, then that lubricant system should be for post sterilisation use only. It is strongly recommended for cleaning & lubricating dental handpieces that automatic flush-through and lubricant systems are used.

35.5 Management of water-quality and aspiration

There is a hierarchy of water quality required for use in dentistry. Water used for surgical procedures should be sterile and water used for a mouth rinse should be of potable standard. Water required for irrigation for tooth preparation and ultrasonic scaling should be of no less than potable standard.

Biofilm in dental unit waterlines is an unknown hazard. It is prudent for immunocompromised patients to be treated using water in which the number of colony forming units (CFU) per mL is less than 200. CFU can be measured using commercially available test strips.

Air and water lines should be flushed for a minimum of two minutes at the start of the day and for 30 seconds between patients. For those dental units equipped with an independent water supply, the manufacturer's instructions must be closely followed for disinfection procedures.

All dental equipment that supplies water to the oral cavity must be fitted with nonreturn valves. Routine maintenance of nonreturn valves is necessary to ensure their effectiveness. Manufacturers should be consulted to establish an appropriate maintenance routine.

35.6 Aerosols

Materials, equipment and instruments must be kept bagged, covered with an impermeable material or in closed drawers until use, to protect them from contamination by aerosols created in the dental environment. Instruments penetrating tissue are required to be sterile at time of use and must be kept bagged. All environmental surfaces, apart from those contaminated in the operating field, must be cleaned at least weekly.

Dental lasers and air abrasion devices create particular bioaerosol hazards. Extra control measures for these aerosols, such as purpose-built ventilators and high-velocity suction devices, are required. Some pathogenic viruses such as human papilloma virus are not inactivated by laser or electrosurgery procedures, and appropriate filtration masks and suction are necessary to prevent inhalation. Air abrasion devices create alumina dust which can become a respiratory irritant for both HCWs and patients. In such instances, high-efficiency particle arrest (HEPA) filtration and vapour filtration is indicated.

35.7 Dental protheses, impressions and materials

Although the efficacy of disinfection of dental materials is still undetermined, standard precautions should be applied whenever handling any dental material. Implantable items must be sterile (see **Implantable items 17.12)**.

The most important step is the thorough cleaning of material that has contacted oral tissue (eg impressions). Thorough rinsing with cold running water, followed by the application of a diluted detergent and further rinsing should continue until all visible contamination is removed.

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Prosthetic work area in the clinic

- Prostheses or appliances that have already been inserted into the mouth require special attention. Any instruments, attachments and materials that contact these prostheses should be cleaned and disinfected between cases.
- A small amount of pumice should be dispensed for individual use. When the treatment is complete the remainder should be discarded and container cleaned with a detergent solution and rinsed for dispensing pumice for the next case.
-
- All burs and rubber wheels should be autoclaved and arbor bands disposed of. Polishing buff and ragwheels must be cleaned, dried and thermally disinfected or sterilised after each case. Splash guards should be cleaned between cases.
- People working on such appliances should wear a clean uniform or laboratory coat, single use gloves, protective eyewear or face shield and a mask if necessary. Exhaust fan is recommended. Vacuum exhaust at benches and fume cupboard should be available for when required.

35.8 The dental laboratory

All materials transported to and from dental laboratories should be firstly cleaned, or disinfected and placed in sealed containers. In each case, the method of disinfection should be noted on the laboratory form. Laboratory staff should be aware that laboratory items present a biological hazard and for their own safety they should practice the necessary precautions in handling biological material. Standard precautions should be applied when handling dental materials.

All prostheses should be cleaned before being polished in the lathe working area.

Receiving area in the laboratory

- An area should be set aside to receive incoming cases. The laboratory request form should be checked for details about which cleaning procedures are required before storing the items.
- Appropriate PPE such as disposable gloves, apron, eye protection or a face-shield should be worn when opening the container. A mask should be worn where there is a risk of aerosolisation or airborne transmission of infection.
- Sometimes items are sent to the laboratory without having been cleaned. When this occurs, items should be rinsed in cold running water, cleaned in a mild detergent solution until all traces of blood, debris and body fluids are removed and rinsed.
- Dispose of all packing materials and waste according to the waste regulations of State/Territory health and environmental authorities. Reusable containers should be cleaned with detergent and then disinfected.

The receiving area should be cleaned with detergent between cases. Placing a single-use impenetrable barrier (ie plastic or plastic-backed paper) on the surface is recommended.

Work area

- Hands should always be washed before leaving the work area.
- Food or drink should not be allowed in the working area.

Outgoing prostheses/appliances

On completion of the laboratory work, items should be cleaned, dried or disinfected and placed in a sealed container for despatch.

35.9 Special precautions for CJD

Information on disposal, quarantine and reprocessing of instruments potentially contaminated with the infectious agent for Creutzfeldt-Jakob disease (CJD) is given in **Section 31**.

36 Midwifery and obstetrics

Key points

- HCWs should wear personal protective equipment (PPE) when attending labouring, birthing or breastfeeding women and also when conducting postnatal checks.
- HCWs should wear gloves when handling body fluids, placental tissue, the newborn baby until any maternal blood has been removed (ie after the first bath), and when changing wet or soiled napkins.
- HCWs should be instructed about hygiene practices associated with vaginal loss in the shower. All vaginal losses should be treated as a 'spill' and cleaned appropriately (see **Section 18)**.
- Patients should be provided with information sheets about postpartum hygiene and clear guidelines about their associated responsibilities in the health care establishment.

It is important that midwifery and obstetric health care workers (HCWs) are trained in infection control procedures and have access to professional counselling services. This training should enable them to anticipate and manage situations in which they may be exposed to infectious organisms. Situations in which infectious agents may be encountered are listed below.

36.1 Antenatal care

- Procedures and physical examinations performed during the antenatal period that may expose HCWs to blood or body fluids include:Management of ante partum haemorrhage (APH)
- cervical smears;
- treatment of a threatened miscarriage and premature labour;
- Chorionic villus sampling (CVS)
- amniocentesis;
- fetal blood sampling (FBS)
- Intrauterine fetal blood transfusions
- Intrauterine fetal therapy and procedures, e.g. cystic drainage
- fetoscopy (to gain foetal blood);

- vaginal examinations; and
- collection of maternal blood for testing.

All vaginal loss or secretions should be treated as being potentially infectious (i.e. regarded as a "body fluid" that is subject to standard precautions).

36.2 Labour and birth

The following procedures performed during labour and birth may expose HCWs to blood and other body fluids:

- insertion of intravenous lines;
- lumbar epidural, where contact with cerebrospinal fluid may occur;
- rupturing of the membranes;
- spontaneous rupture of the membranes;
- vaginal examination;
- attachment of foetal scalp electrode or scalp pH meter;
- birth process either vaginally or by caesarian section; and
- delivery of the placenta and retrieval of a retained placenta.

Used needles and other disposable sharp instruments should be discarded immediately after use into an approved sharps container (see **Section 14.2**). Gross soiling should be rinsed from instruments in the delivery room and cleaning should proceed as described in **Section 16.3.**

Personal protective equipment (long gloves, at least elbow length where available) should be worn when attending labouring/birthing women in baths containing water contaminated by amniotic fluid, blood and/or faeces.

Cutting the umbilical cord

When cutting the umbilical cord, two clamps should be used to clamp the proximal and distal ends of the umbilical cord. Once clamps are in place, absorbent material should be placed over the site and the cutting instrument. This is to prevent spurting of blood during cutting.

If practicable, the umbilical cord should be cut when pulsation has ceased. Active management of 3rd stage labour decreases overall exposure of maternal/fetal blood to the HCW. Cord blood should be taken before the delivery of the placenta by releasing the cord clamp and allowing blood to drain when pressure on the cord is less. Collection of cord blood for banking purposes, which requires handling and drainage,

should be undertaken by a person wearing facial protection (mask and protective eyewear).

Disposal of the placenta

The placenta should be carefully examined with gloved hands and discarded into a plastic bag for incineration. Sink disposal units should not be used for the disposal of placentae because of the risk of generating droplets and aerosols.

36.3 Postnatal care

- Personal protective equipment should be worn to protect HCWs from contact with colostrum and/or breast milk, or blood from traumatised nipples.
- When conducting postnatal checks, HCWs must wear personal protective equipment.
- Used needles and other disposable sharp instruments should be discarded immediately after use into an approved sharps container (see **Section 14.2**).
- Gross soiling should be rinsed from instruments in the operating room and cleaning should proceed as described in **Section 16.3**.
- Gloves should be worn when handling newborns until after all blood contamination has been removed (ie after the first bath).
- Bloodstained/soiled bedding and used pads should be placed into approved leak-proof bags and disposal should be in accordance with waste management procedures (see **Section 15**).
- Mothers should be taught about hygiene practices associated with vaginal loss in the shower. All vaginal losses should be treated as a 'spill' and cleaned appropriately (see **Section 18**).
- Gloves should be worn when changing wet or soiled napkins.

37 Home and community

Key points

- Health care workers should carry personal protective equipment, including waterproof gowns, gloves, masks and goggles, to protect them from any hazards they may encounter in informal health care settings.
- HCWs should wash their hands before and after contact with community-based clients. If soap and water are not available, single-use towelettes (with detergent) may be used before an alcoholic handrub. Hands should then be washed with skin disinfectant and running water at the first opportunity.
- The workcase and all the items carried in it should be cleaned regularly or if they become soiled. Care must be taken to wash hands before removing items from, or returning clean items to, the workcase.
- Waste generated in informal health care settings must be disposed of according to local and State/Territory regulations.
- Medical supplies and client equipment should be stored in a safe place in the home. Where possible, equipment should be dismantled to allow physical removal of all particulate and biological matter, cleaned with detergent and water, and dried thoroughly before moving it into or out of the home.

37.1 Introduction

The home is an unregulated, informal setting in which to provide health care, without the infrastructure or regulations of a hospital setting or office-based practice. Basic requirements such as hot or running water may not be available and the client has control over this environment. Care providers can include family, friends or volunteers, personal care attendants and home help.

Employers have a responsibility to provide their employees with the personal protective equipment required to protect them from any hazards they may encounter.

Standard precautions should be applied in all situations in both remote and urban areas.

Further information on infection control in the home care setting can be found in Thomas (1997), Anon (1998), Davis and Madigan (1999) and Friedman and Rhinehart (1999).

37.2 Handwashing

Community health care workers (HCWs) should wash their hands before and after contact with community-based clients. In situations where access to clean running water is difficult, clean water may be transported in a canister. Canisters may be fitted with a tap. If water is not accessible, single-use towelettes (with detergent) may be used before an alcoholic handrub. Hands should then be washed with liquid handwash and running water at the first opportunity.

Community HCWs may use a clean dry towel provided by the client or employer, provided that a fresh area of the towel is used each time hands are dried. Paper towels can be used in cases where clients are unable to provide a clean dry towel for HCWs to use.

37.3 Personal protective equipment

The employer is responsible for providing personal protective equipment and community HCWs should carry it in anticipation of exposure to blood and body substances. These basic requirements can be carried into the home in a work case and should include waterproof gown, gloves, masks and goggles. Care must be taken to wash hands before removing items from or returning clean items to the work case/bag. The work case/bag and other items carried in the work case/bag such as stethoscope, sphygmomanometers and scales should be cleaned regularly or if they become soiled.

37.4 Waste disposal

Local and State/Territory regulations must be followed for the disposal of waste. The Australian and New Zealand standard for clinical and related wastes (AS/NZS 3816[7]) does not cover general domestic waste. Attempts should be made to segregate wastes at the point of generation. Hazards arise when handling, storing, transporting and disposing of waste. Blood and body substances should be disposed of directly into the sewer system where possible. Heavily exudating wound dressings should be contained in a leak-proof bag and double bagged before disposal. Care must be taken in the handling and disposal of sharps (see **Section 14**). Sharps and other clinical wastes must be disposed of according to State/Territory guidelines.

[7] AS/NZS 3816 (1998) *Management of clinical and related wastes*

37.5 Equipment and supplies

Medical supplies and client equipment should be stored in a dry area out of reach of children and pets and away from the high-traffic areas of the home. All parts of any equipment should be dismantled, where possible, to allow physical removal of all particulate and biological matter. Equipment should be cleaned with detergent and water and dried thoroughly into or out of the home, the equipment before it is transporting.

38 Long-term care establishments

Key points

- Infections in long-term care establishments (LTCE) may be community-acquired, health care associated or endemic. Residents are both susceptible to, and a potential source of, infection.
- LTCE should have an established relationship concerning infection control with any associated acute care and other health care establishments/providers for their residents.
- Each LTCE must have an infection control program coordinated by a designated infection control practitioner. In the United States 1 full-time equivalent infection control practitioner per 250 to 300 LTCE beds has been recommended.
- The home-like atmosphere of LTCE presents some specific issues for infection control (eg visiting hairdressers, podiatrists and companion animals). Companion animals require care programs, including vaccination and hygiene programs.
- Surveillance should be part of the infection control program and use trained personnel for data collection. Published definitions for infection surveillance in an LTCE should be used.
- The infection control program should also address the prescription of antimicrobial agents and LTCE should liaise with other health care establishments to which they regularly refer patients for care about the ongoing surveillance and management of patients colonised or infected with antimicrobial-resistant bacteria.
- The risks of infection can be reduced through patient health programs including immunisation, tuberculosis screening, and prevention and control from time of admission.

38.1 Introduction

A long-term care establishment (LTCE) is a home-like environment that potentially facilitates infection. Residents are often susceptible to infection and may be a source of infection (Smith and Rusnak, 1997). The spread of infection in LTCEs reflects a mixture of aetiologies, including community acquired, health care associated and endemic infections (Strausbaugh and Joseph 1999).

Transferring residents/patients between different health care settings has the potential for transmission of infection from one setting to another. There should therefore be an established infection control relationship between an LTCE and the associated acute care facilities and other health care establishments/providers for its residents. Appropriate infection control measures are required to prevent transmission of infection from one person to another, and between health care establishments (Strausbaugh and Joseph 1999).

All LTCEs must have an appropriate infection control program (see **Section 8.1**) that reflects infection control principles, including standard precautions (see **Section 2.2**) and additional precautions (see **Section 2.3**). For Commonwealth funded residential aged care services, the *Aged Care Act 1997* requires that services meet the Accreditation Standards, including Standard 4: Physical Environment and Safe Systems. Outcome 4.7: Infection Control, identifies the expected outcome that services have an effective infection control program, and policies and practices supporting this outcome.

There is also a requirement under Outcome 4.2: Regulatory Compliance, that aged care services have systems in place to identify and ensure compliance with all relevant legislation, regulatory requirements, professional standards and guidelines, about physical environment and safety systems.

As for other health care settings, a designated infection control practitioner (ICP) should be responsible for the coordination of the infection control program. This ICP can be either a staff member within the LTCE or an external consultant. They should meet the requirements of an ICP listed in **Section 8.3**. Depending on the size of the LTCE a full-time ICP may be required. In the United States it is recommended that 1 full-time equivalent ICP per 250 to 300 LTCE beds should be considered (Smith and Rusnak 1997).

Providing a home-like environment poses specific issues for LTCEs (eg visiting hairdressers, podiatrists and companion animals). These issues require an individual establishment approach within the principles of infection control. Companion animals, for example, require the involvement of a veterinary surgeon to develop a plan of care, including vaccination and hygiene programs (Duncan and APIC 2000). Under food safety legislation, animals are not permitted in kitchen areas.

38.2 Surveillance

An important element of an LTCE infection control program is surveillance of any infections in residents and staff. For residential aged care, Outcome 4.7 of the Accreditation Standards requires that policies and practices implemented in each aged care home provide surveillance programs with regard to infection control (Aged Care

Principles) .To ensure that the data collected are of high quality and useful, the surveillance activities should involve:

- a written plan to outline objectives and key elements of the process;
- consistency in surveillance methodology and standardised written definitions for collection of data;
- a process for data analysis and review.

Variability in data between establishments may occur due to differences in the type of facility and the patient population. This must be considered before rates are compared or benchmarks considered.

For further information on surveillance, see **Section 21**.

38.2.1 Methodology:

Case-finding methods vary according to resources available, including:

- ancillary reports, such as laboratory, pharmacy or radiology reports;
- resident charts; and
- reporting by staff.

The data collection tool must be developed to fit the given surveillance objective, be user friendly and provide accurate information. Personnel responsible for data collection should be trained in the use of the tool and recognition of signs of infection (APIC 1998).

Data should be analysed on a regular basis. The most common and meaningful way to express infection incidence is the number of infections per 1000 resident days (Strausbaugh and Joseph 1999).

38.2.2 Diagnosis and criteria for infection

Published definitions for infection surveillance in an LTCE should be followed (McGeer et al 1991). The following infections may be appropriate for surveying in residents of LTCEs:

- skin and soft tissue infections;
- respiratory tract infections;
- urinary tract infections;
- primary bloodstream infections;
- gastroenteritis; and
- unexplained febrile episodes.

38.3 Antibiotic-resistant bacteria

Residents of LTCEs may already be colonised or infected with multidrug-resistant organisms when they are admitted, or develop these infections through antibiotic medication during their stay (Nicolle et al 1996).

The infection control program should therefore include a component specifically addressing prescription of antimicrobial agents. Using a multidisciplinary approach, recommendations should include: clinical guidelines for empiric antimicrobial prescription, review of antibiotic usage and restricted formulary (Nicolle et al 1996).

LTCEs should liaise with other health care establishments to which they regularly refer patients for care about the ongoing surveillance and management of patients colonised or infected with antimicrobial-resistant bacteria.

38.4 Resident health programs

Health programs for residents are desirable to ensure administration of appropriate vaccines and, where possible, reduce risk of infection in this patient group (Strausbaugh and Joseph 1996). The program should include the following elements.

- Immunisation as recommended in the current edition of the *NHMRC Immunisation Handbook* (NHMRC 2000);
- Tuberculosis screening in conjunction with State/Territory public health authorities;
- Prevention and control (from the time of admission) and monitoring of physical and historical information, to provide a framework for assessing and addressing each resident's specific infection risks, including:
  - previous hospitalisation;
  - past infections (eg TB);
  - immunisation history;
  - skin integrity;
  - bladder and bowel function;
  - baseline chest x-ray; and
  - baseline microbiology from invasive devices.

APPENDICES

Appendices – Table of Contents

Appendix 1 Consensus numerator definitions

Surgical site infection (SSI)

Infections following surgery cause considerable morbidity and economic cost within the health care system. A proportion of such infections are preventable and the appropriate point of intervention can be identified if useful surveillance data are available. The National Centre for Disease Control (NCDC), National Nosocomial Infection Surveillance Service (NNIS) (Gaynes and Horan 1996) have developed definitions for surgical site infection (SSI) that fulfil both clinical and epidemiological requirements to provide useful objective surveillance data. These definitions have been extensively validated in the United States and are already widely used in Australia. Where modification to the NNIS definitions has been made, it is for clarity only with the intent of the NNIS definition continuing.

It is acknowledged that the exclusion of subjective criteria for the diagnosis of SSI may underestimate the infection rate. However, the objectivity of the definitional criteria increases the level of reliability of surveillance data when collected by multiple contributors and allows reliable intrahospital comparison. Caution, however, must be exercised within interhospital, State or national comparisons of SSI rates based on standardised definitions until adjustment can be made for the numerous factors contributing to the risk for infection.

General notes and reporting instructions

1. The SSI definitions are identical to those defined by the NNIS from CDC Atlanta (United States). The intent is to follow exactly the NNIS approach to surgical site infection surveillance. Where the chosen wording differs in the consensus group definition from NNIS, it is solely to improve clarity.

2. For surgical site infections that become apparent after discharge, a medical officer's diagnosis is not accepted unless another criterion for infection is also present, except when the diagnosis is made by the operating surgeon or registrar.

3. Rates of infection determined by post-discharge surveillance should be reported separately as 'post-discharge' (as the combined rates will often be substantially higher than if only 'in-hospital' surveillance is reported).

Definitions for the three different types of SSI (ie superficial, deep and organ space):

1. Superficial incisional

A superficial incisional SSI must meet the following criteria:

Infection involves only skin and subcutaneous tissue of the incision; and
Occurs within 30 days after the operative procedure; and

Patient has at least one of the following -

a. Purulent drainage from the superficial incision; or
b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision. Note that a positive wound swab (in contrast to wound aspirate) without other significant evidence of infection is not adequate for diagnosis of superficial SSI; or

c. At least one of the following signs or symptoms of infection –

- pain or tenderness or localised swelling or redness or heat; or
- superficial incision is deliberately explored by surgeon, and is culture-positive or not cultured. A culture-negative finding does not meet this criterion unless the patient was on antibiotics immediately prior to the wound being explored and / or the culture being taken; or
- Diagnosis of, or antimicrobial treatment of, superficial incisional SSI by the operating surgeon or registrar.

Reporting instructions

1. Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection.
2. If the incisional site infection involves or extends into the fascial and muscle layers, report as a deep incisional SSI.
3. Classify infection that involves both superficial and deep incision sites as deep incisional SSI.
4. Note that for coronary bypass graft operations, infections related to graft and chest sites must be clearly distinguished.

2. Deep incisional

A deep incisional SSI must meet the following criteria:

Infection involves deep soft tissues (eg fascial and muscle layers) of the incision; and

Occurs within 30 days after the operative procedure unless an implant[1] is left in place. If an implant is in place, then a deep SSI is any infection that appears to be related to the operative procedure and occurs within one year of the operation; and

Patient has at least one of the following -

- Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
- A deep incision spontaneously dehisces or is deliberately explored by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), or localised pain or tenderness, and is culture positive or not cultured. A culture-negative finding does not meet this criterion unless the patient was on antibiotics immediately prior to the wound being explored and/or the culture being taken.
- An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
- Diagnosis of, or antimicrobial treatment of a deep incisional SSI by operating surgeon or registrar.

Reporting instructions

Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

3. Organ/space

An organ/space SSI must meet the following criteria -
Infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure (eg appendicectomy with subsequent subdiaphragmatic abscess); and

Occurs within 30 days after the operative procedure if no implant[2] is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure; and

Patient has at least one of the following:

- purulent drainage from a drain that is placed through a stab wound into the organ/space; or

[1] A nonhuman-derived implantable foreign body (eg prosthetic heart valve, nonhuman vascular graft, mechanical heart or hip prosthesis) that is permanently placed in a patient during surgery.

[2] A nonhuman-derived implantable foreign body (eg prosthetic heart valve, nonhuman vascular graft, mechanical heart or hip prosthesis) that is permanently placed in a patient during surgery.

- organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space; or
- an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination; or
- diagnosis of, or antimicrobial treatment of an organ/space SSI by the operating surgeon or registrar.

Reporting instructions

Occasionally an organ/space infection drains through the incision. Such infection generally does not involve re-operation and is considered a complication of the incision. Therefore, classify it as a deep incisional SSI unless other criteria (e.g. radiological examination) for diagnosis of organ/space SSI infection are satisfied.

The following are specific sites of an organor space SSI:

- Osteomyelitis
- Breast abscess or mastitis
- Myocarditis or pericarditis
- Disc space
- Ear, mastoid
- Endometritis
- Endocarditis
- Eye, other than conjunctivitis
- Gastrointestinal tract
- Intra-abdominal, not specified elsewhere
- Intracranial, brain abscess or dura
- Joint or bursa
- Other infections of the lower respiratory tract
- Mediastinitis
- Meningitis or ventriculitis
- Oral cavity (mouth, tongue or gums)
- Other male or female reproductive
- Other infections of the urinary tract
- Spinal abscess without meningitis
- Sinusitis
- Upper respiratory tract
- Arterial or venous infection
- Vaginal cuff

Blood-stream infection

Bloodstream infections (BSIs) or bacteraemias represent a group of infections that have a high morbidity and mortality. Many factors may lead to the development of a bloodstream infection. Some of these are related to healthcare, a proportion of which may be preventable. Surveillance of BSIs has proven to be a useful tool in identifying significant breakdowns in infection control procedures. With ever increasing moves to provide more and more complex forms of health care in the community setting, it has become imperative to include surveillance of BSIs arising in the community. This will ensure that some of the more severe forms of healthcare associated infection are recognised and appropriately included in prevention strategies.

The CDC, NNIS system in the United States have developed a valid and reliable definition for intravascular device associated bloodstream infection (Gaynes and Horan 1996). This was modified by the Public Health Laboratory Services, Nosocomial Infection National Surveillance Scheme (NINSS) in the United Kingdom to provide useful surveillance data on a broader group of BSIs (Glynn et al 1997). Modifications to these definitions were made by the Australian Infection Control Association (AICA) Expert Working Group to include the focus and place of acquisition of infection, the intention being to extend the reach of health care associated infection surveillance beyond hospitals. These databases can now be used in conjunction with other microbiological databases to examine the impact of antibiotic resistance. Caution must be made with interhospital, State or national comparisons of bloodstream infection rates based on the standardised definition without adjustment for the numerous factors contributing to the risk of infection.

Notes

1. The definitions are modified from the National Nosocomial Infections Surveillance System (NNIS) from CDC Atlanta, USA and from the Public Health Laboratory Service of the UK (PHLS) recommendations. With regard to line-associated bloodstream infection, the definition is identical to the NNIS laboratory confirmed (primary) bloodstream infection (LCBI).

2. The Australian Infection Control Association expert working group recognises that these definitions may often require some clinical assessment of patients. The working group believes that to maintain the validity of this indicator, laboratory surveillance without clinical correlation is often inaccurate. This view is incorporated into the recommended definitions.

   The following definitions are included below:

   1. Diagnosis of bloodstream infection
   2. Place of acquisition (health care-associated/community-associated/maternally-acquired)
   3. Focus of infection
   4. Device or procedure-associated infections

1. Diagnosis of bloodstream infection

- Criterion 1 (recognised pathogens)
  Isolation of one or more recognised bacterial or fungal pathogens from one or more blood cultures (eg *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Klebsiella species, Proteus species, Salmonella species, Candida albicans*).
  Note: Where mixed isolates are obtained with one being an accepted pathogen, the potential contaminant[3] organism is to be disregarded.

- Criterion 2 (potential contaminants[b] in patients aged >1 year)
  The patient has at least one of the following signs and symptoms within 24 hours of a positive blood culture being collected:
  – fever (>38° C); or
  – chills, rigors; or
  – hypotension; and

  at least one of the following:
  a. there is isolation of a potential contaminant[b] from two (2) or more blood cultures drawn on separate occasions within a 48 hour period (isolates identified by suitable microbiological techniques); or

  b. there is isolation of a potential contaminant[b] from a single blood culture drawn from a patient with an intravascular line (within 48 hours of the episode) and appropriate antimicrobial therapy is commenced.

- Criterion 3 (potential contaminants[b] in patients aged <1 year)
  The patient has at least one of the following signs and symptoms within 24 hours of a positive blood culture being collected:

  – fever (>38° C rectal); or
  – hypothermia (<37° C rectal); or
  – apnoea or bradycardia;

  and at least one of the following:
  a. there is isolation of a potential contaminant[b] from two (2) or more blood cultures drawn on separate occasions within a 48 hour period; and

[3] Potential contaminant organisms include diphtheroids (Corynebacterium spp., etc), coagulase-negative staphylococci, micrococci, Propionibacterium spp., Bacillus spp., Alpha haemolytic streptococci, environmental Gram-negative rods, non-pathogenic Neisseria spp.

b. there is isolation of a potential contaminant[b] from a single blood culture drawn from a patient with an intravascular line (within 48 hours of the episode) and appropriate antimicrobial therapy is commenced.

General reporting instructions:

- Bloodstream infection due to the same organism(s) that recurs within 14 days of the original event is disregarded.
- Place of acquisition (healthcare-associated/community-associated/maternally acquired)

Each bloodstream infection event is categorised by place of probable acquisition as follows:

A. Healthcare associated
B. Community associated
C. Maternally acquired

A. Healthcare associated infection

Each infection event satisfies at least one (1) of the following criteria.

a. Acquired during hospitalisation and not present or incubating on admission (in inpatient neonates >48 hours after delivery); or
b. Is a complication of the presence of an indwelling medical device (eg. IV catheter, urinary catheter); or
c. Occurs within 30 days of a surgical procedure , where the bloodstream infection is related to the SSI; or
d. An invasive instrumentation or incision related to the bloodstream infection was performed within 48 hours before onset of the infection. If the time interval was longer than 48 hours, there must be compelling evidence that the infection was related to the invasive device or procedure; or
e. Associated with neutropenia (<1000 neutrophils x 10^6/L) contributed to by cytotoxic therapy.

Healthcare-associated events are subcategorised as being -

- non-inpatient associated; or
- inpatient associated.

Inpatient events are those that occur more than 48 hours after hospital admission or within 48 hours of discharge.

B. Community associated infection

These events are defined as -

- Not healthcare-associated; and

- Do not manifest more than 48 hours after admission unless an organism with a long incubation period (ie *Salmonella* Typhi) is isolated.

C. Maternally acquired infection

This type of infection is defined as an infection in a neonate that is acquired from the mother during delivery. Unless strong evidence suggests otherwise, an infection that appears less than 48 hours after birth is considered to be acquired from the mother.

Note: The maternally acquired infection classification may indicate either community or healthcare associated events. Where a neonate is born in the hospital and admitted to a neonatal Intensive Care Unit (ICU), then maternally acquired events, as defined above, would then be termed as healthcare associated consistent with the NNIS system.

2. Focus of infection

Three categories of site are recommended –

1. Unknown focus, including disseminated infections.
2. Line associated bloodstream infection (refer diagnosis of bloodstream infection, criterion 1, 2 or 3).
3. Intervascular line present within the 48 hours of the event.

The organism(s) must not be related to an infection at another site.

Other organ site focus, suggested categories are:

- urinary tract
- respiratory tract
- surgical site
- intraabdominal
- bone and joint
- hepatobiliary
- skin and soft tissue
- genital tract
- central nervous system
- head and neck
- cardivascular
- other: specify

Criteria for diagnosis of infection related to each site are not defined at this point. The published NNIS definitions from CDC may be used.

3. Device or procedure-associated infections

For each healthcare-associated event where an organ site focus is identified, it may be recorded whether the occurrence of an invasive medical procedure (eg. ERCP, arthroscopy etc) or presence of an indwelling medical device (eg. CSF shunt etc) within 48 hours of the event was potentially significant. If the time interval was longer than 48 hours, there must be compelling evidence that infection was related to the procedure or device.

Appendix 2 Australian notifiable diseases

Nationally consistent notification of infectious diseases provides data and distribution across all Australian States and Territories. These data provide a basis for the development of public health policy, a mechanism for the development of response to communicable disease outbreaks of national significance and basic information relating to the development and implementation of a communicable disease control policy. The following list shows the communicable diseases that have been nationally endorsed by Communicable Diseases Network Australia (CDNA).

Australian nationally notifiable diseases

Acquired immunodeficiency syndrome (AIDS)
Anthrax
Arbovirus infections:
- Barmah Forest virus
- Dengue virus
- Japanese encephalitis virus
- Murray Valley encephalitis virus
- Ross River virus
- Kunjin virus
- Arboviruses - not elsewhere classified (NEC)

Botulism (foodborne)
Brucellosis
Campylobacteriosis
Chlamydia trachomatis
Cholera
Cryptosporidiosis
Diphtheria
Donovanosis
Gonococcal infection
Haemolytic uraemic syndrome (HUS)
Haemophilus influenzae type b (HIB) (invasive only)
Hepatitis A
Hepatitis B incident
Hepatitis B unspecified (not Northern Territory)
Hepatitis C incident and unspecified
Hepatitis D
Hepatitis E
Hepatitis – not elsewhere classified (NEC)
Human immunodeficiency (HIV) infection
Influenza (laboratory confirmed)
Legionellosis
Leprosy

Leptospirosis
Listeriosis
Lyssavirus:
- Australian bat lyssavirus
- Rabies
- Lyssavirus – not elsewhere classified (NEC)

Malaria
Measles
Meningococcal infection
Mumps
Ornithosis (psittacosis)
Pertussis (whooping cough)
Plague
Poliomyelitis
Pneumococcal infection (invasive)
Q fever
Rubella, or congenital rubella
Salmonellosis including paratyphoid
Shigellosis
Shiga toxin- and verocytotoxin-producing *Escherichia coli* (STEC/VTEC)
Syphilis, or congenital syphilis
Tetanus
Tuberculosis
Typhoid
Viral Haemorrhagic fevers (quarantinable)
Yellow fever

Australian State/Territory notifiable communicable diseases

In addition to the list of nationally notifiable diseases, each State and Territory in Australia has its own list of notifiable diseases. The diseases that are additional to those on the national register are listed below for each State/Territory. However, the full list relevant to your particular State/Territory should be made available to health care workers in that jurisdiction.

- **Australian Capital Territory**
  Chancroid
  Equine morbillivirus
  Food poisoning
  Giardiasis
  Lymphogranuloma venerum
  Yersiniosis

- **New South Wales**
  Acute viral hepatitis
  Adverse event following immunisation

Chancroid
Foodborne illness in two or more related cases
Gastroenteritis among people of any age, in an institution (eg. among persons in educational or residential institutions)
Lymphogranuloma venerum
Typhus (epidemic)

- **Northern Territory**

  Acute post-streptococcal glomerulonephritis
  Acute Rheumatic Fever
  Adverse Event following Immunisation
  Amoebiasis
  Atypical Mycobacterial disease
  Chancroid
  Chlamydial conjunctivitis
  Human T-Cell Lymphotropic Virus
  Hydatid Disease
  Lymphogranuloma venerum
  Melioidosis
  Rotavirus infection
  Smallpox
  Trichomoniasis
  Thrombotic Thrombocytopaenic Purpura
  Typhus (all forms)
  Vibrio Food Poisoning
  Water or foodborne diseases in two or more related cases
  Yersiniosis

- **Queensland**

  Acute flaccid paralysis
  Adverse event following immunisation
  Alphavirus infections (all alphavirus infections including all on national list plus getah and sindis virus)
  Atypical mycobacterial disease
  Bunyavirus infections (gan gan, mapputta virus, termeil and truanaman, etc)
  Chancroid
  Ciguatera poisoning
  Echinicoccic (hydatid disease)
  Elevated lead levels
  Equine morbillivirus (Hendra virus) infection
  Flavivirus infections (including alfuy, Edge Hill, kokobera, Stratford, unspecified flavivirus, etc)
  Foodborne or water borne disease in two or more related cases
  Lymphogranuloma venereum

Melioidosis
Yersiniosis

- **South Australia**
  Atypical Mycobacterial Infection
  Hydatid disease
  Yersinia infection

- **Tasmania**
  Amoebiasis
  Chancroid
  Gastroenteritis
  Giardia infection
  Hydatid infection
  Lymphogranuloma venereum
  Mycobacterial infection
  Rickettsial infection (including Flinders Island spotted fever and others)
  Ross River Virus
  Suspected cases of food or waterborne illness
  Taeniasis
  Typhus
  Vancomycin resistant enterococci
  Vibrio infection
  Viral haemorrhagic fever
  Yersinia infection

- **Victoria**
  Food and Water borne illness (2 or more cases)
  Giardiasis

- **Western Australia**
  Amoebiasis
  Amoebic meningitis
  Chancroid (soft sore)
  Giardiasis
  Hydatids/echinococcal disease
  Melioidosis
  Methicilin-resistant *Staphyloccocus aureus* (MRSA) infection
  Relapsing fever
  Scarlet fever
  Schistosomiasis (Bilharzia)
  Typhus (Rickettsial infection)
  Yersiniosis

Appendix 3 Australian/New Zealand Standards

Australian/New Zealand Standards™ (AS/NZS) is a registered trademark. AS/NZS are published in Australia by:
Standards Australia
1 The Crescent
HOMEBUSH
NSW 2140
http://www.standards.com.au/

Australian/New Zealand Standards

Australian/NZ Standard Number	Title
AS 1079.1 – AS 1079.5 (1993–94)	*Packaging of items (sterile) for patient care*
AS 1079.1 (1993)	*Packaging of items (sterile) for patient care — Selection of packaging materials for goods undergoing sterilisation*
AS 1079.2 (1994)	*Packaging of items (sterile) for patient care — Non-reusable papers - For the wrapping of goods undergoing sterilisation in health care facilities*
AS 1079.3 (1994)	*Packaging of items (sterile) for patient care — Paper bags — For single use in health care facilities*
AS 1079.4 (1988)	*Packaging of items (sterile) for patient care — Flexible packaging systems — For single use in hospitals*
AS 1079.5 (1994)	*Packaging of items (sterile) for patient care — Non-reusable, non-woven wrapping materials — For goods undergoing sterilisation in health care facilities*
AS 1386 (1989)	*Cleanrooms and clean workstations*
AS 1410 (1987) and Amendments 1 and 2 (1987)	*Sterilisers - Steam - Pre-vacuum*
AS 1668.2 (1991) and Supplement 1 (1991)	*The use of mechanical ventilation and air-conditioning in buildings - Mechanical ventilation for acceptable indoor-air quality*
AS 2182 (1998)	*Sterilisers - Steam – Benchtop*
AS 2192 (1991)	*Sterilisers - Steam - Downward displacement*
AS 2437 (1987) and Amendment 1 (1988)	*Flusher/sanitisers for bed pans and urine bottles*
AS 2487 (1981)	*Dry heat sterilisers (hot air type)*
AS 2610.1 (1993)	*Spa pools - Public spas*

AS 2610.2 (1993)	*Spa pools - Private spas*
AS 2773 (1998)	*Ultrasonic cleaners for health care facilities*
AS 2945 (1998)	*Batch-type washer/disinfectors for health care facilities*
AS SET 3500 (1998)	*National Plumbing Code Set*
AS 3500.1 (1998)	*National plumbing and drainage - Water supply*
AS 3789.2 (1991) and Amendment 1 (1992)	*Textiles for health care facilities and institutions - Theatre linen and pre-packs*
AS 3789.3 (1994)	*Textiles for health care facilities and institutions - Apparel for operating theatre staff*
AS 3864 (1997) and Amendment 1 (1998)	*Medical refrigeration equipment - For the storage of blood and blood products*
AS 4031 (1992) and Amendment 1 (1996)	*Non-reusable containers for the collection of sharp medical items used in health care areas*
AS 4187 (1998)	*Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*
AS 4381 (1996) and Amendment 1 (1997)	*Surgical face masks*
AS 4480.1 (1998)	*Textiles for health care facilities and institutions — Medical sheepskins — Product specification and testing*
AS/NZS 1337 (1992) and Amendment 1 (1994)	*Eye protectors for industrial applications*
AS/NZS 1730 (1996)	*Washbasins*
AS/NZS 2243.3 (1995) and Amendments 1 (1995) and 2 (1998)	*Safety in laboratories — Microbiology*
AS/NZS 3666 (1995)	*Air-handling and water systems of buildings - Microbial control*
AS/NZS 3816 (1998)	*Management of clinical and related wastes*
AS/NZS 3896 (1998)	*Waters — Examination for legionellae including Legionella pneumophila*
AS/NZS 4011 (1997) and Amendment 1 (1998)	*Single-use examination gloves — Specification*
AS/NZS 4146 (2000)	*Laundry practice*
AS/NZS 4179 (1997)	*Single-use sterile surgical rubber gloves — Specification*
AS/NZS 4261 (1994) and Amendment 1 (1997)	*Reusable containers for the collection of sharp items used in human and animal medical applications*
AS/NZS 4815 (2001)	*Office-based health care facilities not involved in complex patient procedures and processes — Cleaning, disinfecting and sterilising reusable and surgical instruments and equipment*

Other Standards

ISO (International Standards Organization) (1999). Draft International Standard (DIS)/ Preliminary Norme (prEN) 15883. *Washer-disinfectors*

ANSI/AAMI (American National Standards Institute / Association for the Advancement of Medical Instrumentation) (1996). SR35. *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*.

Appendix 5 Reviewers of previous edition

Organisations

Australasian Society for Ultrasound in Medicine (ASUM)

Australian College of Midwives Incorporated

Australian Confederation of Operating Room Nurses (ACORN)

Australian Dental Association (ADA)

Australian Health Ethics Committee (AHEC)

Australian Infection Control Association (AICA)

Australian Medical Association Limited (AMA)

Australian National Council on AIDS and Related Diseases (ANCARD)

Australian Nursing Federation

Australian Private Hospitals Association Limited

Australian Red Cross Blood Service (ARCBS)

Australian Society of Anaesthetists

Communicable Diseases Network Australia New Zealand (CDNANZ)

CDNANZ Nosocomial Infection Advisory Group

Consumers' Health Forum of Australia

Dental Hygienists Association

Department of Employment, Training and Industrial Relations, Division of Workplace Healthcare and Safety

Food Science Australia

Gastroenterological Nurses Society of Australia (GENSA)

Gastroenterological Society of Australia (GESA)

Health Department of Western Australia

Infection Control Guidelines Review Project Team, NCDC

Infection Control Guidelines Review Steering Committee

Institute of Ambulance Officers

National Association of Specialist Obstetricians and Gynaecologists

Department of Health and Ageing, National Centre for Disease Control (NCDC)

Department of Health and Ageing, National Centre for Epidemiology and Population Health (NCEPH)

Department of Health and Ageing, Pituitary Hormones Section, NCDC

Respiratory Nurses Group

Royal Australasian College of Surgeons (RACS)

The Royal Australian College of General Practitioners (RACGP)

Royal District Nursing Service

Royal Hospital for Women

St Johns Ambulance Australia

Standards Australia

The Australasian College of Sexual Health Physicians

The Transplant Society of Australia and New Zealand Inc.

Department of Health and Ageing, Therapeutic Goods Administration Laboratories (TGAL) – Microbiology Section

Department of Health and Ageing, Therapeutic Goods Administration Laboratories (TGAL) - Blood Products Section

TheThoracic Society

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David Isaacs (New Children's Hospital)

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Tom Riley (Dept of Microbiology, The University of WA)

Yvonne Cossart (University of Sydney)

Appendix 6 Respondents to public consultation

First public consultation (July 2000)

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Pam Keating

Australian and New Zealand College of Anaesthetists
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Australian Chemical Specialties Manufacturers Association
Bronwyn Capanna, Executive Director

Australian Chemical Specialties Manufacturers Association
Geoff Harris, Technical Manager

Australian Dental Association
Robert Butler, Executive Director

Australian Dental Industry Association
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Australian Divisions of General Practice Limited
Dr Steve Clark, Chief Executive Officer

Australian Federation of AIDS Organisations
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Australian General Practice Accreditation Ltd

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Australian Infection Control Association
Ms Dolly Olesen, President

Australian Medical Association Limited
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Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD)
Hepatitis C Committee
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Australian Self-Medication Industry
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apoda@apodc.com.au
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Australian Acupuncture and Chinese Medicine Association
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West End QLD 4810
Tel: 07 3846 5866
Freecalll: 1800 025 334
aacma@acupuncture.org.au
www.acupuncture.org.au

Australian and New Zealand Association of Nurses in AIDS Care Inc
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Tel: 03 9482 4932
twotrees@ozemail.com.au
www.vicnet.net.au/~anzanac

Australian and New Zealand Clinical Waste Management Industry Group
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Forrest Hill VIC 3131
Tel: 03 9877 9960
Fax: 03 9877 5534
nam@wasteaudit.com.au

Australian and New Zealand College of Anaesthetists
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Tel: 03 9510 6299
Fax: 03 9510 6786

Australian Association of Neurologists

145 Macquarie Street
Sydney NSW 2000
Tel: 02 9256 5443
Fax: 02 9251 8174
aansyd@hotkey.net.au
www.racp.edu.au/aan

Australian Chemical Specialties Manufacturers Association

PO Box 7495, St Kilda Road
Melbourne VIC 3004
Tel: 03 9866 6390
Fax: 03 9866 3020
gharris@acsma.asn.au

Australian College of Midwives Incorporated

1st Floor, Bowen Crescent
Melbourne VIC 3000
Tel: 03 9804 5071
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Australasian College of Sexual Health Physicians

GPO Box 1614
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Tel: 02 9382 7457
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secretariat@acshp.org.au

Australian Council on Healthcare Standards

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Ultimo NSW 2007
Tel: 02 9281 9955
Fax: 02 9211 9633
achs@achs.org.au
www.achs.org.au

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Australian Funeral Directors Association	PO Box 291 East Kew VIC 3102 Tel: 03 9859 9966 Fax: 03 9819 7390 nationaldirector@afda.org.au www.afda.org.au
Australian General Practice Accreditation Limited	PO Box 2058 Milton Business Milton QLD 4064 Tel: 07 3876 6370 Fax: 07 3876 6373 info@agpal.com.au www.agpal.com.au
Australian Healthcare Association	PO Box 54 Deakin West ACT 2600 Tel: 02 6285 1488 Fax: 02 6282 2395 admin@aha.asn.au www.aha.asn.au
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Australian Medical Acupuncture College	PO Box 7930 Bundall QLD 4217 Tel: Freecall: 1800 803 853 Fax: 07 5592 6770 www.ozacupuncture.com
Australian Medical Association Limited	PO Box E115 Kingston ACT 2604 Tel: 02 6270 5400 Fax: 02 6270 5499 http://www.ama.com.au/
Australian Medical Council	GPO Box 4810 Kingston ACT 2604 Tel: 02 6270 9777 Fax: 02 6270 9799 amc@amc.org.au www.amc.org.au
Australian National CJD Registry	Department of Pathology The University of Melbourne Parkville VIC 3010 Tel: 03 8344 5868 Fax: 03 8344 4004 ANCJD-REG@unimelb.edu.au
Australian National Council on AIDS, Hepatitis C & Related Diseases (ANCAHRD)	GPO Box 9848, MDP 13 CANBERRA ACT 2601 Tel: 02 6289 4381 Fax: 02 6289 8098 ANCAHRD@Health_gov_au www.ancahrd.org
Australian Nursing Federation	PO Box 4239

	Kingston ACT 2601 Tel: 03 9639 5211 Fax: 03 9652 0566 anfCanberra@anf.org.au www.anf.org.au
Australian Nursing Homes and Extended Care Association Ltd	PO Box 7 Strawberry Hills NSW Tel: 02 9212 6922 Fax: 02 9212 3488 office@anheca.com.au www.anheca.com.au
Australian Physiotherapy Association	PO Box 6465 St. Kilda Road Central VIC Tel: 03 9534 9400 Fax: 03 9534 9199
Australian Podiatry Association (NSW)	Suite 20/450 Elizabeth Street Surry Hills NSW 2010 Tel: 02 9698 3751 Fax: 02 9698 7116 apoda@podiatry.asn.au www.podiatry.asn.au
Australian Private Hospitals Association Ltd	25 Napier Close Deakin ACT 2602 Tel: 02 6285 2716 Fax: 02 6285 2243 info@apha.org.au
Australian Red Cross Blood Service	PO Box 10325 Adelaide Street Brisbane QLD 4000 Tel: 07 3835 1225 Fax: 07 3835 1304
Australian Self-Medication Industry	Private Bag 938 North Sydney NSW 2059 Tel: 02 9922 5111 Fax: 02 9959 3693 www.asmi.com.au
Australian Society for Microbiology	Unit 23, 20 Commercial Road

	Melbourne VIC 3004 Tel: 03 9867 8699 Fax: 03 9867 8722 admin@theasm.com.au www.vic.net.net.au//~asm
Australian Society of Anaesthestists	PO Box 600 Edgecliffe NSW 2027 Tel: 02 9327 4022 Fax: 02 9327 7666 asasec@ozemail.com.au
Commonwealth Department of Health and Ageing **Australian Council on Healthcare Standards**	**5 Macarthur Street** Ultimo NSW 2007
Australian Drug Evaluation Committee **C/- Therapeutic Goods Administration**	PO Box 100 Woden ACT 2606 Tel: 02 6232 8254 Fax: 02 6232 8103
Australian Health Ethics Committee	GPO Box 9848 Woden ACT 2606 Tel: 02 6289 9149 Fax: 02 6289 9198 www.nhmrc.health.gov.au
Blood and Organ Donation Taskforce	GPO Box 9848, MDP 14 Woden ACT 2606 Tel: 02 6289 8416 Fax: 02 6289 7791
CJD Reference Group	GPO Box 9848, MDP 14 Woden ACT 2601 Tel: Freecall: 1800 802 306
Joint Expert Technical Advisory Committee on Antiobiotic Resistance (JETACAR) is implemented by: **Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG)**	GPO Box 9848, MDP 6 Woden ACT 2606 jetacar@health.gov.au
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Centre for Eye Research Australia Limited	Locked Bag 8 East Melbourne VIC 3002 Tel: 03 9929 8350 Fax: 03 9662 3859 hmaclean@cera.unimelb.edu.au
Communicable Diseases Network Australia (CDNA) **Previously known as CDNANZ**	GPO Box 9848, MDP 6 Woden ACT 2601 Tel: Freecall: 1800 802 306 cdna@health.gov.au
Consumers Health Forum of Australia	PO Box 170 Curtin ACT 2605 Tel: 02 6281 0811 Fax: 02 6281 0959
Dental Hygienists Association of Australia Inc	PO Box 10030 Gougar Street Adelaide SA 5000 Tel: 08 9596 4644
Federation of Sterilizing Research and Advisory Councils of Australia	PO BOX 5004 Mt Gravatt East QLD Tel: 07 3840 1063
Food Science Australia	Suite 1/4 James Street Waterloo NSW 2017 Tel: 02 8399 3996 Fax: 02 8399 3997 aifst@aifst.asn.au
Gastroenterological Nurses College of Australia (Gastroenterological Nurses Society of Australia – Pre 2001)	23 Applewood Drive, Knoxfield Vic 3180 Tel: 03 9801 6352 Fax: 03 9801 6352 admin@genca.org

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Inter-Govermental Committee on AIDS Hepatitis and Related Diseases (IGCAHRD)	GPO Box 9848, MDP 13 Woden ACT 2601 Tel: Freecall: 1800 802 306 igcahrd@health.gov.au
Medical Industry Association of Australia	PO Box 497 Roseville NSW 2069 Tel: 02 9415 1151 Fax: 02 9415 2130 pdavis@miaa.org.au: www.miaa.org.au
National Centre for Immunisation Research & Surveillance	PO Box 3515 Parramatta NSW 2124 Tel: 02 9845 3069 Fax: 02 9845 3082 margarb1@nch.edu.au
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National Health and Medical Research Council Australian Health Ethics Committee	PO Box 9848 MDP 24 Woden ACT 2606 Tel: 02 6289 9802 Fax: 02 6289 9898 ben.battisson@health.gov.au
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Standards Australia	GPO Box 5420 Sydney NSW 2001 Tel: 02 8206 6000 Fax: 02 8206 6001 research@standards.com.au www.standards.com.au
Thoracic Society of Australia and New Zealand	145 Macquarie Street Sydney NSW 2000 Tel: 02 9256 5457 Fax: 02 9241 4162 bpearlman@thoracic.org.au www.thoracic.org.au
Transplant Society of Australia and New Zealand	Westmead Hospital Westmead NSW 2145 Tel: 02 9256 5461 Fax: 02 9241 4083

MANAGEMENT OF EXPOSURE TO BLOOD/BODY FLUIDS IN A HEALTH CARE SETTING

Needlestick and Blood Accidents - This bulletin is about the management of exposure to blood or body fluids contaminated with blood, including needlestick or sharps injuries with a potential for BBV infections.

DEFINITIONS AND ABBREVIATIONS

BBV Blood-borne viruses. In general the management of occupational exposures aims to prevent infection with HIV, HBV or HCV. However, in rare circumstances, other infections may be transmitted by occupational exposure.[1]

Exposed person
The person who has been exposed to blood and/or body fluids. This is assumed to be the health care worker in this document but patients and visitors may also be exposed in health care settings.

Exposure
Contact between blood or body fluids (except sweat) from the source and non-intact skin or mucous membranes of the exposed person.

HBV Hepatitis B Virus

HCV Hepatitis C Virus

HCW Health care worker(s)

HIV Human Immunodeficiency Virus

Post-exposure prophylaxis (PEP)
Medication(s) given after an exposure which may reduce the risk of acquiring an infection from the exposure.

Source
The person whose blood or body fluids were inoculated or splashed onto the exposed person. The source may not always be identifiable.

GUIDELINES FOR MANAGING EXPOSURES

The purpose of these guidelines is to inform policy development and clinical management of occupational exposures.

The potential for exposures should be minimised by the adoption of Standard Precautions and safe sharps handling practices. However, even where there is safe practice, some exposures may still occur: for example, through accidents, faulty equipment, or aggression.

For this reason, all health care settings should have policies and protocols in place for the management of exposures. The aim of protocols is to reduce the potential for transmission of BBV by first aid and post exposure prophylaxis (PEP) where indicated. Even where there are comprehensive national or state guidelines, local health settings need to develop implementation protocols to address the local situation and resources.

Policies and protocols should primarily aim to meet the needs of the exposed person, rather than the employer or health facility. Protocols should be non-punitive and simple to implement so as to encourage reporting and compliance. The immediate management including risk assessment and consideration of PEP should be considered a medical emergency in terms of timeliness and resource allocation. Protocols should ensure that the confidentiality of the exposed person and are maintained.

RECOMMENDED STEPS FOLLOWING EXPOSURE

IMMEDIATE

First aid

The aim of first aid is to minimise contact with any BBV after an exposure. The exposed person should be advised to complete the following:

1. Clean the wound/site with soap and water.
2. Flush mucous membranes/conjunctiva with normal saline or water. If contact lenses are worn, remove after flushing eye and clean as usual.
3. Further management of wound dependant on nature of injury (for example, suturing, application of dressing)

There is no advantage to the use of a stronger solution than soap and water for cleaning, as some disinfectants may inhibit wound healing.

Risk assessment

After first aid, the most important step in the management process is an assessment of the severity of the exposure to determine the risk of BBV transmission. The risk assessment will determine if PEP is warranted. The risk assessment is urgent as initiation of PEP may potentially prevent a life-threatening disease. On the other hand PEP is also expensive and may have significant side effects, so an accurate risk assessment is also important in ensuring PEP is only recommended when warranted.

Because this step is crucial to the management process, the exposed person must be immediately relieved from duty to be assessed. Supervisors must be aware of how to access a person who is able to assess risk 24 hours a day. (The initial risk assessment may be by telephone.)

In assessing whether an exposure has the potential to transmit a BBV, the following would be considered:

- type of exposure
- type of body substance
- volume of blood or body fluids
- length of time in contact with blood or body fluids
- time elapsed since exposure

In addition, after a sharps injury:

- presence of visible blood or body substance on the device causing the injury
- type of device involved
- whether a hollow bore needle or solid sharp object
- procedure for which the device was used (for example, into a vein or artery)
- gauge of the needle or device
- time elapsed since use of device
- whether the injury was through a glove or clothing

Risk of HIV transmission

The overall risk from a needlestick injury from a known HIV positive source has been estimated at 0.3%.[2] However, the factors above determine whether the exposed person is at more or less risk.

A six year retrospective study of health care workers (HCW) exposed to known HIV-infected blood identified the following factors as being associated with HIV transmission: deep injury, a device visibly contaminated with blood, procedures involving a needle placed directly in a vein or artery and terminal illness in the source.[3]

Reviews of the literature show that most cases of HIV seroconversion after occupational exposure occur after percutaneous injury from a hollow bore needle (very few are related to mucocutaneous exposures) – often after venepuncture.[4]

There have been five documented cases of occupational transmission of HIV in Australia, of which four have been in health care workers.[5, 6]

Risk of HBV transmission

It is important to remember that while much of the documentation on risk relates to HIV, the risk of HBV transmission to a non-immune person is much greater than for HIV. While all HCW are encouraged to take up vaccination, not all have done so and some remain non-responders to vaccination.

The risk of HBV transmission to a non-immune person from a single needlestick is more than 30% if the source is hepatitis B ‘e’ antigen positive, and less than 6% if the source is surface antigen positive, but ‘e’ antigen negative.[2]

Risk of HCV transmission

The risk of HCV transmission from a single needlestick injury from a confirmed HCV positive source is about 1.8%, but this rose to 10% in a study where the source patients had HCV RNA in their blood (tested by PCR).[2]

International studies of occupational transmission of HCV, suggest that the risk factors are similar to HIV – predominantly from needlestick injury with a large bore needle used for drawing blood.

Post exposure prophylaxis (PEP)

If the exposure is considered significant (i.e. able to transmit a BBV if the source were infectious) then PEP for HBV, HIV and Tetanus should be considered immediately.

HIV PEP

There is some evidence that taking Zidovudine reduces the risk of transmission of HIV after an occupational exposure.[3] There are also documented cases of seroconversion, despite early use of Zidovudine.[2] Since combination therapy is now the standard of treatment for HIV, two or three antiretroviral mediations should always be prescribed for PEP.

For significant exposures where the source is positive or at high risk, three antiretroviral medications including one protease inhibitor will usually be prescribed. Which mediations are used in combination will depend on current information and local protocols. If the source is known to be on anti HIV medications, the treatment history will influence the medications prescribed.

In general, HIV antiretroviral medications can only be prescribed by S100 prescribers or specialised services. This does not apply to starter packs of medications after occupational exposure. However, anyone who is commenced on HIV PEP should be referred as soon as possible to an S100 prescriber, or a physician specialising in HIV or infectious diseases.

If the exposed person elects to take PEP, it should be commenced as soon as possible. PEP may be commenced within 72 hours of exposure, but, while there is no research evidence for the optimal time, it is recommended that it should be commenced within a few hours if possible.

In some settings, there may not be immediate access to all antiretroviral drugs. In this case Zidovudine or Combivir should be commenced immediately (as this should be available as a starter pack in all health facilities.) Other antiretrovirals can then be accessed as soon as possible.

The following should be discussed with the exposed person before commencing PEP:

- a detailed assessment of their risk
- HIV PEP is an experimental, not a proven, therapy
- it is a 4 week course of oral therapy
- there can be difficulties taking PEP (especially if working)
- side effects - 30 - 40% in several studies do not complete the course due to side effects. It is important that the exposed person knows the difference between PEP side effects and seroconversion symptoms.
- it is the exposed individual's choice whether to take PEP and they can stop at any time
- the possibility of pregnancy

It is advisable to have the exposed person sign a consent form to indicate that these factors have been discussed with them prior to commencing PEP.

If the exposed person is pregnant and the exposure is significant, the use of PEP would be strongly encouraged. If a woman seroconverts to HIV during pregnancy there is an increased risk of the child becoming infected. There is a large body of evidence demonstrating reduction in transmission from mother to child with the use of HIV prophylaxis[2]. Many antiretroviral medications can be safely used in pregnancy. An experienced HIV physician should be consulted about the appropriate regime.

HBV PEP

If the exposed person has ever had a blood test which demonstrates HBV immunity – whether from infection or vaccination – there is no necessity for further boosters or hepatitis B immunoglobulin after a potential exposure to hepatitis B.[7]

If the exposure is significant and the exposed person has not had demonstrated immunity to HBV, hepatitis B immunoglobulin can be given within 72 hours of exposure.

After any exposure (whether significant or not) to a non-immune person who has not been vaccinated, it is advisable to commence a course of HBV vaccination. For a full discussion on the use and doses of HBV immunoglobulin and vaccination, refer to the Australian Immunisation Handbook.[7]

Tetanus PEP

If the exposure involves an injury from an object which may be contaminated with soil or dust, tetanus prophylaxis should also be considered. For a full discussion on the use, types and doses of tetanus prophylaxis refer to the Australian Immunisation Handbook.[7]

Bites and clenched fist injuries

Human bites, clenched fist injuries (which microbiologically are equivalent to human bites) and animal bites often become infected. There is no risk of HIV, hepatitis B or hepatitis C transmission from an animal bite.

The risk of HIV infection following a human bite is minimal as the saliva in HIV infected people has been demonstrated to contain insufficient quantities for transmission to occur. While there is the potential that other infectious diseases such as HBV, tetanus and to a lesser extent, HCV may be spread following a human bite, instances of this happening have rarely been documented.

The recommended management for bites and clenched fist injuries is thorough cleaning, debridement, elevation, immobilisation and prophylactic antibiotics. If obviously infected, a wound swab should be taken. In all cases,

a patient's tetanus immunisation status must be assessed. For recommended antibiotics refer to the current edition of the Therapeutic Guidelines: Antibiotic (Australia)[8]

AS SOON AS POSSIBLE (same day)

Source assessment

After a significant exposure, if information is readily available about the HIV, HBV, or HCV status of the source, this should be used to inform the decision about whether to commence PEP. However, in practice, this is rarely the case and assessing the source should not delay the commencement of PEP if the exposure warrants it.

If the source is known, but they are not known to have HIV, HBV, or HCV, and they have not had a recent negative test, they may be asked to undergo testing (with the consent of their health care provider if they are a patient.) If the source is tested, they must first give informed consent after receiving pre-test counselling according to accepted guidelines. The source must also give consent as to who may be informed of the test results.

If the source refuses or is reluctant to be tested, it must be remembered that if the exposure is not significant, or if the exposed person has elected not to take PEP, knowing the status of the source – while providing epidemiological data – will not affect the immediate management of the exposed person.

Source unknown

If the source of the exposure is unidentifiable (for example, an exposure from a discarded needle), what is known about the local prevalence of BBV should be taken into account when considering PEP. This may vary by service, institution, and geographical area.[9]

Source HIV positive

If the source is known or found to be HIV positive, PEP is still only indicated if there has been a significant exposure. A person who is HIV positive is deemed to be infectious throughout the course of the disease, however, infectivity will be greater if the source is terminally ill, has a high viral load or positive HIV antigen, or if they are seroconverting (after recent infection with HIV.)

If the source is taking or has previously taken antiretroviral medication, PEP medications for the exposed person will be adjusted so that different medications will be prescribed. This is because the virus exposed to may have some resistance to medications the source has taken.

Source HBV antigen positive

If the source is known or found to have a positive HBV antigen, and the exposed person does not have demonstrated immunity to HBV, hepatitis B immunoglobulin should be administered after a significant exposure to blood or blood-contaminated fluids.[7] A source who is hepatitis B ‘e’ antigen positive is significantly more infectious than someone who is surface antigen positive.[2]

Source HCV antibody positive

Although at present there are no specific PEP indicated for HCV, a paper by Jaekel et al (2001) provides evidence that treatment with antiviral agents during the acute phase of the disease may prevent establishment of the carrier state. At the time of writing there are insufficient data on which to base specific recommendations on the place of antivirals in PEP or management of acute Hepatitis C. However, if the source is known or likely to be HCV positive, regular liver function tests and the monitoring of clinical signs and symptoms should be undertaken by an infectious diseases physician or gastroenterologist, and specific therapy considered if appropriate.

Source with negative serology results

If the source has negative serology results, this does not automatically mean that they do not have a BBV. The possibility that they may be in the window period must be considered. In Australia, the window period is considered to be three months for HIV and six months for HBV and HCV. If the injury is significant, a detailed risk history should be taken from the source to determine if infection could have been acquired during that time. It must be realised that the source may be reluctant to disclose all lifestyle-related risk factors to a health care provider. It should also be remembered that if the source is in a window period, they may be at a particularly infectious stage of their disease process, even though test results are negative. If no risk can be determined it is for the exposed person to decide whether to discontinue PEP, if it has been commenced.

Documentation of incident

The exposure should be documented on a standard incident or accident reporting form and reported to the employer. This documentation ensures a record for the employer and the insurer, should there be a later claim and also provides evidence for Infection Control or Occupational Health and Safety personnel about potentially unsafe practices, environments, or equipment.

Prevention of transmission and crisis counselling

If the exposure is considered significant, the exposed person should be advised on ways to prevent transmission of BBVs to others. This will include advice about safe sex, safe needle use, breastfeeding, blood donation and safe work practices. As this may be a stressful time for the exposed person, it is recommended that information is also provided in writing and revisited at the next appointment - for instance with test results or occupational health and safety review. Sexual partners of exposed persons should also be offered counselling on the necessity for safe sex practices until the results of follow up tests are known.

Some people find the experience of an occupational exposure very distressing and they should be given the opportunity for immediate counselling to address anxieties.

AS SOON AS POSSIBLE (within 1 week)

Baseline blood testing

Blood testing should be offered to the exposed person to provide a baseline result against which to measure future test results. If baseline testing is to include a test for HIV, standard pre-test counselling must be provided as per local guidelines **before** blood is drawn.[11]

The baseline test is measuring any past exposures. Because any infection resulting from the current exposure will not be evident by routine blood testing for some time, this testing may be performed up to two weeks after the exposure. Therefore urgency is not a reason to do baseline testing without pre test counselling.

While it is preferable to do baseline testing soon after the exposure, there are reasons why this may not always be appropriate (outlined in the following section.)

Pre HIV test counselling

Because baseline testing is concerned with risks before the current exposure, questions must be asked in pre test counselling about lifestyle as well as occupational risks. It should not be assumed that HCWs are either well informed about HIV transmission, or that they are without lifestyle risks of infection. The majority of HCW in Australia with HIV did not acquire it through their occupation. There is evidence to show that adequacy of pre-test counselling affects adjustment to being HIV positive.

Therefore it is important that someone who has the appropriate knowledge and skills provides pre test counselling for the exposed person. Testing should always be delayed until such a person is available.

It may also be argued that if the exposed person is anxious about the exposure, they may not be able to give true informed consent immediately after the exposure.

The exposed person should be given options as to where they are tested. In a small institution, it is not appropriate to discuss lifestyle risks (such as sexual and drug taking behaviours) with a colleague and testing off-site may be the preferred option. Health care facilities should explore links with local facilities to provide this service when developing policy.

Referral to specialist physician

If the exposed person commenced HIV PEP they should be referred to an HIV specialist physician – this may be a general practitioner who is an S100 prescriber, a doctor in a sexual health centre, or a specialised service in a hospital.

Support for significant others

As information about BBV, exposures and transmission risks is complex, it can be difficult for the partner or family members of the exposed person to understand. This may result in pressure on a HCW to change their area of work. It may therefore be necessary to offer support and education for a partner or family member, as well as the exposed person.

FOLLOW UP

Post test counselling

Results of baseline testing must be given in person with standard post test counselling.

Occupational health and safety review

The exposure should be assessed and followed up by infection control or occupational health and safety staff. This may lead to specific training for the exposed person, or a general review of workplace practices, staffing levels, environmental safety, training requirements, equipment, etc.

Follow up blood tests

Local protocols should be followed for ongoing blood testing. The minimum requirement is to test for HIV antibodies at three months and hepatitis B and C at six months. If HIV PEP has been commenced, HIV antibodies should also be tested at six months.

There have been a few cases where seroconversion has been recorded outside this timeframe[2], but it is not considered necessary to adopt a more stringent testing regime than is advised for the community as a whole. Nevertheless, the treating doctor should advise the patient of this remote possibility.

Follow up testing for the source is often logistically difficult and is not necessary unless the exposed person is positive at follow up testing, or the source was thought likely to have been in the window period at the time of exposure.

OTHER PUBLISHED GUIDELINES FOR EXPOSURE MANAGEMENT

United States Guidelines

Centers for Disease Control (2001) Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis *Morbidity and Mortality Weekly Report* Vol 50/No.RR-11 June 29

Australian state guidelines

ACT Department of Health; Canberra Sexual Health Centre; AIDS Action Council; ACT Division of General Practice (October 2000) *Post Exposure Management Guidelines*

Health Department of Western Australia (September 2001) *Operational Instruction 1333/00: Sharps Injury and Blood and Body Substance Exposure Protocol*

New South Wales Health Department (1998) *Circular 98/11: Management of health care workers potentially exposed to HIV, hepatitis B and hepatitis C.*

Communicable Disease Unit, Public Health Services, Queensland Health (October 2001) *Guidelines for the Management of Occupational and Non-Occupational Exposures to Blood and Body Fluids*

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7. National Health and Medical Research Council (2000) *The Australian Immunisation Handbook: Seventh Edition* Canberra

8. Therapeutic Guidelines Limited, (2000), *Therapeutic Guidelines: Antibiotic, Version 11*. Melbourne

9. National Centre in HIV Epidemiology and Clinical Research (2001) *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance Report* The University of New South Wales, Sydney

10. Jaeckel E, Cornberg M, Wedemeyer H, et al (2001) Treatment of Acute Hepatitis C with Interferon Alpha – 2b *New England Journal of Medicine* Nov 15

11. Australian National Council on AIDS and Related Diseases, Intergovernmental Committee on AIDS and Related Diseases (1998) *HIV Testing Policy* Commonwealth Department of Health and Aged care, Canberra

MANAGEMENT OF EXPOSURE TO BLOOD/BODY FLUIDS IN A HEALTH CARE SETTING

When	What
Immediately after exposure	First Aid Relief from duty Risk Assessment Post exposure prophylaxis (PEP) – if significant injury
As soon as possible (same day)	Source assessment Documentation of exposure Prevention of transmission and crisis counselling
As soon as possible (within 1 week)	Pre HIV test counselling Baseline serology Referral to specialist physician - if PEP commenced Support of significant others
1-3 weeks	Post test counselling with results of baseline serology Occupational health and safety review
3 months	Pre HIV test counselling Follow up serology – HIV, HBV, HCV
6 months	Follow up serology – HBV, HCV – HIV (if PEP taken)

31 Creutzfeldt–Jakob disease

31.1 Preface

This document provides recommendations for infection control management procedures to minimise the risk of transmission of classical forms of Creutzfeldt-Jakob disease in health care settings. CJD is an infectious disease, the aetiological agent of which is relatively resistant to inactivation, and which therefore requires special additional precautions outlined in this chapter. In general, these interim guidelines have been developed to provide some consistency with the current World Health Organization (WHO) *Infection Control Guidelines for Transmissible Spongiform Encephalopathies* (2000) and guidelines that have been developed in the United Kingdom (ACDP, 1998).

Classical CJD (cCJD) was first described in the 1920s. Bovine spongiform encephalopathy (BSE, "mad cow disease"), and its human form, variant CJD (vCJD), were described more recently. BSE was first recognised in 1986 in the UK. The first cases of vCJD were described in 1996 in the UK. All are transmissible spongiform encephalopathies (TSEs). In this document, classical CJD is used generically to refer to all human TSEs except variant CJD. The term CJD is used to include variant CJD. TSEs pose a significant challenge for infection control management because the infectious agent, the prion, is relatively resistant to inactivation using the routine instrument processing and sterilisation methods currently in use in health care establishments.

The incubation period for the acquired forms of TSE may be very long (several decades in some cases). Similarly, in sporadic forms of the disease there may be a period of preclinical infectivity prior to the onset of clinical symptoms. It is therefore possible that individuals with TSEs may be infectious for long periods of time, even if the duration of clinically apparent illness is relatively short.

At the time of writing (August 2002), infection control guidelines for vCJD are still evolving. The recommendations provided in this document specifically address cCJD, and provide a firm foundation for additional recommendations that may be necessary for the control of vCJD in the future. The current infection control issues surrounding vCJD relate to two further factors:

1. While cCJD is a rare disease with a relatively stable incidence, vCJD is potentially an emerging epidemic. The main risk factor identified so far for vCJD is the consumption of BSE-affected bovine products. At the time of writing there have been no cases of vCJD reported in Australia.

2. There is a growing body of evidence that a wider range of tissues may be infectious for vCJD than for cCJD. Tissues that have been shown to be infectious for vCJD include tonsils, lymph nodes and possibly blood. The possibility that blood and lymphoid tissues may be infectious means that many standard surgical procedures may need to be regarded as vCJD risk procedures in terms of risk assessment, informed consent and instrument handling, tracking and processing.

At the time of writing these guidelines, the Communicable Diseases Network Australia (CDNA) and the National Health and Medical Research Council (NHMRC) have determined that the risk of transmitting vCJD in Australia in the course of health care delivery is extremely remote, and does not warrant additional precautions beyond standard precautions. The only precautionary action taken by Australia and many other countries to date, is placing restrictions on blood donors to screen out those who may have been exposed to the vCJD disease agent overseas.

The Australian National CJD Registry (the Registry) assists the Commonwealth Department of Health and Ageing (DHA) with national surveillance for all human TSEs in Australia. It has established and maintains close links with physicians to ensure that there is a high level of awareness about all human TSEs among health care professionals.

Existing infection control guidelines are based on the assessment that the most important risk for infection control with regard to CJD in Australia is from individuals with cCJD. If vCJD becomes prevalent in the Australian community, it could have a profound impact on infection control procedures in health care establishments and in the general community. This document does not address in detail the implications of any future emergence of vCJD in Australia, nor the implications for infection control in preventing health care associated (iatrogenic) transmission of vCJD. However, these implications could be substantial and will affect infection control procedures generally.

The identification of persons “at risk” of developing CJD and persons with CJD raises serious ethical and professional responsibilities in regard to appropriate care of these persons and their families and in regard to how HCWs and health care establishments respond to these responsibilities. Discussion of the principles involved are found in Section 10 **Ethical and legal issues** and 31.11 **Ethical Issues.**

The Department of Health and Ageing is working with the National Health and Medical Research Council's (NHMRC) Special Expert Committee on Transmissible

Spongiform Encephalopathies (SECTSE) to prepare additional guidance on infection control, surveillance and risk assessment with regard to vCJD. This special expert committee has worked with the CDNA Infection Control Guidelines Review Steering Committee (ICGSC) to produce these interim guidelines.

The most up-to-date information about CJD can be found on the Commonwealth Department of Health and Ageing website (www.health.gov.au), or by telephoning the health information hotline on 1800 200 701.

31.2 Disease description

31.2.1 Introduction

The transmissible spongiform encephalopathies (TSEs) are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans (Aguzzi and Weissmann, 1997; Johnson and Gibbs 1998; Prusiner, 1999; Brown et al, 2000; Taylor et al, 2000; Lancet, 2000; Masters, 2001). TSEs are a unique class of infectious agent, as they can be both inheritable and transmissible. A lack of detailed understanding of these diseases has led to concerns about transmission between humans and from domestic animals to humans.

The first authenticated cases of what is now called classical Creutzfeldt–Jakob disease (cCJD) were described in the early 1920s. Other related conditions include kuru, Gerstmann–Sträussler–Scheinker disease (GSS) and fatal familial insomnia (FFI) (see Table 31.2). Most cases of cCJD appear to develop sporadically i.e. with no identifiable source of transmission. However, as incubation periods of 10 years or more have been observed in cases of health care associated CJD, a proportion of the so-called "sporadic" cases may have resulted from undetected or subclinical case-to-case transmissions many years earlier (Collins et al, 1999; Kondo & Kuriowa, 1982). Approximately 5 – 10% of cCJD cases present as familial disorders with an autosomal dominant pattern of inheritance.

Variant CJD (vCJD) was first identified in the United Kingdom in 1996 (Cousens et al, 2001; Will et al, 1996) and approximately 130 cases have been reported to date (August 2002) in the UK, France, Ireland, Italy and Canada. It is believed that vCJD was acquired through the consumption of beef infected with the agent of bovine spongiform encephalopathy (BSE). Patients with vCJD are typically much younger (mean age about 30 years) than those with cCJD (mean age about 65 years) (Will et al, 2000).

Table 31.2 Human and animal transmissible spongiform encephalopathies

Human TSEs	First description
CLASSICAL CREUTZFELDT–JAKOB DISEASE: (cCJD)[a]	
• Sporadic	1920s
• Familial	1920s
• Health care associated (iatrogenic)	1950s
VARIANT CREUTZFELDT–JAKOB DISEASE (vCJD)	1996
GERSTMANN–STRÄUSSLER–SCHEINKER DISEASE (GSS)[b]	1930s
KURU[c]	1950s
FATAL FAMILIAL INSOMNIA (FFI)[d]	1986
Animal TSEs	
SCRAPIE	
• Sheep	Eighteenth century
• Goats	1870s
TRANSMISSIBLE MINK ENCEPHALOPATHY	1960s
CHRONIC WASTING DISEASE OF MULE AND ELK DEER	1960s
SPONGIFORM ENCEPHALOPATHY OF CAPTIVE WILD RUMINANTS	1980s
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)	1986
FELINE SPONGIFORM ENCEPHALOPATHY (FSE)	1990

[a] For simplicity, the term "classical CJD" (cCJD) is used to describe all forms of TSEs in humans except variant CJD (vCJD). Unless otherwise specified, the general term "CJD" is used to cover all the human TSEs (ie cCJD and vCJD).

[b] GSS is a TSE characterised by ataxia in the early stages and which has a much longer clinical course than CJD. Dementia and myoclonus may be absent or minimal. It is a genetic disorder with an autosomal dominant pattern of inheritance.

[c] Kuru is a related disease that occurred as an epidemic in the Fore people of the Eastern Highlands of Papua New Guinea.

[d] FFI is a rapidly progressive TSE characterised by refractory insomnia, with autonomic and endocrine dysfunction. It is a genetic disorder with an autosomal dominant pattern of inheritance.

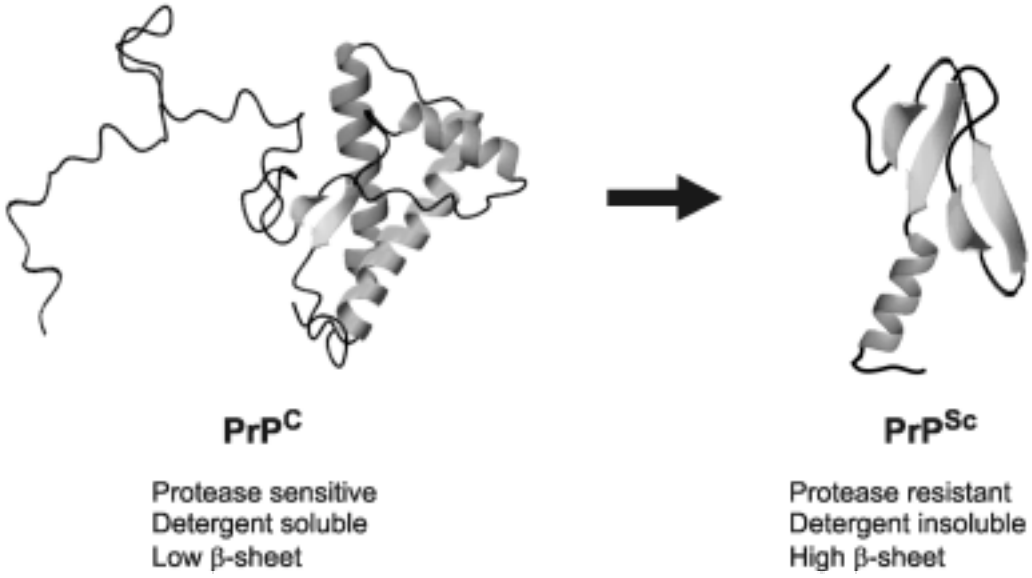
31.3 Infectious Agent

The infectious agents responsible for TSEs have extraordinary properties compared to bacteria, viruses and parasites. TSE agents cause diseases with unusually long incubation periods of months or years and have an unusually high resistance to physical or chemical treatments that inactivate other known infectious agents, including viruses (Brown et al, 2000; Taylor, 1999; Weissmann, 1996). TSE agents are relatively resistant to high temperature, formaldehyde and ultraviolet radiation but are susceptible to procedures that modify or hydrolyse proteins (Prusiner, 1998). Nucleic acids specific for TSEs have never been isolated.

In 1982, Prusiner proposed the term "prion" to denote the small *pro*teinaceous *in*fectious unit that appears to cause TSEs and is resistant to procedures that modify nucleic acids (Prusiner, 1982, 1992). The only macromolecule so far identified in the prion is a protein (PrP), which occurs in two forms: the normal cellular form (PrP^{C}) and the disease-associated form (PrP^{Sc}). PrP^{C} is converted to PrP^{Sc} by a change in its

conformation involving an increase in the β-sheet content of the protein (Prusiner, 1998). Once formed, PrP^{Sc} may act as a template for further PrP^{C} molecules to be refolded to form PrP^{Sc} molecules. However, there is still considerable debate over the exact mechanisms by which the abnormal forms of PrP are generated. Despite extensive epidemiological investigation and animal studies, other amyloid-related diseases, such as Alzheimer's disease, have not been found to be transmissible (Masters et al, 1981; Brown et al, 1982).

Fig 31.3: **<u>The structure of PrP (prion protein</u>). On the left is a schematic representation of the experimentally-determined isoform of PrP^{c}, with three prominent α-helices located towards the C-terminus. The conversion of PrP^{c} into a putative infectious form (PrP^{Sc}) yields a hypothetical structure (on the right) where the α-helices have been replaced by β-sheets (ribbon-like in the diagram). This structure of PrP is capable of self-amplification, with consequent accumulation of insoluble PrP^{Sc} deposits in the brain which are associated with neurodegeneration**.



31.4 Clinical manifestations

CJD presents in several forms, including;

- Sporadic CJD
- Familial CJD
- Health care associated (iatrogenic) CJD
- Gerstmann-Straussler-Scheinker Disease (GSS)
- Kuru
- Fatal familial insomnia (FFI)
- variant CJD

For simplicity, the term classical CJD (cCJD) is used to describe all forms of human CJD except vCJD.

31.4.1 Classical forms of CJD

The classical forms of CJD are characterised by a subacute progressive dementia with widespread neurological impairment. This occurs over a period of months, inevitably leading to death. The nature of the brain damage is unusual; there is no detectable immune response and the disease process is confined to the central nervous system (CNS) (Johnson and Gibbs, 1998). A definitive diagnosis of TSE disease in humans and animals has traditionally been achieved by the histological examination of brain tissue. The term "spongiform encephalopathy" describes the appearance of microscopic holes or vacuoles which occur with variable distribution in the grey matter of the brain.

The characteristic spongiform change observed in the TSE-affected brain is accompanied by a loss of neuronal cells and increase in astrocytes and microglia, which form part of the supporting structure of the central nervous system (CNS) (Ironside, 1998). Amyloid plaques composed of the prion protein are found in approximately 10% of brains with sporadic TSE. They are more common in kuru, some familial spongiform encephalopathies and vCJD.

31.4.2 Variant CJD

The two striking initial features of vCJD, which are unusual in cCJD, are abnormal sensory perceptions such as pain, and prominent psychiatric disturbance (Will et al, 2000). Psychiatric disturbances include depression, insomnia, delusions, paranoia and behavioural changes. Ataxia and myoclonus (abnormal jerking movements) subsequently develop.

Within approximately 12 months of the initial symptoms, patients with vCJD enter a state of akinetic mutism, usually followed by death within several months. The duration of illness in patients with vCJD is usually longer (median 14 months) than

for patients with cCJD (median 5 months), although the range is very wide; 7–38 months for vCJD and 1 month to 5 years for cCJD (Chazot et al, 1996; Will et al, 1996; Zeidler et al, 1996; Schonberger, 1998).

31.5 Occurrence

The basic epidemiological features of cCJD have been reviewed elsewhere (WHO, 1998b). On a global basis, approximately 10% of all patients show a family history of the disease (this includes GSS and FFI). In most of these familial cases, a disease-related mutation of the PrP gene can be identified; such mutations code for a prion protein which is more susceptible to folding into an abnormal form. In the remaining 90% of patients, there is evidence that the proportion with homozygosity at codon 129 of the PrP gene (PRNP) is higher than in a normal population (WHO, 1998b). Since this genetic configuration may confer susceptibility to health care associated (iatrogenic) transmission it is possible that a significant proportion of so-called "sporadic" cCJD may fall into this health care associated category.

The annual incidence of cCJD in Australia is 1.5 cases per million. The Australian National CJD Registry was established in 1993 and, as well as collecting new data, has reviewed data collected from 1970. As of January 2001, the Australian National CJD Registry had recorded 397 deaths that were attributable to suspected or confirmed TSEs, with a further 89 cases that are still under investigation.

The estimated Australian cumulative number of definite and probable cases since 1970 is 397 (Australian National CJD Registry, 2001). The breakdown by State and Territory is:

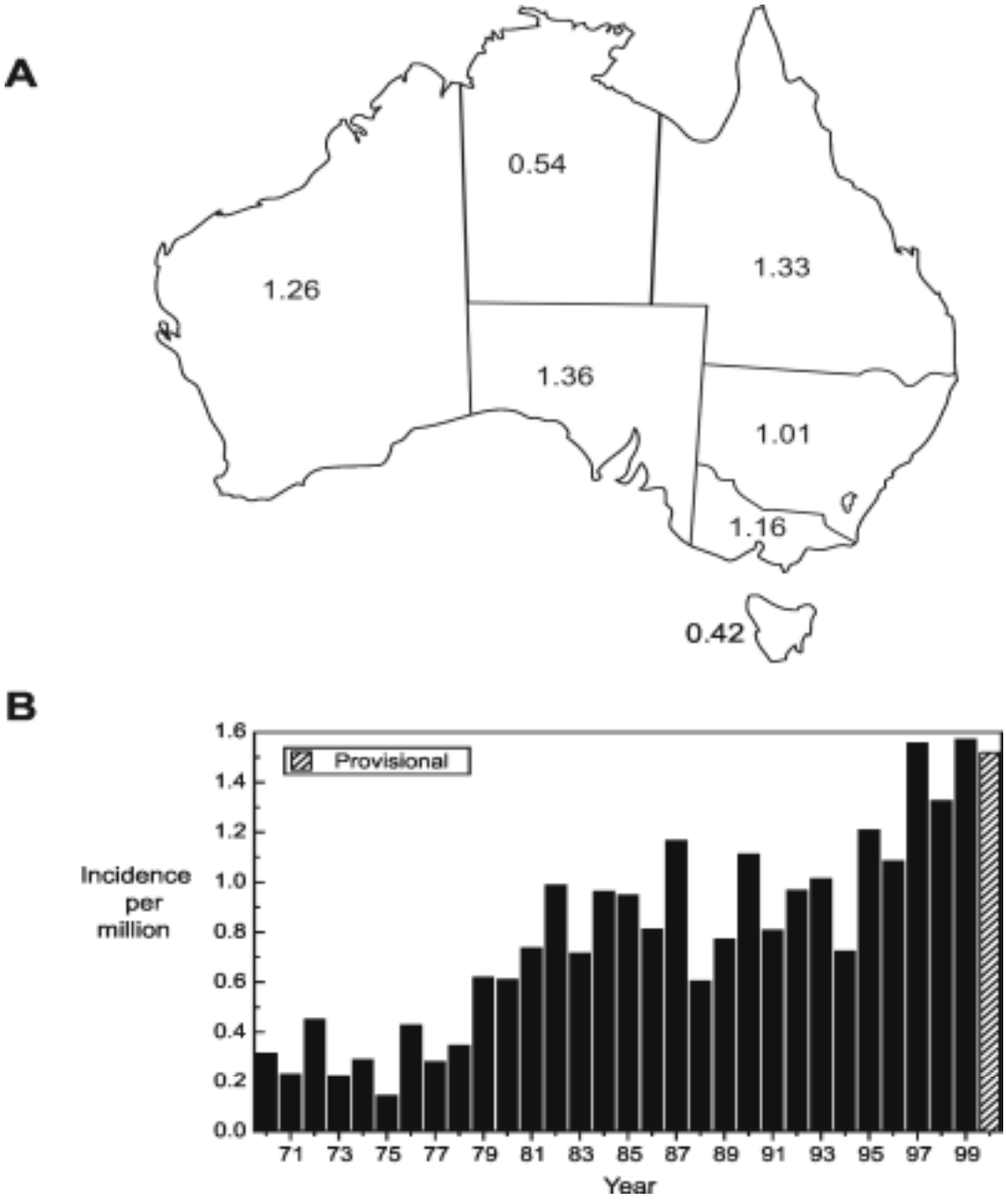
- New South Wales (NSW) (including Australian Capital Territory [ACT]) 144;
- Northern Territory (NT) 1;
- Queensland (QLD) 63;
- South Australia (SA) 48;
- Tasmania (TAS) 4;
- Victoria (VIC) 97; and
- Western Australia (WA) 40

Of these definite and probable cases on the register, 91% (358) are sporadic, 6% (29) are familial (genetic) and 3% (10) are health care associated (iatrogenic).

Approximately 2000 people in Australia were recipients of cadaveric-derived human pituitary-hormones for infertility or short stature. An estimated 5,000 – 10,000 people in Australia received dura mater grafts in a variety of surgical procedures. Of these, 95% had neurological procedures requiring grafting, and it is this group that has a documented, increased risk of cCJD.

There are currently 17 Australian pedigrees (families) with the familial forms of cCJD, with 34 identified affected individuals. In aggregate, possibly less than 200 at-risk first degree relatives are thought to exist within the Australian population.

Fig. 31.5: <u>The incidence and distribution of cCJD in Australia.</u> Part A shows the crude (non-age-adjusted) incidence (per million) by State/Territory, between 1990-1999. Part B shows the national annual incidence figures in Australia between 1970-2000. Active surveillance of the incidence of CJD by the Australian National CJD Registry commenced in Australia in 1993. The low incidence rates in the 1970's reflect poor ascertainment. With the heightened awareness of CJD in 1996 (probably attributable to the emergence of vCJD in the UK), the annual crude incidence increased and peaked at approximately 1.5 cases per million population. The data presented in both illustrations include all sub-types of CJD (sporadic, genetic, iatrogenic). (Source: Creutzfeldt-Jakob Disease in Australia. Semi Annual Update to January 2001. Australian National CJD Registry).



31.6 Diagnosis

31.6.1 Classical forms of CJD

If an individual acquires the infectious agent of cCJD through a health care associated procedure or other means, there may be an incubation period ranging from about 18 months (Nevin et al, 1960; Jones & Nevin 1954; Duff et al, 1974) to more than 40 years (Attenborough & Alpers, 1992; Heckmann et al, 1997; Alpers 2001) before the onset of disease. During this time, the infectious agent does not cause an immune or inflammatory response. At the time of writing, there is no test available to detect infection before the onset of symptoms.

Diagnosis of cCJD is by clinical and neuropathological examination. Currently, the only method for obtaining a definitive diagnosis is by examination of brain tissue by biopsy or autopsy. However, brain biopsy is not recommended as a routine procedure to confirm the clinical suspicion of CJD (WHO, 1998b). Rather, its use should be to exclude other causes of treatable dementia, such as vasculitis.

The presence of periodic triphasic sharp waves on an electroencephalograph (EEG) is often of assistance in making the diagnosis. Imaging techniques such as computerised tomography (CT) and magnetic resonance imaging (MRI) are useful in excluding other causes of subacute dementia. Similarly, a lumbar puncture is often required to obtain CSF for diagnosis and to exclude other disease processes.

Recently, detection of the 14-3-3 protein in cerebrospinal fluid (CSF) has been adopted as a surrogate diagnostic marker for cCJD (Lemstra et al, 2000; Chapman et al, 2000; Zerr et al, 2000; Collins et al, 2001). 14-3-3 is a normal cellular protein expressed in various tissues, and its presence in CSF reflects extensive destruction of brain tissue (Lemstra et al, 2000). The 14-3-3 test has a sensitivity of 94% and specificity of 84% indicating that a small proportion of false positive and negative results occur (Zerr et al, 2000). Consequently, 14-3-3 test results should be interpreted in the context of additional clinical data (Hsich et al, 1996; Rosenmann et al, 1997; Zerr et al, 1998, WHO, 1998ab; Irani and Kerr, 2000). This margin of error should be taken into account when assessing the risk factors associated with implementing infection control procedures in a health care setting.

Auxiliary genetic, biochemical or quantitative immunoassays for PrP^{Sc} protein may soon become available for routine diagnosis of cases with symptoms suggestive of CJD. Currently, the only method for obtaining a definitive diagnosis is by examination of brain tissue by biopsy or autopsy. The pathological criteria of spongiform change (diffuse vacuolation of neuronal dendrites, plus neuron loss and gliosis), coupled with immunocytochemical demonstration of PrP protein deposits allow a definitive diagnosis to be made. However, brain biopsy is not recommended as a routine

procedure to confirm the clinical suspicion of CJD (WHO, 1998b). Rather, its use should be to exclude other causes of treatable dementia, such as vasculitis.

31.6.2 Variant CJD

Neuropathological features of vCJD differ markedly from those of cCJD. The most consistent pathological change in vCJD is the formation of abundant and "florid" PrP plaques. In most cases studied, this type of plaque is distributed extensively throughout the cerebrum and cerebellum, with some plaques seen in basal ganglia, thalamus and hypothalamus. Many resemble plaques seen in kuru cases, and have a dense eosinophilic centre with pale periphery, surrounded by a zone of spongiform change (Will et al, 1996; Zeidler et al, 1996).

At the time of writing vCJD has not been diagnosed in Australia. If vCJD were suspected in a patient, the Chief Health Officer of that State/Territory health department and the Australian National CJD Registry should be notified immediately (see Section 31.16.1). These agencies can arrange appropriate diagnostic and specific confirmatory tests.

Although health care associated (iatrogenic) transmission of vCJD has not been reported, it is reasonable to expect that tissues that are considered infectious in cCJD and that bear a heavy PrP^{Sc} load will also be infectious in vCJD. Aggregated PrP has been detected in tonsil tissue from deceased vCJD patients (Hill et al, 1999) and in the appendix of an asymptomatic patient eight months before clinical onset of vCJD (Hilton et al, 1998). There are no data on whether vertical transmission (mother to child) of vCJD can occur, but neither has this been recorded for any other human TSE.

It is not known if blood or blood products transmit vCJD. However, in a preliminary report yet to be confirmed, it was shown that BSE could be transmitted to a sheep by transfusion of whole blood from another sheep during the preclinical phase of experimental BSE infection (Houston et al, 2000). On the basis of these and other laboratory data, the Australian Red Cross Blood Service (ARCBS) has deferred blood donations from people who lived in the UK for more than short periods of time during the height of the BSE epidemic. Further development of this donor deferral policy is occurring as the epidemic of BSE extends into other European countries.

31.6.3 Genetic testing

Although rare, an increasing number of familial CJD and GSS cases are being identified in Australia. The increase may in part be due to enhanced surveillance efforts since vCJD was recognised in 1996, but also because genetic testing is now more readily available (See Fig. 31.5). Since most familial TSEs carry characteristic mutations in the PrP gene, it is now possible to offer predictive testing, carrier detection and prenatal diagnosis. The results of genetic diagnosis can have profound implications. It is

recommended that referral centres be established where appropriate laboratory testing can be performed in conjunction with genetic counselling by people with expertise in, and a current knowledge of these diseases. As indicated above, people with disease-linked mutations, or all non-genotyped members of a family in which more than one first-degree relative has been diagnosed with a cCJD illness, should be considered as higher risk individuals (see Section 31.9) and should be advised of their risk status. Patients so advised should inform health care workers of their increased risk as outlined in Section 31.10.2.

Whenever possible, all newly identified cases of CJD should be evaluated for possible familial CJD. In addition for testing for the genetic risk factor (PRNP gene codon 129 polymorphism), permission should be sought to examine the proband's DNA for disease-linked mutations in the PRNP gene. As part of pre-test counselling, at-risk individuals should be provided with a complete explanation of the genetic testing process and implications of a positive result. The implications of a positive result for other family members should also be explained during pre-test counselling. Results must be provided in person with appropriate post-test counselling. Please refer to **Section 10** and **Section 31.11** for further information about the Ethical and legal issues pertaining to genetic testing and patient consent.

Enquiries about genetic testing can be directed to:

Australian National CJD Registry
Department of Pathology
The University of Melbourne
Telephone: 03 8344 5868
Facsimile: 03 8344 4004
E-mail: ANCJD-REG@unimelb.edu.au

31.7 Transmission

31.7.1 Sources of infection

For most cases of cCJD, a thorough analysis of the patient's medical and occupational histories fails to disclose clear evidence of an external source or point of infection, and they are therefore considered to be sporadic CJD. However, in a small number of patients there has been a clear instance of health care associated transmission through neurosurgical instruments contaminated with CNS tissue and through tissue implants or products (dura mater grafts, corneal grafts, pituitary products) (see Section 31.7.5). There is no evidence that the disease can be transmitted through normal social contact. There is also no evidence of vertical transmission (see Section 31.7.4) or transmission to humans through blood or blood products.

The documented cases of health care associated (iatrogenic) transmission have indicated that short incubation periods of one or two years may be expected after direct intracerebral inoculation. In contrast, extended incubation periods of 10 years (Brown P, 1988) to more than 30 years (Heckmann et al, 1997) usually occur after low-dose inoculation via a peripheral route.

Although transmission of CJD is rare, health care workers (HCWs) should be aware of the potential for health care associated (iatrogenic) transmission by contaminated instruments or transfer of contaminated tissues or agents. Suitable infection control procedures should therefore be implemented to minimise the risk of cross-contamination.

The remarkable resistance of TSE agents to physicochemical conditions that inactivate conventional viruses and bacteria is a major issue. Infectivity may persist on instruments that have been steam sterilised at 121°C or cleaned using mild chemical procedures (see Section 31.14).

31.7.2 Modes of transmission

Infectious diseases can be transmitted from person to person in various ways. Three possible modes of transmission of cCJD are discussed in this section –

- Vertical transmission (mother to child) – no known cases (see 31.7.4)
- Health care associated (iatrogenic) transmission – (see 31.7.5)
- Occupational transmission (patient to HCW) – (see 31.7.6)

Assignment of different organs and tissues to categories of "*high infectivity*" and "*low infectivity*" is largely based upon the frequency with which infectivity has been detectable, rather than upon quantitative assays of the level of infectivity, for which

data are incomplete. Data from experimental studies of primates and other animals inoculated with tissues from human cases of cCJD have been supplemented in some categories by data obtained from naturally occurring TSEs. Actual infectivity titres in the various human tissues other than the brain are extremely limited but data from experimentally infected animals are generally consistent with the grouping shown in Table 31.7.3.

31.7.3 Infectivity of human tissues (cCJD)

Table 31.7.3 is a guide to the predicted infectivity of body tissues and fluids of symptomatic and asymptomatic patients with cCJD. This information is largely based on studies of experimentally transmitted cCJD in non-human primates and other animals.

Within a highly susceptible species, direct intracerebral inoculation of relatively low doses of infectious material yields close to 100% successful transmission. In contrast, a lower rate of transmission is achieved by inoculation of the same species with a high dose via peripheral routes, such as subcutaneous, conjunctival or oral routes (Scott, 1993). Although the oral route of transmission is inefficient for cCJD, vCJD appears to result from the ingestion of the BSE agent (Bons et al, 1999).

Experimental animal studies have shown that after inoculation by a peripheral route, replication of the infectious agent begins in the spleen and peripheral lymph nodes then spreads to the CNS (Aucouturier et al, 2000). It is not clear whether infectivity spreads to the CNS via the blood stream or peripheral/autonomic nervous system, or both.

High infectivity tissues

Brain, spinal cord, eye (retina and optic nerve), pituitary and dura mater tissues have demonstrable infectivity (see Table 31.7.3). In areas of the brain affected by spongiform change, the CNS may contain levels of infectivity of more than 10^5 infectious units/g (Brown et al, 1994).

As the highest risk of health care associated transmission occurs when the CNS of a CJD patient is exposed, particular care should be exercised in the management of instruments used in neurosurgery, ophthalmic surgery, neurology (lumbar punctures) and laboratory procedures when brain tissue is manipulated, see **Section 31.12**.

Low infectivity tissues

- **Cornea** - The precise distribution of infectivity in the eye remains uncertain. While corneal transplantation has been associated with a few cases of health care associated (iatrogenic) cCJD, it is possible that the cornea was contaminated during harvesting through contact with instruments used to remove the eye after death.

There is increasing evidence that the CJD agent accumulates in the retina and optic nerve which are direct extensions of the CNS

- **Cerebrospinal fluid (CSF)** - Although CSF has been included as a lower infectivity secretion (Table 31.7.3), its reported infectivity has varied in different studies (WHO, 1998b).

A number of other tissues (dorsal root ganglia, kidney, liver, lung, lymph nodes/spleen, maxillofacial neurovascular tissue, placenta, uterus, see Table 31.7.3) have been shown to be infectious in some animal studies, but the results are not conclusive (WHO, 1998b) and for this reason these tissues are regarded as low infectivity.

No known human infectivity

- **Blood** - There is still uncertainty as to whether blood components carry the infectious agent in humans (Brown et al, 2000). Some investigators have reported infectivity and abnormal forms of the PrP molecule in the blood of experimental animals (Tateishi, 1985; Manuelidis et al, 1985; Brown et al, 1994; Houston et al, 2000) (see Section 31.17.5). However, there is no human epidemiological evidence that blood transfusion is a risk factor for cCJD (Esmonde et al, 1993b; Heye et al, 1994; Collins et al, 1999) (see Section 31.17.4).

- **Other body fluids/secretions** - Tears, saliva, sputum, faeces, milk, semen and other bodily secretions have not been shown to transmit the infectious agent using currently available tests (See Table 31.7.3). Most external bodily secretions have not shown infectivity either in humans or in milk-producing experimental animals (WHO, 1998b).

  Tateishi (1985) reported that the urine of a single patient with cCJD was infectious in mice. There is also a recent, as yet unconfirmed report that the abnormal isoform of the prion protein (PrP^{Sc}) has been found in the urine of patients with CJD, in bovines with BSE and hamsters with scrapie (Shaked et al, 2001).

- **Skin** - There is no evidence to suggest that CJD can be spread by contact with intact skin (WHO, 1998b). Therefore, standard infection control procedures should be adequate for the most routine nursing or social interactions. Additional infection control procedures are unnecessary when open wounds (such as bedsores, abrasions or weeping rashes) are present in higher risk or lower risk patients.

- **Other tissues** - The infectious agent has not been detected in heart or skeletal muscle, cartilage, connective tissue, adipose tissue or testes (WHO, 1998b). However, additional infection control precautions apply for procedures involving the exposure of these tissues in higher risk patients, due to the involvement of blood or lymphoid tissue in such procedures.

Table 31.7.3 Demonstrated or predicted infectivity of human body tissues and fluids for cCJD

Infectivity category	Tissues	Secretions and excretions
"High infectivity" sites (Demonstrated or predicted to be consistently infectious)	Brain Pituitary gland Spinal cord Eye (retina and optic nerve)	
"Low infectivity" sites (Demonstrated or predicted to be infectious, but not consistently)	Eye (cornea and anterior chamber) Dorsal root ganglia Kidney Liver Lung Lymph nodes/spleen Placenta Trigeminal ganglia Uterus	CSF
"No infectivity" (Have not been demonstrated to be infectious)	Adipose tissue Adrenal gland Blood Bone marrow Gingival tissue Heart muscle Intestine Peripheral nerve Prostate Skeletal muscle Testes Thyroid gland	Faeces Milk Nasal mucous Saliva Semen Serous exudate Sweat Tears Urine

Source: Modified from WHO 1998b (Table 9, p46)

31.7.4 Vertical transmission

As cCJD is a rare disease, it is difficult to obtain accurate epidemiological data. Nevertheless, studies of kuru (see Table 31.2) indicate that vertical (mother to child) transmission does not occur. There have been two reports of infants born to women with symptomatic cCJD (Bernoulli et al, 1977; Tamai et al, 1992). Each has remained well at 10 and 16 years of age, respectively (Brown et al, 1987; Tamai, et al, 1992).

Studies of scrapie transmission in sheep have indicated that placenta may transmit the disease (Race et al, 1998). In one study, cCJD was transmitted from a human placenta to mice (Tamai et al, 1992). These and other data suggest the possibility of postpartum transmissibility through various forms of environmental contamination.

31.7.5 Health care associated (iatrogenic) transmission

CJD can be transmitted from person to person when tissue (usually brain tissue) infected with CJD is transferred to a recipient via a contaminated instrument, during a surgical procedure. This type of disease transmission is referred to as a health care associated (iatrogenic) infection.

Health care associated (iatrogenic) transmission of cCJD has occurred via stereotactic EEG electrodes (Bernoulli et al, 1977), neurosurgical instruments (Masters et al, 1979; Foncin et al, 1980), corneal grafts (Duffy et al, 1974; Uchiyama et al, 1994; Heckman et al, 1997; Thiel et al, 2000), dura mater grafts (Thadani et al, 1988; Esmonde et al, 1993a; Hoshi et al, 2000) and from human pituitary hormones (growth hormone, gonadotrophins) prepared from pituitary glands obtained at necropsy (Allars, 1994; Fradkin et al, 1991).

Experience to date indicates that the highest risk of health care associated (iatrogenic) transmission occurs when the CNS is exposed in a patient with CJD. To minimise the risk of health care associated or occupational transmission of CJD a one way flow of instruments should be routine during surgical (neurosurgery, ophthalmic surgery, neurology, lumbar puncture) and laboratory procedures in which brain tissue and CSF are exposed or manipulated. Special care should also be exercised to ensure that instruments potentially contaminated with CJD infectious agents do not contact other instruments during the process of manual cleaning, sterilisation and quarantine.

31.7.6 Occupational transmission

There have been reports of cCJD in health care workers (Berger and David, 1993; Matthews, 1993; Ridley and Baker, 1993; Weber et al, 1993) and in farmers who were exposed to cattle with BSE, a bovine TSE (Davies et al, 1993; Sawcer et al, 1993). It remains unclear whether there is any statistically significant association between occupational exposure and cCJD.

31.7.7 Variant CJD transmission

There is considerable evidence that vCJD results from the transmission of the infectious agent in BSE to humans through the ingestion of BSE infected beef (Hill et al, 1997; Will et al, 1992). Experimental BSE transmission from cattle to non-human primates (Bons et al, 1999) and mice (Carp et al, 1997; Maignien et al, 1999) and other species has been shown. The neuropathological changes in mice inoculated with the infectious agent derived from vCJD affected patients were similar to those seen in mice inoculated with the infectious agent derived from cattle with BSE (Bruce et al, 1997).

Additionally, during the BSE epidemic in cattle in the UK, several other species developed TSEs in Europe. These included felines (domestic cat, puma, lion, tiger and cheetah) and antelopes in the United Kingdom (Kirkwood et al, 1994). In France, a rhesus monkey and two lemurs housed in the Zoological Park in Montpellier died of neurological illnesses associated with spongiform encephalopathy (Bons et al 1996, 1997). In Australia, a cheetah imported from the UK in 1989 was culled after suffering neurological illness in 1991 (Peet and Curran, 1992). Autopsy and histopathological analysis revealed a spongiform encephalopathy, and it was concluded that the animal probably ingested the infective agent while caged in England.

To date, there is no convincing evidence that scrapie of sheep or goats can be transmitted to humans. However, BSE has been experimentally transmitted to sheep and goats (Foster et al, 1993) and there is concern that sheep and goats may have been exposed to the same contaminated feedstock responsible for the spread of BSE in cattle (Brown, 2001).

At the time of writing (August 2002) Australia is free from animal TSE diseases. The most likely presentation of vCJD in Australia will be in persons who have resided in the UK and other affected countries in continental Europe during the high risk period of transmission.

Another potential threat to human health in Australia is related to the importation of animal products from Europe or health care associated transmission. The Australian Quarantine and Inspection Service (AQIS), Australia New Zealand Food Authority (ANZFA), and Therapeutic Goods Administration (TGA) regulate the importation of animal products into Australia. In 1966 AQIS banned “meat and bone meal” (MBM) imports from all countries except New Zealand (NZ). ANZFA is responsible for controlling the importation of foods (in conjunction with AQIS). In March 1996 imports of specified beef products from the UK into Australia were banned and in January 2001 imports of a range of products containing bovine materials from a specified list of countries in Europe were also banned.

In response to the potentially global spread of BSE through the widespread export of MBM from the UK and Europe, Australian authorities announced a system of certification for imported beef and beef products commencing September 2001. Countries seeking to export beef into Australia are now required to provide evidence of their BSE status using this new system of certification. Countries with indigenous BSE are not be permitted to export their beef products to Australia.

The TGA is responsible for the regulation of medicines and medical devices supplied in Australia and has in place strict requirements to minimise the potential risk of transmission of TSE through the use of animal ingredients in the manufacture of these products. These include rigorous assessment of the nature and origin of the ingredients and the manufacturing process involved, to ensure any potential TSE risks are

minimised. TGA regulations only allow bovine ingredients to be sourced from countries where BSE has not been reported.

Although there is some evidence for the experimental transmission of TSEs via blood in animals (see Section 31.7.3), there is currently no confirmed evidence of vCJD transmitted by blood transfusion in humans (See Section 31.17.4). However, in the interests of public health, health authorities in Australia, New Zealand, Canada and USA have excluded blood donations from those individuals with a history of more than short periods of residence in the UK between 1980 and 1996 (see Section 31.17.10).

In vCJD patients, deposits of PrP amyloid have been found to be widespread in lymphoid tissues including tonsillar tissue; such deposits are not evident in cCJD patients. A diagnostic test has been developed from this finding (Hill et al, 1997; Hill et al, 1999). PrP deposits have also been found in the appendix of a person who subsequently developed the symptoms of vCJD (Hilton et al, 1998). Other tissues that may be affected and potentially transmit vCJD include adrenals, rectum, retina and trigeminal ganglia (Wadsworth et al, 2001).

31.8 Basic infection control measures

31.8.1 Standard and additional precautions

In 1996, the National Health and Medical Research Council (NHMRC) and Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD) Infection Control Working Party adopted the terms “standard precautions” and “additional precautions” based on modes of transmission of infectious agents to define appropriate work practices for the prevention of transmission of infectious diseases in health care settings.

Standard precautions are standard operating procedures that apply to the care and treatment of all individuals, regardless of their perceived infectious risk. They include aseptic technique, compulsory hand washing, using personal protective equipment (PPE), appropriate reprocessing of instruments and equipment and implementing environmental controls. Standard precautions should incorporate safe systems for handling blood (including dried blood), other body fluids, secretions and excretions (excluding sweat), non-intact skin and mucous membranes.

Additional precautions are required when standard precautions may not be sufficient to prevent transmission of infection (eg. tuberculosis, methicillin-resistant *Staphylococcus aureus*, CJD). Additional precautions are tailored to the specific infectious agent concerned and may include measures to prevent airborne, droplet, contact or health care associated transmission. This two-tiered approach in health care establishments should provide high-level protection to patients, HCWs and others.

Comprehensive information is provided in Section 2 (Basic infection control principles).

31.8.2 Principles of reprocessing

Any infectious agents introduced into sterile body sites can establish infection or colonise mucosal surfaces. Infectious agents are always present on skin and are likely to be carried through the air on dust particles (fomites). The reprocessing procedures required for items potentially contaminated with CJD agents are detailed in Section 31.14. Refer to Section 16 for general principles of reprocessing.

31.8.3 Tracking and traceability of equipment

Systems should be in place to track "high infectivity" site reusable items of equipment, especially for procedures where transmission of infection has been known to occur. Instruments that have been in contact with neural or ocular tissue such as brain, spinal cord, retina, optic nerve and pituitary should not only be tracked but also handled in such a way as to avoid cross contamination of any other instruments, eg. maintaining a one way flow of instruments during surgical procedures and separating instruments potentially contaminated with CJD infectious agents from other instruments.

31.8.4 Disinfectants and sterilants

Most chemical disinfectants and sterilants are not effective against the TSE agents (see Table 31.8.4). The only chemicals that have any activity are hypochlorites (at 20,000 ppm available chlorine), iodine and harsh acids and alkalis (eg sodium hydroxide). Section 31.14 gives further details of the procedures required for disinfection and sterilisation of items potentially contaminated with CJD agents.

Table 31.8.4 Activity against TSE infectious agents by the active chemical substances used to formulate disinfectants and antiseptics

Disinfectant group	Activity against TSEs	Other properties/comments
Hypochlorites	Partially effective	• May be used at 20,000 ppm available chlorine (2%) for 1 hour if more stringent procedures are not suitable for higher risk CJD spills/contamination (see Table 31.14.1)
Iodine preparations	Variable/partially effective	• May be inactivated by organic matter • May corrode metals (eg aluminium) • Useful as a skin disinfectant but some preparations may cause skin reactions (povidone–iodine is much less irritant than iodine itself) • May only be used on instruments if labelled as an instrument grade disinfectant
Sodium dichloroisocyanurate (SDIC) granules	Ineffective	—
Acids (formic)	Restricted use for CJD see 12.2.1	• Corrosive/caustic • Use only with special care
Alkalis (sodium hydroxide)	Restricted use for CJD (see Table 31.14.1	• Corrosive/caustic • Use only with special care
Alcohols	Ineffective	—
Aldehydes	Ineffective	—
Chlorhexidine and biguanide polymers	Ineffective	—
Peracetic acid and other peroxide compounds	Ineffective	—
Phenolics	Ineffective	—

31.9 Identifying and managing the risk

The recommended approach (WHO, 1998b) for managing the risk of health care associated transmission of CJD is to identify individuals who pose a risk in the health care environment and manage them under conditions that prevent disease transmission.

The standard method of preventing CJD transmission in health care environments is to destroy all instruments and fomites (materials capable of harbouring infectious

agents) that have come into contact with infected tissue. Using this approach is not only expensive and resource-intensive but it may lead to discrimination against people in recognised risk groups for CJD by limiting their access to health care services.

An alternative method of minimising disease transmission that is cost effective and efficacious can be achieved by applying more stringent methods of instrument processing and using less invasive clinical procedures when they are available. Taking these factors into account, it is international convention to define two risk categories that reflect the theoretical and demonstrable risks of transmitting CJD:

- higher risk — people who represent a definite risk of CJD transmission; and
- lower risk —people who represent a potential risk of CJD transmission.

These risk categories are described in more detail below. Infection control procedures and recommendations are adjusted according to the risk category of the individual and the nature of the procedure.

31.9.1 Higher risk individuals

The only certain method of diagnosing cCJD is by neuropathological examination of brain tissue.

An individual is diagnosed as "higher risk" when they present with symptoms (of cCJD) coupled with results of medical investigations that are usually associated with cCJD. These individuals, who are highly likely to have cCJD but have not had a confirmatory brain biopsy, are classified according to WHO case definitions as "definite".

Individuals diagnosed as "definite", "probable" and "possible" are all regarded as highly likely to harbour prions that can be transmitted during invasive procedures. These individuals are classified as "higher-risk" individuals.

In the WHO Manual for Strengthening Diagnosis and Surveillance of Creutzfeldt-Jakob Disease (WHO 1998b), the higher risk category includes individuals fulfilling the WHO recommended case definitions for cCJD subtypes:

- definite
- probable
- possible

Each of these higher risk categories is defined below for the Australian health care setting. An additional group has also been included in these guidelines and defined as *other higher risk individuals* (see Section 31.19.1). This group includes carriers of a pathogenic mutation and those with two or more first-degree relatives who have been

diagnosed with cCJD. The definition of "probable" cases has been extended to include the results of the assay for 14-3-3 protein in CSF (Zerr et al, 2001). It should be noted that the sub-type of a case can change as more diagnostic information becomes available.

Table 31.9.1 Individuals in the higher risk category for CJD

Higher risk individuals	
Definite	Individuals with a confirmed clinical diagnosis of cCJD as determined by the combination of progressive dementia, myoclonus and multifocal neurological dysfunction associated with a characteristic periodic EEG and/or Individuals with a diagnosis of cCJD as determined by standard neuropathological examination
Probable	Individuals with high probability of cCJD as determined by a combination of • progressive dementia • **AND** at least two of the following four clinical features: – Myoclonus – visual or cerebellar disturbance – pyramidal/extra pyramidal dysfunction – akinetic mutism • **AND** – an atypical EEG during an illness of any duration; **or** – a positive 14-3-3 CSF assay and a neurological illness of less than 2 years duration • **AND** routine investigations which do not suggest an alternative diagnosis
Possible	Individuals suspected to have cCJD as determined by a combination of • progressive dementia • **AND** at least two of the following four clinical features: – Myoclonus – visual or cerebellar disturbance – pyramidal/extra pyramidal dysfunction – akinetic mutism • **AND** – no EEG or an atypical EEG • **AND** – a clinical illness of less than 2 years duration **NOTE:** Most human pituitary hormone related cases and up to 40% of sporadic cases do not demonstrate characteristic EEG appearances
Other	The following people are also classified as being at higher risk: • carriers of disease-linked mutations of the PrP gene; and • persons in whom the PrP gene has not been sequenced but who have two or more first-degree relatives with cCJD (including GSS or FFI)

31.9.2 Lower risk individuals

The following groups are defined as being at lower risk:

- Any person with a progressive neurological illness of less than one year's duration, with or without dementia. These people should have a competent and complete neurological assessment at the earliest possible opportunity to determine whether they should be moved into the *higher risk* category or moved out of the risk categories altogether (i.e. at no risk for the purposes of CJD management). Persons for whom a determination cannot be made following competent professional review to assess the parameters for higher risk people (as specified above) should remain in the *lower risk* category.

- Any person with progressive neurological illness of less than one year's duration, with or without dementia, who is waiting the outcome of assessments as specified above.

- Patients who are subject to neurosurgical investigations. During the investigation, instruments should be regarded as potentially contaminated until the patient's risk status is confirmed. Where possible use disposable instrument or apply the reprocessing and quarantining procedures detailed in Section 31.12.4 for this group of individuals where CJD cannot be ruled out on clinical grounds. These recommendations apply to –

  (a) Patients undergoing a diagnostic biopsy for progressive brain disease; or

  (b) Patients undergoing neurosurgical investigations (including brain biopsy) for a progressive disorder that includes dementia eg. possible normal pressure hydrocephalus.

- All genetically related members of a family in which there is a strong family history (two or more first-degree relatives) of dementia or neurological illness, in which affected individuals have not been competently and completely assessed neurologically, specifically for cCJD.

- Recipients of cadaver derived human pituitary hormones (growth hormone and gonadotrophins) before 1986 (Allars, 1994).

  In Australia, five persons have developed cCJD as a result of exposure to contaminated human pituitary hormones. This is from an estimated exposed population of 2000 persons. No new cases have occurred since 1990 and it appears that the risk of further cases in this exposed population is extremely small. In contrast, the exposure of individuals of small stature to contaminated products in France and the UK has resulted in a larger number of cases per capita. New cases are still occurring in this group and this factor should be considered when a patient from UK or Europe presents for assessment.

- Recipients of dura mater homografts or transdural neurosurgery before 1990, or for neurosurgical patients for whom the use of dura mater homografts cannot be excluded by reference to patient records.

  In Australia, five persons have developed CJD as a result of exposure through dura mater grafts. New cases of dura mater–associated CJD are continuing to occur (the last occurred in 2000). Worldwide, significant numbers of cases also continue to occur (particularly in Japan where the dura mater product was used extensively). An estimation of the relative risks between dura mater-exposed population and pituitary hormone-exposed population would therefore indicate diligent approaches to identification.

- Although corneal graft recipients are not accepted as blood donors under the ARCBS blood donor deferral policy, this group does not present a risk in the health care environment and therefore have not been included in the lower risk category for CJD.

31.9.3 Variant CJD

Whilst vCJD has not been identified in Australia at the time of writing these guidelines, clinicians should consider this diagnosis in people with undiagnosed neuropsychiatric disorders that fulfil the criteria outlined in WHO (1998b) and subsequent updates (Will et al, 2000). If vCJD is suspected, then immediate specialist assessment should be undertaken and the case reported to the regional health authority and to the Australian National CJD Registry.

People deferred from giving blood donations because they have spent time in UK during the BSE epidemic are not classified in either higher risk or lower risk category for infection control purposes.

Case definition for vCJD

The following outline presents the current diagnostic criteria for vCJD as used by the Department of Health, UK.

Categories	
I	A. Progressive neuropsychiatric disorder B. Duration of illness more than 6 months C. Routine investigations do not suggest an alternative diagnosis D. No history of potential latrogenic exposure
II	A. Early psychiatric symptoms (depression, anxiety, apathy, withdrawal, delusions **)** B. Persistent painful sensory symptoms (this includes both frank pain and/or unpleasant dysaesthesia) C. Ataxia D. Myoclonus or chorea or dystonia

	E. Dementia
III	A. EEG does not show the typical appearance of sporadic CJD (generalised triphasic periodic complexes at approximately one per second) or no EEG performed B. Bilateral pulvinar high signal on MRI scan
IV	Positive tonsil biopsy

Definite diagnosis
Category IA (progressive neuropsychiatric disorder) and neuropathological confirmation of vCJD (spongiform change and extensive PrP deposition with florid plaques, throughout the cerebrum and cerebellum)

Probable diagnosis
Category I and four out of five of Categories II together with Category IIIA and III B; or Categories I and IV

31.10 Responsibilities

Health care establishments, HCWs and patients all have specific responsibilities for infection control management that are described in Section 5. One specific aspect that applies to CJD is that HCWs should fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting (see Section 31.7). The awkward situations that have occurred in the past have generally been resolved by providing adequate education to HCWs about the real and perceived risks of transmitting CJD during medical or surgical procedures.

Specific aspects of the overall infection control responsibilities that apply to CJD are as follows.

31.10.1 Health care establishments

Health care establishments should provide a program of education and training on infection control principles for all health care workers and students that also emphasises the importance of on-going education and training. Health care establishments should also provide a specific program of education and training for all HCWs and students about infection control principles, policies and procedures relevant to the establishment. Education and training responsibilities are discussed in detail in Section 9 ICG. The following key points should be included in an education program designed to equip HCWs to work with patients in either risk category for CJD.

- HCWs should fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting (see Section 31.7).

- Principals should ensure that HCWs are appropriately trained and adequate facilities are available to practise medical procedures to minimise the risk of health care associated transmission of CJD.

- Principals should ensure HCWs are aware of privacy legislation as it relates to their particular work area and are trained to understand the importance of collecting adequate medical histories from individuals or their carers and ensuring that appropriate information from the medical history is provided to other HCWs involved in the individual's treatment and care. This approach should ensure that all infection control issues are resolved before patients are prepared for medical or surgical procedures and avoid potential embarrassment, stress or inconvenience to patients. The awkward situations that have occurred in the past have generally been resolved by providing adequate education to HCWs about the real and perceived risks of transmitting CJD during medical or surgical procedures.

- Principals and HCWs should maintain confidentiality in relation to the identity of people who may be in a risk group for CJD, including those people who may be genetically at risk of developing the disease.

- HCWs should implement additional precautions for the use and reprocessing of instruments to minimise the risk of health care associated transmission of CJD (see Section 31.12 and 31.14).

- HCWs should implement and maintain procedures for tracking instruments as appropriate to minimise the risk of health care associated transmission of CJD (see Section 31.12).

31.10.2 Patients, HCWs and carers

Individuals who have, or are likely to have, CJD have a moral obligation to avoid any activity that could knowingly lead to the transmission of infection to others. Patients (or their carers) should notify HCWs about anything that may affect infection control procedures. This obligation will, in practice, be constrained by the extent to which people are aware of their status. As recognition of that status is likely to become evident, in the first instance, to their medical attendants, patients will be entitled to sensitive counselling as discussed in Section 31.11.

Current epidemiological evidence indicates that health care associated transmission of CJD may occur during some surgical procedures. Therefore, people in a *higher risk* or *lower risk* category for CJD have an obligation to advise HCWs of their status in the interest of public health. Carers also have a moral obligation to disclose the status of their patient during hospital admission procedures (see Section 31.9).

31.11 Ethical issues

Major ethical and legal considerations arise in the implementation of guidelines for the prevention of transmission of infectious disease in health care settings. Broadly, ethical issues relate to consideration of the rights of infected individuals and the responsibilities of health care workers (HCWs) to do no harm to their patients. Legal issues arise in relation to the duty of care of health care establishments to protect both patients and HCWs from infection and in relation to various State/Territory legislation concerning infectious diseases. Please refer to Section 10 of these guidelines for comprehensive information about -

- Developing and implementing policy and procedures around ethical considerations
- Isolation policies
- Duty of care — emergency care
- Referring patients to another practitioner
- Patient decision making and consent
- Preoperative testing
- Patient testing for hospital admissions
- Privacy and confidentiality
- Antidiscrimination

31.11.1 Patient decision making and consent and genetic testing

Informed and voluntary consent must be obtained before taking a clinical specimen to test for any purpose. (For further information see **Section 10.6**) For example, screening for PrP mutations without the patient or carer's consent is unethical. Specific consent should be obtained for each blood or DNA test. In addition, the patient and the patient's family must be provided with relevant information concerning the purpose of a blood, DNA or other specific test recommended.

If family members are to be asked to undertake genetic testing for CJD, careful thought needs to be given to the ethical issues involved and to the practical consequences of being tested or of refusing to be tested. Pre and post test counselling must be offered and should be provided, preferably by a knowledgeable professional who is aware of the skills needed and the matters that should be covered, and who is prepared for the issues that might arise during counselling. Additional ethical considerations arise if parents are being asked to provide consent for their children to be tested. (For a detailed discussion of counselling for genetic tests, see NHMRC publication *Ethical Aspects of Human Genetic Testing; An Information Paper, 2000*).

The need for pre and post test counselling is based on ethical considerations relating to good patient care, there being no legal requirement for the provision of counselling for testing for this infectious disease. Special care is needed in counselling if there are barriers to communication (such as the need for an interpreter) or to comprehension. A uniform level of comprehension about the consequences of testing cannot be assumed. Pre-test counselling for genetic testing implies (among many things) that the possible consequences of any result for other family members be discussed. As this is also an infectious disease, counselling will need to cover other outcomes of a positive result, such as the requirement to notify authorities, which could lead to restrictions on the patient, or to a change in the manner in which health care is provided. Refer to Section 10.6 for further information.

31.11.2 Patient competency

In obtaining consent for testing, treatment or other procedures, other than in an emergency, the treating medical practitioner must assure him/herself that the patient is an adult and has the cognitive capacity to understand what is being proposed. In general, the more complex or risky the procedure , the higher the level of understanding will be required.

Thus obtaining consent which is ethically acceptable and legally valid can be problematic when caring for a patient whose mental competence may be fluctuating or deteriorating due to CJD.

The commonly accepted ethical goal of a consent process is to reach a decision that expresses and implements the patient's own choice, made for reasons that are most important for her or him. The expression "authentic" is sometimes used to describe a decision that so expresses an individual's well considered choice. It is implicit that the decision should not be influenced by other people's preferences or wishes.

Legally speaking, while it is customary to converse with and obtain informal consent from relatives for very minor aspects of medical and nursing care, health care workers need to be aware that a relative cannot legally give consent on behalf of a patient unless that person has been officially appointed as a decision maker, eg as guardian.

Health care workers therefore need to be conversant with the relevant guardianship or health decision legislation in their state or territory and if in doubt should not hesitate to contact the local Guardianship Board which in most jurisdictions provide a 24 hour advice service.

As the patient’s children will bear most of the burden of a positive result for genetic testing for familial CJD, the HCW should demonstrate an advantage to each individual for whom consent is given. The HCW should also explain that an individual might be required to demonstrate legal and ethical *benefice* at some future time for providing consent (to genetic testing for familial CJD) on behalf of a child. The short-term and

inevitable consequences and implications of a positive test result should be discussed with the patient and the patient's family in the pre-test counselling session. The results, consequences and implications for each individual should also be discussed in post-test counselling sessions. Refer to Section 10.6 for further information.

31.12 Patient management

31.12.1 Triage policy

When individuals are being admitted to hospital or presenting at an outpatient/emergency unit or health care waiting room a detailed medical history should be collected from an individual or their carer. Triage staff should use a "checklist" to assess patients for conditions that require additional precautions, as well as prioritising those who may require urgent attention or immediate treatment. Using a triage "checklist" may also reveal a patient with a medical history relating to CJD, for example:

- a pre-existing neurological disease that requires further evaluation;
- a family history of two or more first degree relatives with CJD or other undiagnosed neurological illness;
- a history of receiving human pituitary derived gonadotrophin (for infertility) or growth hormone (for short stature); or
- a dura mater graft in a neurosurgical or other surgical procedure before 1990.

Principals should ensure HCWs are trained to understand the importance of collecting adequate medical histories from patients or their carers and ensuring that appropriate information from the medical history is provided to other HCWs involved in the patient's treatment and care. This approach should ensure that all infection control issues are resolved before patients are prepared for medical or surgical procedures and avoid embarrassment, stress or inconvenience to patients. Some awkward situations that have occurred previously have generally been resolved by providing adequate education to HCWs about the real and perceived risks of transmitting CJD during medical or surgical procedures and disseminating information about patients' medical histories in an appropriate manner.

31.12.2 Standard and additional precautions

Standard precautions should apply to the routine management of all patients.

Additional precautions that apply to the handling and reprocessing of surgical instruments and diagnostic equipment are shown in Table 31.12.5. These and other additional precautions necessary in the care of patients in a CJD risk category (see Section 31.9) are described in Sections 31.12.6 to 31.12.10, below.

31.12.3 Disposal of Single Use Instruments

Single use instruments potentially contaminated with the infectious agent for CJD should be disposed of according to NHMRC National Guidelines for Waste Management in the Health Care Industry (see Section 15).

31.12.4 Reprocessing and quarantining instruments

Instruments used for neurosurgery, neuroradiology or ophthalmic surgery (see Table 31.12.5) should be manually cleaned and sterilised using routine methods then labelled and quarantined either -

- until the patient's CJD risk status is clarified (at which time the instruments should be destroyed if CJD is confirmed or they may be put back into circulation if there is no risk); **or**

- for the future exclusive use of that individual patient in the higher or lower risk category for CJD for the duration of the course of their therapy then disposed of by incineration (see Section 31.14.3).

31.12.5 Reprocessing instruments using additional levels of heat or chemical sterilisation

This option refers to patients in the higher risk category and only applies to instruments used for "low infectivity sites" and "no infectivity sites" (see Table 31.7.3). This option must only be used for instruments that are approved by TGA as multiple use instruments that are also capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods as detailed in Table 31.14.1.

A routine practice in many neurosurgical units is to sterilise all instruments, used in procedures involving high risk tissues, at higher temperatures and longer holding times (see table 31.14.1). This practice is encouraged for patients who are not in a risk group for CJD as a preparation for a development of procedures that can routinely be applied to risk tissues. However, there is insufficient evidence at present to confirm that this is a safe "standard practice" for patients in CJD risk groups. All instruments used on 'high infectivity' tissues in higher or lower risk patients should be destroyed.

The TGA's advice about reprocessing "single use" instruments is as follows – *Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use" should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and that this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good*

Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices, but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.

Table 31.12.5 Additional precautions required for handling instruments and equipment for patients in the higher or lower risk categories for CJD[a]

Patient risk category	Neurosurgery, neuroradiology or ophthalmic (posterior segment) surgery	Other surgery or diagnostic procedures including ophthalmic (anterior segment) surgery
Higher risk patient[a]	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess and quarantine instruments pending determination of risk status (then destroy or put back into circulation if there is no risk) OR keep for the exclusive use of an individual patient involved in a course of therapy (then destroy)[c]	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess instruments that are approved by TGA as multiple use and can withstand additional heat or chemical sterilisation methods. These instruments may only be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1). Consideration could be given to offering alternative procedures if available and patient care is not compromised.
Lower risk patient	Use single-use instruments[b] OR Destroy instruments[c] OR Reprocess and quarantine instruments pending determination of risk status (then destroy if there is a CJD risk, or put back into circulation if there is no risk) or keep for the exclusive use of an individual patient involved in a course of therapy (then destroy)[c]	Routine reprocessing

[a]See Section 31.9 for a description of definite, probable and possible higher risk CJD patients.

[b]See Section 31.12.3.

[c]See Section 31.12.4

31.12.6 Surgical procedures at CJD "high infectivity" sites

Neurosurgery, neuroradiology and ophthalmology

When the brain, spinal cord, eye (retina, optic nerve), or pituitary are penetrated or exposed, maximum containment and cleaning procedures should be used for the whole area, including surfaces, for patients in both CJD risk groups (see Table 31.12.6).

The performance of neurological, interventional neuroradiological or ophthalmological procedures (retina, optic nerve) on either higher or lower risk patients is not contraindicated, but additional precautions are required as shown in Tables 31.12.5 and 31.12.6.

- All surgical procedures involving "high infectivity" sites in patients in the higher and lower risk categories should be undertaken at centres with appropriate neurological facilities and staff who fully understand the theoretical and demonstrable risks of transmitting CJD in a health care setting.

- All instruments and equipment exposed to CJD "high infectivity" sites (brain, spinal cord, CSF, retina or optic nerve) of higher or lower risk CJD patients should be immediately destroyed; or

- reprocessed and quarantined for the exclusive reuse by an individual patient involved in a course of therapy (and then destroyed).

- A one way flow of instruments should be maintained during surgical procedures. Instruments potentially contaminated with CJD infectious agents should be separated from other instruments until they are destroyed or reprocessed. In the latter case, surgical instruments and equipment should be manually cleaned, reprocessed using routine methods, labelled and quarantined pending subsequent treatment on the same patient. Packs of instruments should be maintained together as integral units. During reprocessing, potentially contaminated instruments should not be processed with other instruments that are destined for general re-use.

- Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should also be single use equipment (MacMurdo et al, 1984; Hernandez-Palazon et al, 1998).

Worldwide, only a handful of cases of iatrogenic CJD have been associated with corneal transplantation; none has occurred in Australia. Given this low risk (Kennedy et al, 2001) and because of the current uncertainty of the potential infectivity present in the anterior segments of the eye (cornea, sclera, lens, etc.), instruments used in procedures in this region may be reprocessed after use in lower risk patients. Such re-use should not be allowed for instruments contacting the optic nerve or posterior segments of the eye.

Table 31.12.6 Additional precautions for neurosurgery, neuroradiology, ophthalmology and other procedures on higher or lower risk CJD patients[a]

Procedure	Recommendations	
	Higher risk patient[a]	**Lower risk patient[a]**
Use of instruments	HCWs should maintain a one-way flow of instruments for all procedures and instrument potentially contaminated with CJD infectious agents should be separated from other instruments. Equipment should be single-use.	HCWs should maintain a one-way flow of instruments for all procedures and instrument potentially contaminated with CJD infectious agents should be separated from other instruments.. Equipment should be single-use.
Reusable equipment	See Table 31.12.5	See Table 31.12.5
Tonometers	Non-contact air or puff tonometers that do not contact the cornea should be used. Tonometers that come into direct contact with corneas should be discarded after use, or reprocessed using additional heat or chemical sterilisation methods (see Table 31.14.1). If non-contact tonometers are not available, disposable plastic tonometer covers should be used and discarded immediately after use.	Non-contact air or puff tonometers that do not contact the cornea are recommended. If non-contact tonometers are not available, disposable plastic tonometer covers should be used and discarded immediately after use.
Anaesthetic equipment	Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should be single use equipment.	Routine precautions should be applied.
Scheduling of patients	Operations or procedures should be scheduled at the end of the day to allow appropriate cleaning of facilities.	Operations or procedures should be scheduled at the end of the day to allow appropriate cleaning of facilities.
Training for HCWs	HCWs should be trained to understand CJD risk and be trained and tested in appropriate infection control procedures. The minimum number of HCWs should participate in the operation/procedure.	HCWs should be trained to understand CJD risks and trained and tested in appropriate infection control procedures.
Personal protective equipment (PPE)	HCWs should wear single-use PPE at all times.	HCWs should wear PPE at all times. Single-use PPE is recommended.
Surgical drapes	Surgical drapes should be single use and disposed of by incineration.	Surgical drapes should be single use and disposed of by incineration.

HCW = health care worker; CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective equipment

[a]See Section 31.9 for patient risk categories

[b]Seal items in yellow clinical waste bags with international biohazard symbol and the words " clinical waste" and dispose of by incineration. See Table 31.15.

Table 31.12.6 Continued

Procedure	Recommendations	
	Higher risk patient[a]	**Lower risk patient[a]**
Disposal or laundering of contaminated personal protective equipment and drapes[b]	Single-use gowns, other PPE and drapes should be incinerated after use.	Single-use gowns, other PPE and drapes should be incinerated after use. Non-disposable gowns or other PPE soiled with brain or CNS tissue should be incinerated. Normal laundering and steam sterilising is suitable for non-disposable gowns that are soiled with other tissues including blood and CSF.
Collection of specimens	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.
Disposal of specimens[b]	All spent specimens should be disposed of by incineration.	Brain, CNS tissue and CSF samples should be incinerated. Standard infection control procedures and environmental landfill recommendations should be followed for disposal of other spent specimens.
Other articles used in procedures[b]	Reusable articles should not be reused. All swabs, dressings, linen, etc used during operations should be disposed of by incineration. Needles and other sharps should be placed in appropriate containers for disposal by incineration (in accordance with AS 4031[c]).	All articles that contact brain, CNS tissue or CSF during a procedure should be disposed of by incineration. Standard infection control procedures and environmental landfill recommendations should be followed for disposal of other waste materials.

HCW = health care worker; CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective clothing

[a]See Section 31.9 for patient risk categories

[b]Seal items in yellow clinical waste bags with international biohazard symbol and the words "clinical waste" and dispose of by incineration. See Table 31.15.

[c]AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas*.

31.12.7 Neurology services

Neurologists often have the primary responsibility for the initial diagnosis and management of patients with CJD. Consequently, there is an increased likelihood of contamination of neurological instruments. Particular attention should be given to electromyography (EMG) needles, sensory testing pins and lumbar puncture needles.

For patients in both risk groups, contaminated instruments should be treated in the same way as for neurosurgical instruments (see Section 31.12.4 and Table 31.12.5).

31.12.8 Interventional radiology, general surgery, anaesthesia and obstetrics

The additional precautions required for interventional radiology, general surgery and anaesthesia are shown in Table 31.12.8. For higher-risk patients, surgical instruments in contact with tissues outside the "high infectivity" CNS sites described in Section 31.12.6 still carry a risk of CJD contamination (see Table 31.7.3) and single-use instruments should be used where possible. If reusable equipment is used, it should be either destroyed or reprocessed and quarantined for possible future exclusive use of an individual patient (see Table 31.12.5), as described in Section 31.12.6.

For other surgery in higher risk patients where instruments are not exposed to "high infectivity" tissues the instruments may be reprocessed if they comply with TGA regulations as described in Section 31.12.5 using additional levels of steam and/or chemical sterilisation as detailed in Table 31.14.1

Anaesthetic equipment including tubing and masks that is in direct mucosal contact with higher risk patients should be single use equipment (MacMurdo et al, 1984; Hernandez-Palazon et al, 1998).

Additional CJD precautions should be taken when dealing with the placenta and amniotic fluid from a person with higher risk CJD (see Table 31.12.5)

Table 31.12.8 Procedures for interventional radiology, general surgery and anaesthetics for higher risk CJD patients[a]

Procedure	Recommendations
Surgical instruments	Use single-use equipment wherever possible. All instruments that have been in contact with brain, spinal cord or CSF should be destroyed. Instruments that have been in contact with blood or other tissues should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1). This only applies to instruments as detailed in Section 31.12.5.
Reusable equipment (ie, equipment not normally regarded as single-use instruments)	Avoid using endoscopes, bronchoscopes, other fibre-optic scopes and diagnostic ultrasound probes, wherever possible (see Section 31.14.6 for further information on special instruments).
Anaesthetic equipment	Anaesthetic equipment including tubing and masks that has direct mucosal contact with patients should be single-use equipment.
Scheduling of patients	Operations or procedures should be scheduled at end of day to allow adequate cleaning of facilities.
Training and HCWs	HCWs should be trained to understand CJD risk management and be trained and tested in appropriate infection control procedures. The minimum number of people should participate in the operation/procedure.
Personal protective equipment (PPE)	HCWs should wear single-use PPE (eg gowns, caps) at all times.
Surgical drapes	Single-use surgical drapes should be used.
Disposal or laundering of contaminated PPE and drapes[b]	Single-use gowns, other disposable PPE and drapes should be incinerated. Non-disposable PPE that has been soiled with brain tissue or CNS tissue should be incinerated. Normal laundering and steam sterilising is suitable for non-disposable PPE that are soiled with other tissues including blood and CSF.
Collection of specimens	Specimens should be collected into a secure-closing container and enclosed in a plastic bag for transportation. The container should be clearly labelled with patient identification details, including a CJD risk alert to laboratory and other HCWs.
Disposal of specimens[b]	Dispose of all specimens according to NHMRC National Guidelines for Waste Management in the Health Care Industry.
Other articles used in procedures[b]	Reusable articles should not be reused. Dispose of swabs, dressings, linen etc used during operations by incineration. Needles and other sharps should be placed in appropriate containers for disposal by incineration (in accordance with AS 4031[c]).

CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid; CNS = central nervous system; PPE = personal protective equipment

[a] Additional precautions conditions are not required for patients in the lower risk category (see Table 31.12.5)

[b] Seal items for disposal in yellow clinical waste bags with international biohazard symbol and the words "clinical waste" and dispose of by incineration. See Table 31.15.

[c] AS 4031 (1992) and Amendment 1 (1996) Non-reusable containers for the collection of sharp medical items used in health care areas.

31.12.9 Dentistry

There is no epidemiological evidence that dentistry is a risk factor for cCJD (Collins et al, 1999; Chan et al 2001), although some experimental studies suggest that it is possible to transmit a TSE through the dental route (Ingrosso et al, 1999; Blanquet-Grossard et al, 2000; Porter et al, 2000). Standard precautions apply for routine dental procedures on lower risk individuals. Additional precautionary recommendations for maxillofacial surgery and endodontic procedures are shown in Table 31.12.9. As for all procedures involving body fluids, standard precautions should also apply. Single-use items, clothing and equipment, including dental syringes should be used wherever possible.

Dentists and other HCWs should wear masks, protective eyewear, single-use gloves and gowns during all dental procedures.

Dentists should take an appropriate medical history of all patients.

Dental work on higher risk patients involving maxillofacial surgery or endodontic procedures should be carried out at a central referral facility designated by the relevant State/Territory Health authority (such as a specialist dental hospital or a dental unit in a major hospital) and by HCWs who are familiar with CJD infection control procedures.

A separate isolated water supply and separate isolated suction should be used for all patients in the higher and lower risk group involved in maxillofacial surgery and endodontic procedures.

A separate isolated water supply and separate isolated suction should be used for all patients in the higher risk group involved in all other operative dental procedures.

Table 31.12.9 shows the additional precautions necessary for dentistry on patients in a risk category for CJD.

Table 31.12.9 Additional precautions for dentistry on patients in CJD risk categories[a]

Patient risk category	Maxillofacial surgery and endodontic procedures	Other procedures
Higher risk patient	Patients should be treated in a specialised facility. A separate isolated water supply and suction should be used. Disposable handpieces should be used. All burs, broaches, reamers, files, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks.[b] All other instruments should be destroyed OR Provided that OH&S concerns are satisfied all other instruments should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of an individual patient involved in a course of therapy and then destroyed.	A separate isolated water supply and suction should be used. Disposable handpieces should be used OR Hand pieces should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of a patient involved in a course of therapy. All burs, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks.[b] All other instruments should be destroyed OR Provided that OH&S concerns are satisfied all other instrument should be reprocessed using additional levels of steam and/or chemical sterilisation (see Table 31.14.1) and quarantined for the exclusive use of an individual patient involved in a course of therapy and then destroyed.
Lower risk patient	A separate isolated water supply and suction should be used. All burs, broaches, reamers, files, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks.[b] Provided that OH&S concerns are satisfied, all other instruments should be reprocessed using additional levels of steam and/or chemical sterilisation (see table 31.14.1).	Routine infection control procedures should be applied. • Anti-retraction (non-return) valves in water lines should be checked and functioning. • All burs, matrix bands and hard-to-clean small instruments should be disposed of as sharps; reprocessing incurs unacceptable OH&S risks.[b]

[a]See Section 31.9 for patient risk categories

[b]Items should be sealed in yellow clinical waste bags marked with the international biohazard symbol and the words "clinical waste" and collected for disposal by incineration. See Table 31.15.

31.12.10 Routine hospital, long-term residential or community care

Routine contact with people in either risk group does not represent a risk, as there is a low potential for transmitting CJD via non-parenteral routes. Standard precautions

apply and no additional precautions are required for the routine care of patients/residents. As CSF in people in the higher risk group is potentially infective, HCWs, and visitors who assist with the care of patients should understand and follow the special requirements and infection control procedures necessary for personal safety as detailed in Table 31.12.10.

HCWs have a duty of care to advise visitors assisting in patient care to wear disposable gloves and wash their hands after removing the gloves. This applies to activities such as such as changing bed linen, bathing or toileting or other procedures that may involve handling soiled linen or clothing.

Table 31.12.10 Procedures for management of higher risk CJD patients in routine hospital, long-term residential or community care[a]

Procedure	Recommendations
Infection control policy	All major hospitals should have procedures in place to identify and manage higher risk patients. Standard precautions also apply at all times.
Ward accommodation	Hospital patients should (ideally) be accommodated in single rooms (but not for infection control management reasons).
Specialist nursing requirements	HCWs should be fully trained in the precautions required for each risk group and in appropriate infection control procedures. Additional precautions are not required.
Eating utensils	Cutlery, plates, cups etc should be cleaned as usual. There is no evidence that CJD can be transmitted via saliva.
Bath towels and face washers	Patients should be allocated their own personal face washers and towels that should be laundered as usual. Bath towel and face washers that are soiled with CSF should also be laundered as usual.
Laundering of normal bed linen and clothes	Linen, towels and clothes soiled with CNS tissue should be incinerated. All other linen (including linen soiled with blood or CSF) should be laundered as usual. Single-use absorbent sheet covers should be used wherever practical.
Razors and toothbrushes	Razors and toothbrushes should be used for the exclusive use of individual patients only. Discarded razor blades and toothbrushes should be disposed of by incineration.
Disposal of contaminated materials	Disposable gloves should be worn when collecting contaminated material and should be disposed of by incineration. Needles and other sharp articles should also be placed in appropriate biohazard containers and collected for incineration (in accordance with AS 4031[b]).
Collection of specimens	Blood, tissue or CSF specimens should be collected into sealable containers and labelled clearly with the patient details, including CJD risk status.
Cleaning contaminated surfaces — spills	Spills of CNS tissue should be absorbed onto paper towels and disposed of by incineration. The contaminated surface should then be soaked with 1 molar sodium hydroxide or 2.0–2.5% sodium hypochlorite, left for 1 hour and cleaned again with paper towels that are disposed of by incineration. Spills of blood or other body fluids and tissues should be cleaned using standard spills management procedures. Gloves used for protection when cleaning contaminated surfaces should be incinerated after use.

CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid

[a]See Section 31.9 for patient risk categories

[b]AS 4031 (1992) and Amendment 1 (1996) *Nonreusable containers for the collection of sharp medical items used in health care areas.*

31.13 Health care worker responsibilities

All HCWs and other people, who are responsible for caring for patients with CJD, should be trained in appropriate infection control and risk management procedures relating to CJD that may affect personal safety.

31.13.1 Needlestick or other body fluid exposure

There are no special requirements following a needlestick or other body fluid exposure from an individual with CJD or an individual in the higher or lower risk category for CJD. If a needlestick or other exposure to blood or body fluids from a person in a CJD risk category occurs refer to Section 23.6 for standard wound cleansing procedures, and if applicable, post exposure prophylaxis (PEP).

31.13.2 Laboratory staff

In the clinical pathology laboratory, specimens from both higher and lower risk individuals should be treated according to standard precautions. However, in the anatomical/surgical pathology laboratory, appropriate containment and reprocessing procedures are necessary when handling brain tissue and other surgical specimens from patients in either the higher or lower risk groups (DHSS, 1978; Chatigny and Prusiner, 1980; Brown et al, 1986ab; Budka et al, 1995; Baron et al, 1999).

Cut-up/blocking of tissue samples from either risk category should be performed in a biohazard hood, preferably located in a circumscribed area that can be easily cleaned. Because of the known resistance of CJD infectivity to aldehydes (Brown et al, 1986a) and alcohols, the safest manner in which to handle biopsy material is by fixation of small blocks of tissue, followed by immersion in formic acid for one hour (Brown et al, 1990). After washing, these blocks can then be processed routinely for histology. Procedures for CJD infection control in laboratories are shown in Table 31.13.

31.13.3 Postmortem examinations

Guidelines relating to the conduct of postmortem examination in CJD have been reported (Bastian and Jennings, 1984; Brown et al, 1990; Bell and Ironside, 1993), and should follow the same protocols established for other infectious diseases such as HIV and tuberculosis.

In general, it is recommended that at least one centre in each Australian capital city be designated as a referral centre with expertise in the conduct of such an autopsy. Removal of the brain (Bell and Ironside, 1993) should be performed with sufficient containment to avoid aerosol contamination with the electric bone saw. Alternatively, a handsaw may be used.

After immersion-fixation of the brain in formalin, blocks can be taken and treated in formic acid as described for laboratory specimens (Table 31.13). If frozen tissue is to be retained for genetic testing, diagnosis or research, then appropriately labelled containers should be used. Dedicated sets of instruments should be used for autopsies when CJD is suspected. All instruments in the autopsy room that contact CJD infectious tissue should be destroyed to avoid cross contamination of instruments that are used to harvest tissue for donation.

31.13.4 Mortuaries and funeral industry workers

Cleaning and reprocessing of instruments and surfaces in the mortuary should follow the guidelines set out for higher and lower risk patients in Tables 31.13 and 31.14.1.

Funeral industry workers employed in mortuaries should clean working surfaces and instruments according to the guidelines in Table 31.13 and Section 31.14 when working with the bodies of higher or lower risk patients.

Embalming of bodies from higher risk patients should be avoided. No special precautions are required when transporting bodies.

Table 31.13 Infection control procedures in the laboratory setting for tissues from patients in the higher or lower risk groups for CJD.

Procedure	Minimum safety requirements for laboratories
Standard precautions	Standard precautions apply at all times.
Steam-sterilising facilities	Facilities for steam sterilising and/or chemical sterilisation of instruments and surfaces should be available in proximity to the cut-up area and mortuary.
Personal protective equipment (PPE)	Single-use gloves should be worn for all procedures involving contact with body fluids or tissues. Gowns (preferably single-use), masks and protective eyewear should be worn, particularly where splashing of blood, tissue and other body fluid may occur. All other linen (including linen soiled with blood) should be laundered as usual. Gowns contaminated with CNS tissue from CJD patients or patients in the higher or lower risk groups should be destroyed by incineration[a]. Gowns contaminated with blood or other tissues may be laundered normally.
Cleaning of contaminated surfaces (eg bench tops, floors)	Single-use absorbent bench-coats or other bench coverings should be used wherever possible and disposed of by incineration. Spills of CNS tissue or CSF should be absorbed onto paper towels and disposed of by incineration. The surface should then be soaked with 1 molar sodium hydroxide or 2.0–2.5% sodium hypochlorite, left for 1 hour and cleaned again with paper towels that are disposed of by incineration. Spills of blood or other body fluids and tissues should be cleaned using standard spills management procedures. Gloves used for protection when cleaning contaminated surfaces should be incinerated after use.
Specimen preparation and handling	Blood, tissue or CSF specimens should be collected into sealable containers and labelled clearly with the patient details, including CJD risk status. Special safety precautions should be applied when handling brain tissue and other surgical specimens from both higher and lower risk patients in anatomical/surgical pathology laboratories. A separate area with a biohazard hood should be available for cut-up/blocking of tissue samples from higher and lower risk patients. Because of the known resistance of infectivity to aldehydes and alcohols, biopsy material should be fixed in 4% formaldehyde solution (10% formol–saline), followed by immersion in formic acid (>96%) for one hour. For machine processing, tissues should be rewashed in formalin, as formic acid may damage plastic containers. Where tissues are processed by hand they should be transferred directly from formic acid into ascending alcohol solutions. Cryostat microtome should be cleaned and disinfected when frozen sections are prepared. All "high infectivity" site specimens should be treated as potentially infectious for CJD until proved otherwise. Waste tissue should be disposed of by incineration. Note: Do not steam sterilise formaldehyde solutions.
Cadavers for teaching purposes	Cadavers from either higher or lower risk patients should not be used for teaching purposes.

CJD = Creutzfeldt–Jakob disease; CSF = cerebrospinal fluid

[a] See Section 31.9 for patient risk categorisation

31.14 Instruments and equipment

This section describes the basic principles of cleaning and reprocessing. Contaminated objects and surfaces, which cannot be discarded, should be disinfected with heat and/or chemicals. Information about disinfectants and sterilants is given in Section 31.8.4. The following reprocessing procedures may not completely inactivate the CJD infectious agent:

- normal steam sterilising (121°C at 15 psi or 101 kPa);
- dry heat sterilisation;
- ultraviolet or gamma irradiation;
- boiling;
- ethylene oxide;
- low-temperature hydrogen peroxide plasma and peracetic acid systems;
- glutaraldehyde and other aldehydes; and
- acetone, alcohols and most other chemical disinfectants (see Table 31.8.4).

Although there is not currently a method that guarantees complete sterilisation (Taylor and McConnell, 1988; Brown et al, 1990), the methods believed to be most effective in reducing the level of infectivity are presented in Table 31.14.1.

Table 31.14.1 Additional instrument reprocessing or disposal methods.

Note: Some instruments and devices, eg power drills, may not withstand some sterilisation methods intended for reusable items. In such cases, the manufacturer should be consulted to determine the most appropriate course of action. Additional methods are detailed in WHO, 2000.

Instruments for which additional reprocessing methods are indicated (see Tables 31.12.5 and 31.12.9) should be kept immersed in a dedicated container in an anionic detergent solution, at ambient temperature, until they are manually cleaned and reprocessed using the methods shown in the following table. Contaminated instruments from each patient should be cleaned and reprocessed in separate batches, and not mixed with other surgical instruments at any stage of the reprocessing cycle. Ultrasonic cleaners and automatic washing appliances should not be used in the preparatory cleaning process. Instruments should not be exposed to instrument-grade disinfectants or sterilants prior to the above manual cleaning procedures.

NB HCWs should adhere to State/Territory OH&S requirements at all times	
Method of Reprocessing.	**Application**
A. Incineration Soiled articles should be immediately placed into the correct container (yellow infectious waste bag with international biohazard symbol and the words " clinical waste") for disposal by incineration (see Section 14.2). Needles, blades and other sharp articles should be placed in containers (in accordance with AS 4031[a]) and disposed of by incineration.	All tissues, disposable instruments and wastes including: swabs, wound dressings, needles, catheter tubing, single-use personal protective equipment (PPE) and other single-use equipment from surgical or other procedures involving treatment of higher risk patients. Also suitable for linen soiled with CSF from higher risk patients and for disposing of contaminated organs and tissue sections. This is the preferred method for instruments exposed to tissues from higher risk patients and suitable for hospital and office practice.
B. Reprocessing alternatives for heat-resistant instruments involving steam or chemical sterilisation ***Method 1.*** Autoclave at 134°C for 18 minutes. ***Method 2.*** Immerse in 2% sodium hypochlorite solution[d] (20,000 ppm available chlorine) or 1M NaOH at ambient temperature for 1 hour. Clean, rinse in water and subject to routine sterilisation. Methods involving NaOH are not suitable for instruments containing metals that are corroded by this compound (eg aluminium alloys). 1M NaOH is very caustic, ensure adequate ventilation, avoid contact with eyes and mucous membranes and adhere to State/Territory OH&S requirements. Instruments should be completely submerged in NaOH and sodium hypochlorite solutions. Instruments should be scrubbed by hand to remove any adherent material before sterilisation. Items used to clean instruments should be either destroyed or adequately sterilised.	
C. Reprocessing alternatives for heat-sensitive instruments and surfaces ***Method 1.*** Flood with 1M NaOH or 5% sodium hypochlorite; let stand for 1 hour; mop up and rinse with water. ***Method 2.*** Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefit may be derived from the use of one or another of the partially effective methods listed in Table 7.1.	Instruments should be completely submerged in sodium hypochlorite or NaOH solution. Surfaces, eg benchtops and floors, should be thoroughly soaked in the solution for a full hour.

[a] AS 4031 (1992) and Amendment 1 (1996) *Non-reusable containers for the collection of sharp medical items used in health care areas*

Source: WHO (2000)

[b] Unless otherwise specified, the recommended concentration is 1M. 1M NaOH is readily inactivated by air, forming Na_2CO_3. 1M NaOH solutions should be prepared fresh from dry NaOH or by dilution of a stock solution of 10M NaOH.

[c] Sodium hypochlorite). Efficacy depends on the concentration of available chlorine, that (unless otherwise stated) should be 20,000 ppm (2 %). Chlorine is evolved continuously by hypochlorite solutions that affects both the concentration in solution and the concentration in the environment (which is a potential health hazard). Working stocks should be prepared freshly.

Source: WHO (2000)

31.14.1 Reprocessing of reusable instruments and devices

HCWs and other people working with patients diagnosed with CJD or individuals in the higher or lower risk category should be appropriately trained and tested in the special requirements and infection control procedures necessary for personal and public safety. Education and general training requirements are discussed in the ICG Section 9.

31.14.2 Single-use instruments and equipment

Single-use sterile instruments and equipment should be used wherever possible for procedures involving interventional radiology, general surgery and anaesthetics for higher risk patients and whenever the instruments or equipment may contact CJD contaminated neurological tissues.

The Therapeutic Goods Administration's (TGA) advice about reprocessing "single use" instruments is as follows –

Devices listed on the Australian Register of Therapeutic Goods (ARTG) as "single use", should be used only once. In July 2001, the Australian Health Minister's Advisory Council (AHMAC) agreed that any reprocessing of single use devices for reuse is a manufacturing activity and this should be regulated by the TGA. AHMAC also agreed that the regulation of the re-manufacture of single use devices for reuse should meet the same regulatory requirements and standards as apply to the original manufacturer. Any reprocessing would therefore only occur in a Good Manufacturing Practices (GMP) licensed facility that includes a monitoring system to ensure microbiological safety and product integrity. The TGA is developing a regulatory proposal for reprocessing of single use devices but is not in the position to license reprocessing facilities until this regulatory proposal has been fully considered by all relevant stakeholders and finalised.

This option only applies to instruments and equipment that are also capable of withstanding reprocessing that involves additional heat or chemical sterilisation methods as detailed in Table 31.14.1

31.14.3 Reusable instruments and equipment

Additional precautions apply for reprocessing instruments and equipment possibly contaminated with CJD. These procedures are described in Section 31.12, and Tables 31.12.5 and 31.12.6 of these guidelines.

High infectivity tissue: Higher risk patients - When an instrument contacts "high infectivity" tissue (brain, spinal cord, retina, optic nerve or pituitary; see Table 31.7.3) of patients identified in the higher risk CJD category, that instrument should be either destroyed or subjected to reprocessing and quarantined for the exclusive use of an individual patient involved in a course of therapy, and then destroyed (see Section 31.12.4, Table 31.12.5 for more detail).

Other surgery: Higher risk patients - Instruments used for other surgery on higher risk patients should be either single use or destroyed. If the instruments have been approved by TGA as multiple use and can withstand additional heat or chemical sterilisation methods (see Section 31.12.6 to 31.12.10, Tables 31.12.5 and 31.14.1) then these instruments may be reprocessed using these additional sterilisation methods.

High infectivity tissue: Lower risk patients - When an instrument contacts "high infectivity" tissue (brain, spinal cord, retina, optic nerve or pituitary; see Table 31.7.3) of patients in the lower risk CJD category, that instrument should be destroyed, or if a re-useable instrument, may be subjected to reprocessing and quarantined for the exclusive use of an individual patient involved in a course of therapy, and then destroyed (see Section 31.12.6 to 31.12.10, Table 31.12.5 for more detail).

Other surgery: Lower risk patients – Reusable instruments used on lower risk patients may be subjected to routine reprocessing (see Section 31.12.6 to 31.12.10 and Table 31.12.5).

31.14.4 Manual cleaning procedures

CJD infectivity may be stabilised by drying on metal surfaces (Zobeley et al, 1999; WHO 2000) and become more difficult to inactivate. Therefore instruments potentially contaminated with CJD agents should be kept immersed in a dedicated container in an anionic detergent solution, at ambient temperature, until they are manually cleaned and reprocessed using the methods shown in Table 31.14.1. Contaminated instruments from each patient should be cleaned and reprocessed in separate batches, and not mixed with other surgical instruments at any stage of the

reprocessing cycle. Ultrasonic cleaners and automatic washing appliances should not be used in the preparatory cleaning process. Instruments should not be exposed to instrument-grade disinfectants or sterilants prior to the above manual cleaning procedures.

31.14.5 Disinfection and sterilisation

Most routine methods are not suitable for reprocessing items contaminated with the infectious agents of CJD (see Section 31.14). Suitable methods for inactivating these agents are described in Table 31.14.1.

31.14.6 Instruments that cannot be adequately reprocessed

There are several instruments, due to the equipment design and/or current technology available for reprocessing that cannot be cleaned and reprocessed adequately in respect of the agents of CJD and related diseases. These include, for example, endoscopes, bronchoscopes, cystoscopes, other fibreoptic scopes (e.g. laparoscopes), diagnostic ultrasound transducers, and certain ophthalmic and optometric equipment. Diagnostic or therapeutic procedures using these instruments on patients in the higher risk category for CJD should be avoided when possible.

If instruments have been in contact with “high infectivity” tissue (see Table 31.7.3) and have been reused (after use on a patient who has been subsequently diagnosed with CJD), a lookback investigation may be necessary to identify at-risk patients (see Section 31.16.1).

Alternative approaches to diagnosis and management of routine health conditions in patients at risk of CJD should be considered, if available, provided the care of the patient is not compromised. Best quality health care should be provided without incurring unnecessary discrimination or expense for infection containment. For example, Radiological investigations may substitute for endoscopy in some situations.

In some cases, however, the treating medical practitioner may consider it essential to perform a procedure where an instrument which can not be adequately reprocessed in respect of CJD, comes into contact with "low infectivity tissue". In that situation, instruments should be handled as follows in respect of the patient groups described below.

Patient group A. Higher risk patients as defined in Table 31.9.1, and symptomatic patients in the lower risk group as defined in Section 31.9.2. All parts of instruments which cannot be adequately reprocessed and which come into contact with "low infectivity tissue" should be destroyed. This would include, for example,

bronchoscopes, endoscopes and colonoscopes, and instruments which come into contact with the anterior components of the eye.

Patient group B. Asymptomatic patients in the lower risk group as defined in Section 31.9.2. Instruments should be kept immersed in an anionic detergent before being manually cleaned in accordance with the procedures outlined in Section 31.14.4, followed by routine reprocessing.

Patient group C. Patients for whom there is no identified risk of CJD. Instruments should be kept immersed in an anionic detergent before being manually cleaned in accordance with the procedures outlined in Section 31.14.4, followed by routine reprocessing.

> It should be noted that while these guidelines have been endorsed by the Communicable Diseases Network Australia and the National Public Health Partnership, not all members of these committees agreed with the recommended action for instruments used on Group A patients. This is due to the very limited data available to assess the possible level of risk of transmission of infectious material from "low infectivity tissue". Some health authorities may place a different interpretation on the data, and have policies which vary from these guidelines. Therefore, before undertaking procedures of this type in Group A patients, the treating medical practitioner should seek advice from the relevant State or Territory health authority.

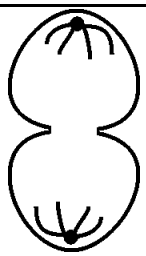
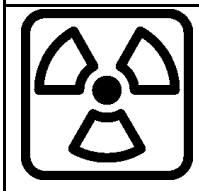
Where a patient in Group B or Group C has undergone a procedure of this type, and is subsequently diagnosed with CJD or a related TSE, a lookback may be considered (See Section 31.16). In this situation, an instrument which has come into contact with low infectivity tissue in the patient, and has been re-used ten or fewer times before diagnosis of the patient, should be taken out of circulation. If it has been re-used more than ten times before diagnosis, it may continue to be used.

31.15 Waste management, spills and linen

See Section 15 for guidelines on the collection and management of clinical and related waste.

HCWs should ensure there is adequate ventilation, avoid contact with eyes and mucous membranes and adhere to State/Territory OH&S requirements when working with toxic agents, such as sodium hydroxide or sodium hypochlorite.

Table 31.15 Categories of waste and recommended containment and disposal

Symbol	Waste	Container colour	Disposal
None	General	Black, buff, green, white	Landfill Consider recycling (Confidential waste to be shredded or incinerated)
	Clinical waste • Sharps • Nonsharps • Liquid	 Yellow, rigid container Yellow bag	Licensed contractor (for disposal by approved technologies) Incineration Incineration or validated steam–sterilisation then supervised landfill Sewer: local regulations should to be followed
	Cytotoxic	Purple	Licensed contractor Incineration: 1100°C
	Radioactive	Red	Licensed contractor Monitor before disposal by incineration or supervised landfill Dilute isotopes may be disposed of via sewerage system in accordance with relevant guidelines

Note: Any waste, contaminated or stored with another waste requiring a higher level of destruction should be classified at the higher level.

Source: NHMRC 1999

31.15.1 Spills

Spills of brain or CSF from a higher risk CJD patient on a bench top or the floor should be cleaned with sodium hydroxide according to the guidelines given in Table 31.14.1. Spills of blood, other body fluids and tissues from patients in either the lower or higher risk CJD categories should be cleaned using standard spills management procedures as described in Section 18.

31.15.2 Cleaning equipment (spills kit)

A sodium hydroxide spills kits (that includes OH&S recommendations) for higher risk CJD spills should be available in areas of increased risk, such as neurosurgery units, mortuaries and laboratories.

31.15.3 Collection and disposal of clinical and related wastes

Clinical and related wastes potentially contaminated with the infectious agent of CJD should be disposed of according to NHMRC procedures (see Table 31.15) and in accordance with best practice guidelines as prescribed under the laws, procedures, codes of practice or other regulatory provisions in force in the relevant State or Territory that are most consistent with these guidelines. See also Section 15.

31.15.4 Linen and laundry

Disposable linen and PPE should be used when neurosurgery, ophthalmological surgery or interventional neuroradiology is carried out on higher risk CJD patients. Used or contaminated linen should be disposed of by incineration. Re-useable linen and personal protective equipment contaminated with brain from higher or lower risk CJD patients should be disposed of by incineration.

Re-suable linen and PPE contaminated with blood, other body fluids or tissues should be laundered normally (see Section 19).

31.16 Surveillance and “lookback” investigations

State and Territory health authorities are responsible for the surveillance and control of all communicable diseases that affect the Australian population, including CJD. Nationally notifiable diseases and some selected non-notifiable infectious diseases of public health importance are regularly reported to the Commonwealth Department of Health and Ageing as part of the National Notifiable Diseases Surveillance Scheme (NNDSS). Although CJD is not currently a notifiable disease in Australia, health care establishments have a responsibility to contact local public health authorities or State/Territory Chief Health Officers directly about any incident related to possible

CJD exposure. Timely notification will be especially important if look-back studies are required and/or if the media is involved (see Section 21.5).

31.16.1 Australian National CJD Registry

The Commonwealth Department of Health and Ageing has established and funded the Australian National CJD Registry (Registry), based in the Department of Pathology at the University of Melbourne. The Registry assists the Department with the ongoing surveillance of CJD cases in Australia and identifies risk factors associated with CJD occurrence that affect population health. The Registry can also provide expert advice about management of infection control breaches and should be notified at the same time as public health authorities.

The Registry records the occurrence of CJD through regular contact with neurologists and anatomical pathologists. The registry also reviews death certificates and discharge diagnoses from hospitals. Upon notification of a suspected or confirmed CJD case, a registry neurologist, neuropathologist and research nurse assess the clinical and pathological information. The Registry contacts relatives of an individual with a confirmed case of CJD and request they complete a questionnaire designed to identify known or suspected risk factors. The contact details are:

Australian National CJD Registry
Department of Pathology
The University of Melbourne
PARKVILLE VIC 3052
Telephone: 03 8344 5868
Facsimile: 03 8344 4004
E-mail: ANCJD-REG@unimelb.edu.au

31.16.2 Lookback investigations

It is possible that patients or HCW may have been inadvertently exposed to CJD in the past, before the implementation of these guidelines, or that there may be future exposures resulting from infection control breach incidents. If such exposures are suspected by a medical practitioner or other HCW, or by a health care establishment, there is an ethical obligation to investigate the incident, to "lookback" and trace the individuals concerned, and to notify and counsel them about the level of risk and its potential implications. HCWs associated with suspected exposure incidents should also be informed.

The health care establishment, in consultation with the State or Territory Health Authority, is responsible for tracing individuals suspected of exposure to CJD.

Health care establishments should develop a "lookback" contingency plan that can be activated in the event that an exposure is suspected. The plan should allow for tracing of potentially exposed individuals, assessment of their potential exposure to risk and consider ethical and legal issues and counselling requirements. The contingency plan should also ensure that a lookback investigation is initiated only after the level of risk is fully assessed and the need for lookback warranted.

In determining the need for a lookback study, consideration should be given to the benefit of informing individuals of a hypothetical risk of CJD and their "right to know" against the real risk of psychiatric injury and their right "not to know" about the risk of developing a disease that has no treatment or cure. Psychiatric injury is well documented after notification of increased CJD risk among some recipients of human pituitary hormones (Allars, 1994). Because of the ethical and legal implications, every effort must be made by health authorities to protect the confidentiality of the individuals concerned and to avoid publicity and media involvement in the "lookback" unless it is strictly necessary to locate those affected.

The level of risk may be considered substantial where, for example, instruments contaminated with proven CJD-affected CNS tissues have been mistakenly re-used after inadequate cleaning and reprocessing. In contrast, the level of risk may be considered minimal or theoretical in situations, for example, where endoscopy equipment has been reprocessed and re-used many times after use on an individual who is retrospectively diagnosed as having had CJD at the time of their procedure.

Where a patient has undergone a procedure such as endoscopy or bronchoscopy where the instrument can not be adequately reprocessed for CJD, and the patient is subsequently diagnosed with CJD or a related TSE, lookback is not routinely indicated. This question should be considered on a case by case basis. A decision as to whether a lookback is to be undertaken should be made in accordance with the principles outlined in these Guidelines, and in compliance with the policies of the State or Territory health authority in which the procedure was performed. Issues to be considered in assessing the appropriateness of a lookback would include, for example; the invasiveness, and hence the relative risk of the procedure, the number of times the instrument has been reprocessed since it was used on the patient (and hence the extent of diminished risk to subsequent patients), the public health implications of not conducting a lookback, and the personal health benefits, or otherwise, of notifying patients possibly at risk.An important consideration will be the degree to which the establishment can identify those exposed to the risk. In some circumstances it may not be possible to identify those exposed by direct tracing and notification. In this circumstance, the use of a community announcement may be required for lookback. The establishment must also be responsible for remedying any situation that results in a breakdown of infection control procedures.

An important consideration will be the degree to which the establishment can identify those exposed to the risk. In some circumstances it may not be possible to identify those exposed by direct tracing and notification. In this circumstance, the use of a community announcement may be required for lookback. The establishment must also be responsible for remedying any situation that results in a breakdown of infection control procedures.

Any medical practitioner or organisation proposing to initiate a look-back investigation for CJD should in the first instance notify their regional health authority of the circumstances and proposed look-back method and obtain appropriate advice.

31.17 Blood and blood products for transfusion

31.17.1 Introduction

Scientific advances in testing and manufacturing have greatly decreased the infectious risk of blood. Blood donor medical examination and questioning have been mainstay practices of blood banking for many years. It should be recognised that blood today is safer than it has ever been with respect to infectious risks. Nevertheless, pressures brought about by public and political perceptions demand higher and higher safety levels. It is crucial that in pursuing very small reductions in risk from hypothetical risk factors such as vCJD the blood industry does not introduce additional risks. While vCJD is still a hypothetical and unquantifiable risk, HIV and hepatitis C are real risks with potentially lethal side effects from transfusion with infected blood.

31.17.2 TSE contamination

Accumulating epidemiological information and laboratory studies have indicated that transmission of the classical forms of the CJD infectious agent by blood products is highly unlikely. However, the emergence of vCJD has raised new concerns that are still under investigation at the time of preparing these guidelines.

31.17.3 Epidemiological evidence

Five published case–control studies have analysed over 600 cCJD cases. None of these studies showed that blood transfusion increased the risk for cCJD (Esmonde et al 1993b). Components from known CJD donors have not revealed transmission of the infectious agent (Heye et al, 1994; Evatt et al, 1998). However, the small number of recipients limits the value of these cohort studies. Because of the need for long-term follow-up, the value of these studies will continue to be limited unless there is a high transmission rate of the infectious agent (Wientjens et al, 1996; van Duijn et al, 1998).

31.17.4 Investigations of recipients of blood

National mortality surveillance performed by the United States of America (USA) Centers for Disease Control and Prevention (CDC) indicate that patient populations with increased exposure to blood or blood products are not at increased risk of cCJD (Holman et al, 1996). During an 18-year period (1979–96), 4468 cases of cCJD were reported to CDC. When death records were searched, none of these cases were reported to have had haemophilia, thalassemia, or sickle cell disease.

More directed evaluation of people with haemophilia have shown no link to CJD. In one study, brain tissue from 24 persons with haemophilia who died with neurologic disease was examined; none had evidence of CJD (Evatt et al, 1998). In a second study, brain tissue from 33 persons with haemophilia in the UK, who died of various causes, was examined, and none had evidence for CJD (Lee et al, 1998). Additional surveillance of cryoprecipitate recipients is under way in Seattle in the USA. In 1997, no CJD cases had been reported among 101 patients who together received over 238,000 units of cryoprecipitate between 1979 and 1985; 76 of these recipients are alive between 11.5 and 18.5 years later (CBER, 1999). Three of these recipients were known to have received at least one unit of cryoprecipitate from donors known to have developed CJD.

31.17.5 Laboratory studies

Whilst some laboratory experiments have demonstrated that the manufacturing processes significantly lowers the amount of the CJD infectious agent in plasma derivatives, others have shown that blood and plasma fractions from experimentally infected animals transmit CJD to recipient animals when directly injected into the brain but not through transfusion of blood (Brown et al 1994, 1998; Brown, 1995). In only a single case did transfusion of blood directly from an infected hamster transmit disease to a recipient animal (TSEAC, 1998).

31.17.6 Donor selection

Despite the evidence cited above, universal policies are in place to exclude donors at risk of developing CJD. This is done more on the basis that blood should be collected from healthy individuals than because of any perceived risk of CJD transmission by blood. ARCBS permanently defers donors with:

- a diagnosis or family history of two or more first degree relatives with TSE, including CJD, FFI and GSS;
- donors with possible exposure through treatment with cadaveric human hormones, including growth hormone and gonadotrophins prior to 1986;

- recipients of dura mater before 1990; and
- corneal graft recipients (ARCBS, 1998).

This is consistent with international practice. In the USA, the Food and Drug Administration (FDA) requires "indefinite" deferral of donors with a family history of CJD and individuals with a possible exposure through treatment with pituitary hormones, including growth hormone and gonadotrophins, and recipients of dura mater grafts (ARCBS, 1998). The European position permanently defers such individuals (Council of Europe 1995).

31.17.7 Plasma fractionation

Plasma derivatives are less likely to transmit cCJD in humans because:

- a cCJD-implicated plasma unit would be diluted into a large plasma pool, leading to a low number of infectious units in a dose of the final product;
- intravenous and intramuscular inoculation alone is less efficient than intra-cerebral inoculation for CJD transmission; and
- further processing of plasma pools by Cohn's fractionation and manufacturing processes such as column chromatography, precipitation and filtration, have been shown to diminish titres of CJD-like agents in spiking experiments using scaled-down manufacturing procedures (TSEAC transcript, December 1998).

31.17.8 Recall policies for CJD

In Australia, including a blood donation from a high-risk cCJD individual in a pool used for the manufacture of plasma products is not in itself grounds for a product recall. However fresh components should be recalled if the products are still "in-date".

In the USA the FDA's original policy required recall of both plasma products and fresh components (CBER, 1996). This was modified (CBER, 1998) to restrict plasma product recall to cases where a donor is diagnosed with vCJD (see below), but the recall provision for "in-date" fresh components was maintained. This mandatory recall of any fresh components is limited to "in-date" whole blood and "in-date" cellular products when a blood donor is identified as being at high risk of cCJD.

Modifying the policy for plasma products brought the FDA into line with European guidelines as stated by the European Medicines Evaluation Agency (EMEA), which has never required recall of plasma products because of CJD (CPMP, 1995). Given that the impact on the blood supply of such a recall is significantly less than a recall of plasma products, this policy is reasonable. Never the less, certain European

authorities have elected to recall plasma products when a donor at risk of CJD (or diagnosed with CJD) contributed to the pool, despite the EMEA policy.

ARCBS and most individual national health authorities in Europe follow a similar recall policy for fresh components. This recall policy is also reflected in WHO consensus statements.

31.17.9 Variant CJD

The risk of transmission of vCJD by blood or blood products has not been accurately determined although laboratory and epidemiological studies are currently under way to evaluate this risk. vCJD appears to be distinct from the classical forms of CJD in respect of its clinical presentation, histopathology and distribution of PrP^{Sc} in tissues. Therefore until more is known about the possibility of vCJD transmission by blood components or plasma derivatives, a conservative policy in respect of blood donation has been adopted by the Australian Commonwealth and State/Territory health departments as detailed below.

31.17.10 vCJD Donor policy

As vCJD has largely affected the United Kingdom, some countries have revised their blood donor policies to exclude donors who have resided in the United Kingdom for a cumulative period of six months or more.

In September 2000, Australian Commonwealth and State/Territory health ministers agreed to place a temporary ban on blood donations from people who have lived in the United Kingdom for more than six months between 1980 and 1996. Potential vCJD risks to the Australian community are continually monitored and reviewed by the SECTSE, established by the NHMRC.

31.17.11 vCJD Recall policies

In Australia, the TGA broadly follows current practice in Europe and USA as mandated through EMEA and FDA in respect to plasma products.

Both the FDA and the EMEA recall plasma products manufactured from a pool subsequently shown to include product donated from a patient diagnosed with vCJD (CBER, 1999: CPMP, 1998). This policy extends to excipients included in certain biological drugs.

In the case of fresh blood products, TGA follows a policy of recall for donations from both cCJD and vCJD donors.

31.18 Organs and tissues for transplantation

Organs and tissues are transplanted in several situations. Solid organs such as kidneys, livers and lungs are transplanted immediately after donor death, tissues such as corneas, heart valves and skin are stored in a tissue 'bank' prior to implantation, and materials are sometimes collected for the preparation of therapeutic or diagnostic products.

In all situations the following people should be excluded from the routine donation of organs and tissues:

- people in the higher and lower risk groups (see Section 31.9);
- people who die in psychiatric hospitals, with the exception of those in whom CJD has been specifically excluded; and
- people who die with any obscure undiagnosed neurological disorder, including dementia (AGMPSE, 1981; Lazarus, 1993).

Agencies that are responsible for recruiting organ/tissue donors, and for the banking of tissues (eg corneas, heart valves, skin) should be aware of the public health implications of CJD and should have exclusion criteria and procedures in place (Busch, 1997; Eastlund, 1995; Hogan, 1999; Lazarus, 1993).

When tissues are collected at autopsy for storage in a 'bank', the brain of the cadaveric donor should be assessed by a pathologist and the paraffin blocks archived for future reference. The stored tissue should not be transplanted until examination of the autopsy material has been completed.

Particular attention should be paid by Eye Banks that harvest corneas. These should be obtained using procedures that prevent contamination of the cornea from instruments that are used to remove the eye and hence have come into contact with optic nerve and/or retina.

Material from patient groups at risk of transmitting CJD and related TSEs should not be used for the preparation of any therapeutic products or laboratory reagents (eg thromboplastin or Kveim test material) (de Silva, 1993; du Bois, 1993).

31.19 Future issues relating to vCJD

These guidelines will also be published in an electronic form on the Department of Health and Ageing website. This facility will allow regular updates to be posted on scientific and technical developments relating to vCJD that affect infection control procedures. The NHMRC Special Expert Committee on TSEs (SECTSE) is currently

considering the implications of vCJD for infection control. Two of the major issues raised by vCJD that will be examined by SECTSE are the following:

- Diagnosing and testing people who may be infected with vCJD with tests that directly identify the CJD agent in tissues. The exact role of these tests in human and animal management will provide challenges that require resolution before widespread application.
- Minimising the risk of infection through surgical procedures and/or blood/tissue/organ donations.

31.19.1 Diagnosing and testing people who maybe infected with vCJD

The tissues, procedures and circumstances that present risks of transmitting vCJD between humans are not fully understood; it is particularly difficult to know how to protect against the possibility of transmission from someone who is incubating vCJD but has yet to develop symptoms. At present, a possible or probable diagnosis of vCJD may be made on the basis of western blot or immunohistochemical identification (or both) of PrP^{Sc} in tonsillar and/or other tissue together with documentation of specific neurological signs and symptoms. However, new diagnostic procedures may soon be available to identify people in the incubation stages preceding symptomatic presentation.

Until specific and sensitive diagnostic tests for prions are available and validated, the detection of vCJD must rely on clinical signs and symptoms, which can be uncertain in the early stages of any illness. If presymptomatic testing for vCJD becomes available in future years this will greatly simplify early diagnosis and disease tracking. However the availability of such sensitive tests would also pose important ethical questions which should be discussed with individuals as part of the information, consent and counselling procedures before such tests are ordered.

31.19.2 Minimising the risk of infection through surgical procedures and/or blood/tissue/organ donation

There are many instances that have been documented where contaminated instruments have transmitted CJD prions; hence the stringent recommendations for instruments used on patients in the risk categories for CJD. If blood, tonsils, lymph nodes and retina are also proved to be a source of infection for vCJD, then instrument sterilisation and reprocessing procedures will require revision (DH, 2001). These risks underscore the importance of effective instrument tracking systems.

Appendix 10 - State and Territory Chief Health and Medical Officer Contacts

Chief Health Officer – Australian Capital Territory	02 6205 5111 ☎
ACT Department of Health, Housing &	02 6205 1884
Locked Bag No 5	
WESTON CREEK ACT 2601	
Chief Medical Officer – Commonwealth of Australia	02 6289 8408☎
Department of Health and Ageing	02 6289 1994
GPO Box 9848, MDP 84	
CANBERRA ACT 2600	
Chief Health Officer – New South Wales	02 9391 9181 ☎
NSW Health Department	02 9391 9092
Locked Bag 961	
NORTH SYDNEY NSW	
Chief Medical Officer – New Zealand	0011 64 4 496 2336 ☎
New Zealand Ministry of Health	0015 64 4 496 2340
PO Box 5013 WELLINGTON	
NEW ZEALAND	
Chief Health Officer – Northern Territory	08 8999 2768 ☎
Territory Health Services	08 8999 2600
PO Box 40596	
CASUARINA NT 0810	
Chief Health Officer – Queensland	07 3234 1137 ☎
Queensland Health Department	03 3221 7535
GPO Box 48	
BRISBANE QLD 4001	
Chief Health Officer – South Australia	08 8226 6315 ☎
South Australian Department of Human Services	08 8226 6316
PO Box 6 Rundle Mall	
Chief Health Officer - Tasmania	03 6233 3297 ☎
Department of Health and Human Services	03 6233 9392
PO Box 125B	
HOBART TAS 7001	
Chief Health Officer - Victoria	03 9637 4200 ☎
Department of Human Services	03 9637 4250
GPO Box 1670N	
MELBOURNE VIC 3000	
ADELAIDE SA 5000	
Chief Health Officer – Western Australia	
Health Department of Western Australia	08 9222 4080 ☎
189 Royal street	08 9222 4014
EAST PERTH WA 6000	

Glossary

Term	Explanation
α-helices	One of the basic shapes of a protein, like a corkscrew.
β-sheets	One of the basic shapes of a protein, like a ribbon.
14-3-3 protein	A protein released from degenerating nerve cells, used as a non-specific marker for CJD.
Additional precautions	Precautions required when standard precautions may not be sufficient to prevent transmission of infection. These are used for patients known or suspected to be infected or colonised highly transmissible pathogens that can be transmitted by airborne, droplet or contact transmission, or for those patients suspected of being infectious for CJD. Additional precautions are designed to prevent transmission of infection by these agents and should be used in addition to *standard precautions* when transmission of infection might not be contained by using standard precautions alone (see Section 2.3). See also *Airborne transmission, Droplet transmission, Contact transmission, Creutzfeldt-Jakob disease.*
Airborne transmission	Transmission by air of infectious agents from respiratory secretions. See also Droplet transmission
Akinetic	Immobility, loss of all voluntary movement.
Allele	The basic unit of gene expression.
Amyloid plaques	Microscopic aggregates of the prion protein.
Amyloid-related diseases	Disorders associated with amyloid deposition .
Antibiotics	A subset of antimicrobial agents that include antibacterial agents.
Antimicrobial	A chemical agent that, on application to living tissue or by systemic administration, will selectively kill or prevent growth of susceptible organisms. This definition includes antibacterials, antiprotozoals, antifungals, antiseptics and disinfectants
Antisepsis	The prevention of infection by topical application of bacteriostatic agents to tissues.
Antiseptic	A substance that is recommended by its manufacturer for dermal application to kill microorganisms or to prevent the growth of microorganisms to a level that may cause clinical infection, and that is not represented to be suitable for internal use. [Ref: Therapeutic Goods Order 54, based on Therapeutic Goods Act and Regulations 1989]
Asepsis	The prevention of microbial contamination of living tissues or sterile materials by removal, exclusion or destruction of microorganisms.

Aseptic technique	Is one in which the instruments, the drapes and the gloved hands of the surgical team are sterile.
Astrocytes	Cells which support nerve cells.
Asymptomatic infection	Infection which does not display any clinical symptoms, but may still be capable of transmitting disease.
Ataxia	Uncoordinated voluntary movements.
Australian standard 4031	AS 4031 (1992) and Amendment 1 (1996): Non-reusable containers for the collection of sharp medical items used in health care areas.
Autonomic nervous system	Part of the peripheral nervous system controlling blood vessels and viscera; not normally under voluntary control.
Autosome	Any chromosome other than a sex chromosome; autosomes normally occur in pairs in somatic cells and singly in gametes.
Bacteriuria	The presence of bacteria in the urine with or without consequent urinary tract infection. Since bacteriuria is a clinical entity, the term does not preclude the use of urine/microbiology for technical discussions on the isolation and segregation of bacteria in the urine.
Beneficence	Beneficence is the obligation to maximise possible benefits and minimise possible harms. The obligation to do no harm is referred to separately as non-maleficence.
Biological indicator	A preparation of standardised bacterial spores on, or in, a carrier which is packaged in such a manner that the integrity of the inoculated carrier is maintained, and which is used to monitor a sterilising process.
Body substance	Includes any human bodily secretion, excluding sweat, or substance other than blood.
Bovine spongiform encephalopathy (BSE)	Also known as ‘mad cow disease’, a new form of TSE which emerged in the UK in 1986.
C-terminus	The carboxyl end of the amino acid chain of a protein.
Chemical indicator	Dye which can be impregnated into materials or contained within a device, and which changes colour when subjected to a sterilising process.
Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning physically removes rather than inactivates microorganisms. Cleaning is accomplished with water, detergents and mechanical action. Cleaning must precede disinfection and sterilisation.
Clinical contact	All health care workers (HCWs) who have clinical contact with patients.

Clinical pathways	Predefined sets of provider interventions that should be achieved in a certain time frame and address a particular diagnosis, patient problem, or procedure.
Clinical waste	Includes discarded sharps, laboratory and associated waste directly associated with specimen processing, human tissues, including material or solutions containing free-flowing blood, and animal tissue or carcases used in research. See also Related waste, General waste.
Codon	A basic unit of the gene (three nucleotide base sequence) of DNA which encodes a particular amino acid.
Cohort management	Management of a group of individuals infected with the same infectious agent in the same place (eg MRSA infected patients managed in one ward).
Contact transmission	Transmission of infectious agents by person-to person contact.
Contamination	The introduction of microorganisms or foreign matter (or both) to sterile or nonsterile materials or living tissue [Reference: AS 4187].
Creutzfeldt-Jakob disease (CJD)	A progressive neurologic disorder, one of the subacute TSEs caused by prions. Clinical features of CJD include a progressive cerebellar syndrome, including ataxia, abnormalities of gait and speech, and dementia.
Critical site	Entry or penetrations into sterile tissue, cavity or bloodstream. The instruments used must be sterile.
Decontamination	The removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue.
Directed therapy	Antimicrobial therapy selected on the basis of culture and susceptibility testing (laboratory culture or other molecular tests) of the infectious agent. Often, a narrow-spectrum agent specific for the organism can be used.
Disinfectant	A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms; and that is not represented by the manufacturer to be suitable for internal use.
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. See High-level disinfection, Thermal disinfection, High-level disinfectant, Intermediate-level disinfectant and Low-level disinfectant.
DNA	Deoxyribonucleic acid.
Dominant gene mutation	Expressed even when the other allele is “normal”.
Droplet transmission	Transmission of infectious agents in droplets from respiratory secretions. See also Airborne transmission.
Dysaesthesia	Abnormal sensations, such as “pins and needles” in fingers.

Endocrine	The hormonal system of cellular communication.
Eosinophilic	Red colour in tissue sections stained with eosin dye.
Exposure-prone procedures	A subset of 'invasive procedures' characterised by the potential for direct contact between the skin (usually finger or thumb) of the health care worker (HCW) and sharp surgical instruments, needles, or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, and for the purpose of these guidelines, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of bloodborne disease from HCW to patient during medical or dental procedures. See also *Invasive Procedures*.
Fatal familial insomnia (FFI)	Fatal familial insomnia is a rapidly progressive TSE characterised by refractory insomnia, with autonomic and endocrine dysfunction. It is a genetic disorder with an autosomal dominant pattern of inheritance.
General waste	Includes other wastes that do not fall into the categories of clinical or related wastes. This forms the bulk of waste generated by health care establishments and is not more of a public health risk than domestic or household waste. See also *Clinical waste*.
Gerstmann–Sträussler–Scheinker disease (GSS)	GSS is a TSE characterised by ataxia in the early stages and which has a much longer clinical course than CJD. Dementia and myoclonus may be absent or minimal. It is a genetic disorder with an autosomal dominant pattern of inheritance.
Gliosis	Proliferation of astrocytes in response to brain injury.
Gravity displacement steam sterilisers	Steam sterilisers designed for general decontamination and sterilisation of solutions and instruments. They function by displacing air with steam, via a port in the bottom of the chamber. See also Porous load steam sterilisers.
Haemovigilance	A surveillance system for monitoring and analysing transfusion hazards of blood and plasma products in order to improve the safety of the transfusion process.
Hazard	An agent (biological, chemical or physical) that has the potential to cause harm.
Health care associated (iatrogenic) infection (HAI)	Denoting response to medical or surgical treatment, induced by the treatment itself; usually used for unfavourable responses. Previously referred to as iatrogenic.
Health care environment	Includes all environmental surfaces, including furnishings and fittings, and supplied services such as air and water. Other fixed services such as piped gases should also be considered part of the environment.
Health care establishment	The institutional/organisation responsible for health care delivery.

Health care establishments	The various centres that are delivering health care services on a commercial or public health basis (eg hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health providers, and other community services such as needle exchanges).
Health care setting	Refers to the setting within which health care is provided (eg acute care, long-term care, office practice, community care). See *Health care establishments* and *Office practice*.
Health care workers	Refers to all health care professionals, including students and trainees, and employees of health care establishments who have contact with patients or with blood or body substances from patients.
High infectivity	Relates to the predicted infectivity of human tissues and fluids for CJD. High infectivity sites are those sites demonstrated to be consistently infectious. See Table 6.1.
High-level disinfectant	A disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores, when used as recommended by its manufacturer. The specified exposure time is generally shorter than the time required to achieve sterilisation with the same formulation. High-level disinfectants used in Australia must comply with Therapeutic Goods Order Number 54 — *Standard for Composition, Packaging, Labelling and Performance of Disinfectants and Sterilants*.
High-level disinfection	The minimum treatment recommended for reprocessing a device or item of equipment for use in a semicritical site, if it cannot be sterilised.
Holding time	For sterilisation by steam under pressure or by dry heat, the holding time is the minimum time for which the load must be held at the selected sterilising temperature.
Homozygosity	Having identical genes at one or more loci.
Hydrolyse	Chemical or enzymatic cleavage of proteins into amino acids.
Iatrogenic infection	See: Health care associated infection
Immunoassays	Using immunologic techniques for measuring proteins.
Immunocompromised patients	People whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or radiation.
Incubation period	The time that elapses between infection and the appearance of symptoms of a disease.
Indwelling devices	Medical devices which remain insitu in the body, such as intravascular catheters or urethral catheters.
Information Privacy Principles	Standards established under the Privacy Act 1988, for the handling of personal information collected by Commonwealth and ACT public sector agencies.

Informed and voluntary consent	A voluntary decision is one made without undue pressure, without coercion, force or persuasion against one's will.
Intermediate-level disinfectant	A disinfectant that kills all microbial pathogens except bacterial endoscopes, when used as recommended by the manufacturer. It is bactericidal, tuberculocidal, fungicidal against asexual spores but not necessary dried chlamydospores or sexual spores), and virucidal.
Invasive procedure	Any procedure that pierces skin or mucus membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities, or organs or repair of traumatic injuries. See also Exposure-prone procedures.
Isoform	Identical or closely related forms of protein variants.
Kuru	A TSE that occurred as an epidemic in the Fore people of the Eastern Highlands of Papua New Guinea.
Latent infection	Infection which is not clinically apparent or is hidden. See also Asymptomatic.
Lookback investigation	The process of identifying, tracing, recalling, counselling and testing patients or HCWs who may have been exposed to an infection, usually a bloodborne virus, due to a breakdown in infection control procedure or protocols.
Low infectivity	Relates to the predicted infectivity of human tissues and fluids for CJD. Low infectivity sites are those sites demonstrated to be infectious, but not consistently. See Table 6.1.
Low-level disinfectant	A disinfectant that rapidly kills most vegetative bacteria as well as medium sized lipid containing viruses, when used according to labelling. It cannot be relied upon to destroy, within a practical period, bacterial endospores, mycobacteria, fungi or all small nonlipid viruses.
Macromolecule	A large molecule - protein or other.
Medical device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of: • diagnosis, prevention, monitoring, treatment or alleviation of disease; • diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap; • investigation, replacement or modification of the anatomy or of a physiological process; • control of conception. and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Microglia	Brain cells that react to injury.
Mutism	Speechless, inability to speak voluntarily.

Myoclonus	Abnormal jerking movements of muscles.
NaOH	Sodium hydroxide, caustic soda.
National Privacy Principles	Standards established under the Privacy Act 1988, for the handling of personal information collected by private sector organisations.
Needle exchange	Program for the exchange of needles/syringes to reduce the risk of BBV infection associated with sharing needles/syringes, most often community-based.
Needlestick injury	Percutaneous injury with any sharps designed for use in health care that may potentially transmit infectious agents, and in particular blood borne viruses. Sharps may or may not have been used on a patient. See Sharps.
Negative pressure	Used to denote airflow which is negative in relation to surrounding air pressure, that is, air flows away from the surrounding area. Usually created by mechanical airflow devices (eg exhaust fans).
Neuronal dendrites	Fine branches of nerve cells that receive incoming signals.
Neutropenic patients	A patient who has a very low neutrophil white cell count in the blood and is at high risk of bacterial infection.
Non-maleficence	See Beneficence.
Nonclinical contact	HCWs who do not have clinical contact with patients.
Noncritical site	Body site with intact skin. Instruments should be cleaned and disinfected if necessary.
Nosocomial infections	Infections that occur as a result of being in a health care establishment, strictly a hospital, but term now used more generally refer to any health care settings where infection can be spread from person to person. See also *health care associated infections*.
Notifiable disease	Disease or condition which is notifiable to State/Territory health department by legislation
Nucleic acids	The building blocks of genes.
Occupationally-acquired infection	Infection which was acquired as a result of an injury or exposure that was work related.
Office practice	The provision of health care services in sites outside routine hospital in-patient and operating theatre settings; such sites include private consulting rooms, health clinics, including mobile health clinics, ambulatory day care centres and outpatient departments. See also *Health Care Establishments*.
Pasteurisation	In the context of this guideline, a thermal disinfection process using hot water at a temperature of 75?C for a contact time of at least 30 minutes.

Patient	Includes (but is not limited to) a person who is accessing medical or health services, or who is undergoing any medical or health care procedure.
Pedigree	Used in genetics to analyse inheritance.
Penetration time	For sterilisation by steam under pressure or by dry heat, is the time required for every part of a load to reach the selected sterilising temperature after that temperature has been reached in the sterilising chamber.
Percutaneous	Through the skin, as in an injection or piercing.
Porous load steam sterilisers	Steam sterilisers optimised for sterilisation of clean instruments, gowns, drapes, towelling and other dry materials required for surgery. In PL steam sterilisers air is exhausted by a mechanical pump, which creates a vacuum that is replaced by steam. They are not suitable for liquid sterilisation. See also *Gravity displacement steam sterilisers*.
Prion	The small proteinaceous infectious unit that appears to cause TSEs.
Privacy Principles	See 'Information Privacy Principles' and 'National Privacy Principles'.
PrPc	The normal isoform of the prion protein.
PrPsc	The abnormal isoform of the prion protein which is central to the causation of scrapie, other abnormal isoforms cause other TSEs.
Pyramidal/extra pyramidal dysfunction	Disease of motor tracts in brain and spinal cord lead to defective or abnormal movements.
Recessive genetic mutation	Only expressed when present on both loci in the same individual.
Related waste	Related waste includes cytotoxic waste, pharmaceutical waste, chemical waste and radioactive waste. See also Clinical waste, General waste
Reprocessing	All steps necessary to make a contaminate reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation. [References: AS/ANZ 4815 and AS 4187].
Respiratory isolation room	A single room with an ensuite and engineered such that the interior of the room can be made to be at a negative pressure with respect to the corridor, and that air from the room is not recirculated into other areas within the facility.
Reusable item	An item designated or intended by the manufacturer as suitable for reprocessing and reuse. It is not a device that is designated or intended by the manufacturer for single use only.

Risk analysis	A process for assessing the risk posed by an identified hazard, managing (minimising) the risk and communicating risk information to all stakeholders (includes risk assessment, risk management and risk communication).
Semicritical site	Contact with intact mucosa or nonintact skin. Instruments should be sterilised where possible, or high-level disinfected.
Sharps	Any objects capable of inflicting penetrating injury, and includes needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.
Single rooms	Rooms for accommodation of one patient only. May or may not have adjacent ensuite bathroom.
Single-use equipment	Equipment designated by the manufacturer for single use or single patient use only.
Skin disinfectant	An antiseptic that is intended for application to intact, healthy skin to prevent the transmission of transient or resident skin bacteria from person to person or from a surgical operation site to underlying tissue. Skin disinfectants include antimicrobial and antiseptic soaps, hygienic handwashes, hygienic hand rubs, surgical hand rubs and surgical handwashes.
Soil	Visible dirt or debris that may protect, harbour or assist the growth of microorganisms. Includes organic matter, organic substances, residual soil, inorganic matter, blood and body substances.
Standard precautions	Are work practices required for the basic level of infection control. Standard precautions are recommended for the treatment and care of all patients, and apply to all body fluids, secretions and excretions (excluding sweat), regardless of whether they contain visible blood (including dried body substances such as dried blood or saliva), nonintact skin and mucous membranes. Standard precautions include good hygiene practices, particularly washing and drying hands before and after patient contact, use of protective barriers which include gloves, gowns, plastic aprons, masks eye shields or goggles, and appropriate handling and disposal of sharps and other contaminated or infectious waste and the use of aseptic technique. See also *Additional precautions*.
Sterilant	A chemical agent, other than a gas, which is used to sterilise critical medical devices.
Sterile operating field	An area specifically designed to be free from microorganisms, as used for performing invasive procedures (see *also Asepsis, Aseptic technique*).
Sterilisation	Complete destruction of all microorganisms, including spores.
Sterilisation time	The total time of the sterilisation stage after the sterilising chamber has reached the sterilising temperature (penetration time plus holding time).

Sterility assurance level	The acceptable sterility assurance level (SAL) for a terminally sterilised product is one in a million or 10-6. This means that of a million products being sterilised by the same method you may statistically expect one to be unsterile.
Therapeutic devices	Medical devices used for the purpose of treatment or medical therapy; specifically, for the purpose of this document, devices that may be left indwelling and may provide an infectious hazard.
Thermal disinfection	Disinfection achieved by the action of moist or dry heat. [Reference: prEN ISO 15883-1:1999].
Transmissible spongiform encephalopathies (TSEs)	TSEs are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans.
Triphasic	Characteristic shape of brain waves (EEG) in CJD.
Universal precautions	Previously applied to work practices which require everyone to assume that all blood and body substances are potential sources of infection, independent of perceived risk. The terms 'standard precautions' and 'additional precautions' are used in these guidelines, replacing the term 'universal precautions'. See *Standard precautions*.
Vacuoles	Microscopic spaces or holes in nerve cells, which are characteristic features of the TSEs.
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications (Note: validation broadly encompasses three activities — commissioning, verification of a process specification and performance qualification.). [Reference: AS 4187 and AS/ANZ 4815].
Window period	The period immediately after a person is infected with an agent, during which the infection is not detectable by laboratory tests, although the person may be infectious. See also *Asymptomatic*.

Abbreviations and acronyms

ACHS	Australian Council on HealthCare Standards
AFB	acid fast bacilli
AGAR	Australian Group on Antibiotic Resistance
AGMPSE	Advisory Group on the Management of Patients with Spongiform Encephalopathy (UK).
AHMAC	Australian Health Ministers Advisory Council
AICA	Australian Infection Control Association
AIDS	acquired immune deficiency syndrome
AMA	Australian Medical Association
ANCA	Australian National Council on AIDS
ANCAHRD	Australian National Council on AIDS, Hepatitis C and Related Diseases.
ANCJDR	Australian National CJD Registry.
ANZCA	Australian and New Zealand College of Anaesthetists
ANZFA	Australia New Zealand Food Authority
ANZFA	Australia New Zealand Food Authority.
APIC	American Practitioners in Infection Control and Epidemiology
AQIS	Australian Quarantine and Inspection Service.
ARCBS	Australian Red Cross Blood Service
ARCBS	Australian Red Cross Blood Service.
ARTG	Australian Register of Therapeutic Goods
AS	Australian Standard
AS	Australian Standards
AS/NZS	Australian Standard/New Zealand Standard
ASA	Australian Society of Anaesthetists
AUST L	medicines or devices listed on the ARTG
AUST R	medicines or devices registered on the ARTG
AZT	azidothymidine
BCG	Bacille Calmette-Guerin (vaccine)
BSE	bovine spongiform encephalopathy
BSE	Bovine spongiform encephalopathy.

BSI	bloodstream infection
CAUTI	catheter-associated urinary tract infections
CBER	Centre for Biologics Evaluation and Research.
cCJD	Classical Creutzfeldt-Jakob disease.
CDC	Centers for Disease Control and Prevention (United States)
CDC	Centers for Disease Control and Prevention.
CDNA	Communicable Diseases Network Australia
CDNANZ	Communicable Diseases Network Australia New Zealand (now known as CDNA)
CEN	European Committee on Standardization (Comité Européen de Normalisation)
CFU	colony forming units
CHCI	Committee on Health Care Issues (United States)
CHEC	Canadian Hospital Epidemiologist Committee
CJD	Creutzfeldt-Jakob disease.
CMV	cytomegalovirus
CNISP	Canadian Nosocomial Infection Surveillance Program
CNS	Central nervous system.
CPMP	Committee for Proprietary Medicinal Productions
CPMP	Committee for Proprietary Medicinal Productions.
CQO	chief quarantine officer.
CSF	cerebrospinal fluid
CSF	Cerebrospinal fluid.
CSS	central sterile supply.
CT	Computerised tomography.
CVC	central venous catheter
ddC	dideoxycytidine
ddI	dideoxyinosine
DH	Department of Health (UK).
DHAC	Department of Health and Aged Care.
DHA	Department of Health and Ageing.
DHSS	Department of Health and Social Security (UK).
DNA	dexoyribonucleic acid
EBV	Epstein Barr virus
EEG	electroencephalograph

ELISA	enzyme-linked immunosorbent assay
EMEA	European Medicines Evaluation Agency
EMG	Electromyography.
EO	ethylene oxide
ERCP	endoscopic retrograde cholangiopancreatography
ESBL	extended spectrum beta-lactamase producing bacteria
FDA	Food and Drug Administration (United States)
FDA	Food and Drug Administration (USA).
FFI	fatal familial insomnia
FFI	Fatal familial insomnia.
FFP	fresh frozen plasma
FSE	Feline Spongiform Encephalopathy.
GENCA	Gastroenterological Nurses College of Australia
GENSA	Gastroenterological Nurses Society of Australia (Pre – 2001)
GESA	Gastroenterological Society of Australia
GSS	Gerstmann–Sträussler–Scheinker disease.
GMP	Good Manufacturing Practice
HACCP	hazards analysis critical control points
HAV	hepatitis A virus
HBcAb	HBV core antibody
HBeAg	HB ‘e’ antigen
HBIG	HBV immunoglobulin
HBsAg	HBV surface antigen
HBV	hepatitis B virus
CTARC	Clinical Trials and Research Committee (ANCAHRD working group)
HCV	hepatitis C virus
HCVAb	hepatitis C virus antibody
HCW	health care workers
HEPA	high-efficiency particle arrest
HICPAC	Hospital Infection Control Practices Advisory Committee (USA)
HIV	Human immunodeficiency virus.
HPP	hydrogen peroxide plasma
HSV	herpes simplex virus (HSV1 an HSV2)

ICG	Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting (a publication of CDNA).
ICGSC	Infection Control Guidelines Review Steering Committee
ICP	infection control practitioner
IgG/IgM	Immunoglobulins
ISO	International Organization for Standardization
IV	Intravenous
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
LCBI	laboratory confirmed bloodstream infection
LTCE	long-term care establishment
MB	methylene blue
MDR-TB	multidrug-resistant tuberculosis
MMR	measles-mumps-rubella (vaccine)
MRI	Magnetic resonance imaging.
MRSA	methicillin-resistant Staphylococcus aureus
MSDS	material safety data sheets
NARSP	National Antimicrobial Resistance Surveillance Program
NAT	nucleic acid amplification testing
NATA	National Association of Testing Authorities
NCDC	National Centre for Disease Control
NCHECR	National Centre in HIV Epidemiology and Research
NEHF	National Environmental Health Forum
NHMRC	National Health and Medical Research Council
NIGH	normal immunoglobulin (human)
NINSS	Nosocomial Infection National Surveillance Scheme (UK)
NNDSS	National Notifiable Diseases Surveillance Scheme.
NNIS	National Nosocomial Infection Surveillance Service (USA)
NOHSC	National Occupational Health and Safety Commission (USA)
OH&S	Occupational health and safety.
PAA	peracetic acid
PCR	polymerase chain reaction
PEP	postexposure prophylaxis
PHMB	polyhexamethylene biguanide

PPE	Personal protective equipment.
PRNP	Prion protein gene
PrP	Prion protein.
RACS	Royal Australasian College of Surgeons
RCPA	Royal College of Pathologists of Australasia
RSV	respiratory syncytial virus
SD	solvent detergent
SEAC	Spongiform Encephalopathy Advisory Committee (UK)
SECTSE	Special Expert Committee on Transmissible Spongiform Encephalopathies (NHMRC)
SHOT	Serious Hazards of Transfusion Scheme (UK)
SSI	surgical site infection
SSU	sterilisation service/supply unit
TB	Tuberculosis
Td	adsorbed diphtheria tetanus vaccine - adult formulation (Td)
TGA	Theraeutic Goods Administration
TGA	Therapeutic Goods Administration (Australia).
TIG	tetanus immunoglobulin
TSANZ	Transplantation Society of Australia and New Zealand
TSE	transmissible spongiform encephalopathy
TSEAC	Transmissible Spongiform Encephalopathies Advisory Committee (USA).
TSN	The Surveillance Network
vCJD	variant Creutzfeldt–Jakob disease
VHF	viral haemorrhagic fever
VRE	vancomycin-resistant enterococci
VZV	varicella-zoster virus (chickenpox and shingles)
WHO	World Health Organization
ZDV	Zidovudine
ZIG	varicella-zoster immunoglobulin

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