

# *Infection prevention and control standards*

**For general practices and other office-based  
and community-based practices**

5th edition



## Infection prevention and control standards for general practices and other office-based and community-based practices (5th edition)

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The Royal Australian College of General Practitioners  
100 Wellington Parade  
East Melbourne VIC 3002 Australia

T 03 8699 0414  
F 03 8699 0400  
[www.racgp.org.au](http://www.racgp.org.au)

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*We recognise the traditional custodians of the land and sea on which we work and live.*



RACGP

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## *Acknowledgements*

This is the fifth edition of the RACGP *Infection prevention and control standards for general practices and other office-based and community-based practices*.

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## Acronyms

ADT	adult diphtheria and tetanus
CAMRSA	community-acquired methicillin resistant <i>Staphylococcus aureus</i>
dTpa	diphtheria, tetanus and pertussis
EPPs	exposure-prone procedures
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
MERS	Middle East respiratory syndrome
MMR	measles, mumps and rubella
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
MSDS	material safety data sheets
PCD	process challenge device
PEP	post-exposure prophylaxis
PPE	personal protective equipment
RSV	respiratory syncytial virus
SARS	severe acute respiratory syndrome
VRE	vancomycin resistant enterococci

# Contents

<i>Acknowledgements</i>	<i>iii</i>
<i>Acronyms</i>	<i>iv</i>
<i>Introduction</i>	<i>1</i>
<i>Chapter 1. Infection prevention and control principles</i>	<i>3</i>
Section 1.1. Infection prevention and control and the practice team	3
Table 1.1. Example risk matrix	4
Section 1.2. How microorganisms are acquired and grow	6
Section 1.3. Hand hygiene	8
Table 1.2. Methods of hand hygiene	9
Section 1.4. Precautions	14
Table 1.3. Use of personal protective equipment for transmission-based precautions	17
Section 1.5. Personal protective equipment	19
<i>Chapter 2. Protecting the health of staff</i>	<i>24</i>
Section 2.1. Staff immunisation	24
Section 2.2. Safe sharps management	28
Box 2.1. Safe sharps management	29
Section 2.3. Managing blood and body fluid exposure	31
Table 2.1 Summary of actions relating to blood and body fluid exposure	33
<i>Chapter 3. Managing the practice physical environment</i>	<i>34</i>
Section 3.1. Cleaning policy for the practice	34
Table 3.1. Example of cleaning schedule	38
Section 3.2. Managing blood and body fluid spills	39
Section 3.3. Linen	41
Section 3.4. Waste management	43
<i>Chapter 4. Processing reusable equipment</i>	<i>46</i>
Section 4.1. Risk assessment and processing reusable equipment	46
Table 4.1. The Spaulding classification	46
Section 4.2. Staff training	47
Section 4.3. The sterilisation process	48
Section 4.4. Equipment processing area	49
Figure 4.1 Suggested processing area design and layout	50
Section 4.5. Reprocessing equipment	51
Table 4.2. Time-temperature relationship for thermal disinfection	52
Section 4.6. Cleaning reusable medical devices	57
Section 4.7. Sterile barrier systems (packaging) for sterilisation	61

Section 4.8. Loading the steriliser	64
Section 4.9. Sterilisation cycle parameters	66
Table 4.3. Recommended temperature, pressure and holding times in a steam steriliser	67
Section 4.10. Monitoring the sterilisation cycle	68
Table 4.4. Types of chemical indicators and their use	72
Section 4.11. Unloading the steriliser	73
Section 4.12. Storing sterile stock	74
Section 4.13. Documenting the cycle	75
Section 4.14. Steriliser maintenance	76
Section 4.15. Validating the sterilisation process	78
Section 4.16. Dry heat sterilisers	81
Section 4.17. Instrument disinfection	82
Section 4.18. Tracking reusable medical devices and patient tracing	83
Section 4.19. Single-use items	84
Section 4.20. Offsite sterilisation	86
Section 4.21. Sterile equipment used outside the practice	88
<i>Chapter 5. Disease surveillance</i>	<i>89</i>
Section 5.1. Disease surveillance	89
Section 5.2. Reception and triage	91
<i>Appendix 1. Staff task competency records</i>	<i>94</i>
<i>Appendix 2. State and territory health department communicable disease contacts</i>	<i>96</i>
<i>Appendix 3. Transmissible diseases and precautions</i>	<i>97</i>
<i>Appendix 4. Skin disinfection</i>	<i>99</i>
Table A4.1 Products suitable for skin disinfection	99
<i>Appendix 5. Staff immunisation record (example)</i>	<i>100</i>
<i>Appendix 6. Immediate action following blood and body fluid exposure</i>	<i>101</i>
Table A6.1. Classification of exposure to blood and body fluids	103
<i>Appendix 7. Infection prevention and control kit</i>	<i>105</i>
<i>Appendix 8. Processing reusable equipment</i>	<i>106</i>
<i>Appendix 9. Choosing a steriliser</i>	<i>108</i>
<i>Appendix 10. Steriliser/maintenance logbook (examples)</i>	<i>110</i>
<i>Appendix 11. Simple first validation template</i>	<i>111</i>

Table A11.1. Validation certificate	115
Table A11.2. Challenge pack (examples)	116
Table A11.3. Penetration and drying time (example)	116
Table A11.4. Heat distribution (example)	117
Table A11.5. Processing time (example)	117
Table A11.6. Results of physical and microbiological checking (example)	117
Figure A11.1. Chamber loading details and position of biological indicators	118
<i>Appendix 12. Complex validation template where validation has been performed previously</i>	<i>119</i>
Table A12.1. Validation certificate	124
Table A12.2. Challenge packs (examples)	125
Table A12.3. Challenge loads: contents and loading details (examples)	126
Table A12.4. Penetration and drying time (examples)	126
Table A12.5. Heat distribution (example)	126
Table A12.6. Challenge load setting (examples)	127
Table A12.7. Results of physical and microbiological checking (examples)	128
Figure A12.1. Chamber loading details and position of biological indicators	128
<i>Appendix 13. Infection prevention and control and risk management</i>	<i>129</i>
Table A13.1. Risk analysis scoring system	131
Box A13.1 Risk analysis scoring (examples)	132
Box A13.2. Risk evaluation matrix	133
Box A13.3. Worked example of a practice's risk evaluation matrix	133
<i>Appendix 14. Community-acquired methicillin resistant Staphylococcus aureus</i>	<i>135</i>
<i>Glossary</i>	<i>137</i>
<i>Resources</i>	<i>141</i>



## Introduction

In many respects, the principles of infection prevention and control (eg hand hygiene) and standard and transmission-based precautions are constant across the health sector. However, the translation of hospital policies and procedures to general practices and other office- and community-based practice settings is often not appropriate due to differing risks, equipment and staff factors.

The RACGP *Infection prevention and control standards for general practices and other office-based and community-based practices* recognises the increasing need for a broader guide to infection prevention and control for use not just in general practice, but in the varied settings of clinical practice outside the hospital setting. This edition may be useful for consultants, physiotherapists, occupational therapists and practitioners who operate outside a formal establishment, such as those providing outreach and home visit services.

High levels of evidence – such as systematic reviews, randomised controlled trials or nonrandomised studies – relating to most areas of infection prevention and control in primary care are generally not available. Most evidence quoted in this manual is Level IV evidence, which includes descriptive studies, expert opinion and the reports of experts. Where higher levels of evidence are available, the source is given in the text.

The sources of evidence include:

- the National Health and Medical Research Council *Australian guidelines for the prevention and control of infection in healthcare* (2010)
- AS/NZS 4187:2003 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*
- AS/NZS 4815:2006 *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*.

In addition, experts in the fields of infectious diseases, microbiology and infection prevention and control have reviewed this edition as well as doctors, practice nurses, practice managers and accreditation surveyors.

### An important note on terms

The wording of this document is reflective of the level of evidence used. Wording includes **must**, **need(s) to**, **should** and **may**.

- Where the word **must** is used, there is strong documentary evidence of a risk of harm to patients if the direction is not followed. Where **need(s) to** is used, there is a risk of harm to patients or staff if the direction is not followed. Essentially, where **must** or **need(s) to** is used, the direction is considered to be a requirement.
- Where the word **should** is used, this indicates what is thought to be best practice by experts in the primary care field and is a recommendation.
- Where the word **may** is used, there is more scope for the practice to consider alternatives to what is suggested.

This edition recognises that healthcare is increasingly being delivered by teams that include doctors, practice nurses and other health professionals, and that many practice staff have a responsibility for infection prevention and control in the practice, the terminology for this edition includes all those with a responsibility for implementing infection prevention and control processes.

This edition focuses strongly on risk analysis and management. Practices differ greatly in their day-to-day function; it is not possible to write a 'one size fits all' rulebook for infection prevention and control for all general practices and other office- and community-based practices. Practices need to be able to determine risk in their own context and decide on the appropriate course of action. It is vital to ensure that practices regularly conduct infection prevention and control risk assessments within their facilities and that all staff understand their responsibilities in managing these risks. This edition emphasises the need for a staff member to have designated responsibility for the various facets of infection prevention and control.

It is essential that staff are educated and competent in relation to effective infection prevention and control. This edition includes information on staff education and induction relating to infection prevention and control, and competency checking.

The codified responsibility of employers in respect of duty of care in providing a safe working environment highlights the requirements for personal protective equipment, hand cleaning and immunisation against vaccine-preventable diseases.

This edition includes a section on disease surveillance. Emerging health issues that may impact general practices and other office- and community-based practices include pandemic influenza, severe acute respiratory syndrome (SARS), avian influenza, community acquired methicillin-resistant *Staphylococcus aureus* (CAMRSA) and bioterrorism threats such as anthrax.

This edition is organised into the following chapters:

- Chapter 1. Infection prevention and control principles
- Chapter 2. Protecting the health of staff
- Chapter 3. Managing the practice physical environment
- Chapter 4. Processing reusable equipment
- Chapter 5. Disease surveillance.

The appendices provide useful templates and resources to assist practices in implementing effective infection prevention and control strategies.

## Chapter 1. Infection prevention and control principles

### Section 1.1. Infection prevention and control and the practice team

Employers and managers have a responsibility under work health and safety laws to protect their staff from injury at work.

All members of the practice team need to be educated about their role in preventing the spread of infection. Education includes teaching the principles of infection prevention and control, checking competency (where a person competent to check observes others), and performing ongoing auditing and education of staff.

Practice team member education and competency should be recorded.

All members of the practice team are involved in the practice's infection prevention and control program.

Each practice needs to appoint an infection prevention and control coordinator. This practice team member has the primary responsibility for overseeing a comprehensive infection prevention and control program. Their duties include:

- assessing the risks of infection transmission throughout the practice
- drafting and finalising infection prevention and control policies and protocols for the practice
- regularly reviewing the infection prevention and control protocols
- organising training and education for the entire practice team about infection prevention and control protocols
- monitoring compliance with practice infection prevention and control protocols
- educating patients on infection prevention and control activities
- monitoring patients' infection prevention and control activities
- ensuring the cleaner complies with the practice infection prevention and control protocols.

### Risk assessment

Each practice will need to perform regular infection prevention and control risk assessments (ie identify risks and estimate the likelihood of infection and the consequences if it occurs). A risk matrix can be used to calculate risk level of various situations and events (*Table 1.1*). Risks are then managed through education, training and redesign of work practices.

Table 1.1. Example risk matrix

Likelihood	Consequences				
	Negligible	Minor	Moderate	Major	Extreme
Rare	Low	Low	Low	Medium	High
Unlikely	Low	Medium	Medium	High	Very high
Possible	Low	Medium	High	Very high	Very high
Likely	Medium	High	Very high	Very high	Extreme
Almost certain	Medium	Very high	Very high	Extreme	Extreme
Low risk	Manage by routine procedures				
Medium risk	Manage by specific monitoring or audit procedures				
High risk / Very high risk / Extreme risk	This is serious and must be addressed immediately				

## Education and training

Education of all members of the practice team is crucial to effective infection prevention and control. Education and training should be relevant to the duties performed by the team member, their prior knowledge and the individual practice's risks. All members of the practice team must know who is responsible for ensuring certain activities (eg environmental cleaning) are carried out.

Education should enable staff to understand the various infectious agents, their modes of transmission, appropriate work practices for infection prevention and control, and what personal protection is required and when to use it. All staff need to know what to do in the event of an accident or incident.

Education about infection prevention and control begins at staff orientation/induction and continues as new information comes to light (eg notification of a disease outbreak). It includes teaching the principles of infection prevention and control, competency checking by a person deemed already competent, and performing ongoing auditing and education of staff.

## What needs to be taught?

All doctors and staff need to be taught and demonstrate competency in:

- hand hygiene
- standard precautions
- transmission-based precautions
- managing blood and body fluid spills
- managing blood or body fluid exposure (appropriate to their role)
- principles of environmental cleaning and reprocessing medical equipment (appropriate to their role)
- where to find information on other aspects of infection prevention and control in the practice.

## What needs to be documented?

Employers should:

- maintain a register of staff training and task competences achieved in respect of infection prevention and control in the practice. These should be at the level required by the staff member's position description – *Appendix 1* gives an example of such a register
- include infection prevention and control in the practice's work health and safety policy and procedures.

There must be a documented policy for environmental cleaning which includes scheduled cleaning activities.

## Protecting the practice team and patients from infection

Employers and managers have a responsibility under work health and safety laws to protect their staff from injury at work. Work health and safety policies relating to infection prevention and control include:

- immunisation appropriate to duties
- provision and use of personal protective equipment as required
- hand hygiene
- safe sharps management
- management of blood and body fluid exposure
- written practice policies and procedures covering all aspects listed above.

Occasionally a staff member may be at increased risk of exposure to, or transmitting, an infectious disease. The following health professionals and staff may require particular management.

## Immunocompromised health professionals and staff

People with immune deficiencies are more at risk of acquiring infections. Management and health professionals need to decide on the type of employment that will minimise these staff members' exposure risk. It may be necessary to redeploy a staff member that has developed immune deficiency if the condition has occurred subsequent to their employment.

## Health professionals with infections

To protect staff members and patients, health professionals with signs and symptoms of an infectious disease (eg varicella, measles, influenza) should be excluded from work until they are no longer infectious.

## Pregnant health professionals

If a pregnant health professional or staff member has no known immunity or immunisation to infectious diseases such as influenza, rubella, varicella, cytomegalovirus or parvovirus, they should be redeployed (if possible) if at risk of contracting these diseases through their employment.

## Exposure to infectious diseases

If a health professional or staff member is exposed to other infectious diseases (such as varicella, tuberculosis, HIV, hepatitis B) they should be referred for medical advice, appropriate testing and consideration of post-exposure prophylaxis (PEP) if available.

## Section 1.2. How microorganisms are acquired and grow

Microorganisms can multiply exponentially given the right environmental conditions. They can be acquired or transmitted in several ways.

Microorganisms include bacteria, viruses, yeasts, fungi and prions. Many infectious microorganisms are present in healthcare settings. Some microorganisms have specific temperature, nutrient, oxygen and intracellular requirements. When these requirements are met, microorganisms can multiply exponentially in number.

Infection prevention and control measures aim to minimise the numbers of microorganisms in the practice environment and prevent their transmission. Cleaning and drying hands and equipment surfaces minimises the number of organisms.

### Transmission

Microorganisms which cause disease (pathogenic microorganisms or pathogens) can be transmitted in many ways. In healthcare settings, the main modes for transmission are contact, droplet and airborne. Other modes are vehicle and vector transmission.

Some individual microorganisms can be transmitted in multiple ways, for example, measles transmission is airborne, droplet, direct contact with infected nasal or throat secretions and by indirect contact. Influenza is also spread through multiple routes (droplet and contact).

### Contact transmission

Transmission may occur through direct or indirect contact with contaminated objects. Staff may get microorganisms on their hands during patient contact or contact with objects contaminated with secretions or excretions, and then may transfer organisms to others.

Examples of such microorganisms are vancomycin resistant enterococci (VRE), methicillin resistant *Staphylococcus aureus* (MRSA), salmonella, norovirus, rotavirus, *Clostridium difficile* and varicella zoster (shingles).

### Droplet transmission

Large droplets (>5 micron) are produced by an infected patient coughing or sneezing, or through procedures such as throat examination, suction and nebuliser treatment. These droplets may make contact with the mucous membranes (eyes, mouth and nose) of people within a 1-metre radius.

Examples of such microorganisms include: pertussis, influenza, severe acute respiratory syndrome (SARS), rubella, mumps, adenoviruses, respiratory syncytial virus (RSV) and avian influenza.

There is debate as to whether droplet transmission is a form of direct contact: microorganisms can land directly on respiratory membranes or be swallowed (eg norovirus).

### Airborne transmission

Particles are produced by an infected patient coughing or sneezing, or through procedures such as suction and nebuliser treatment. Particles of this size can remain suspended in the air for long periods and can be dispersed in air currents.

Pathogens can be transmitted when susceptible people inhale contaminated air. Examples of such microorganisms include tuberculosis, SARS, varicella and measles.

Nebulisers generate particles of this size and should not be used when treating patients suspected of having such infections. The risk is currently considered low when used in the treatment of patients for asthma precipitated by a viral infection.

## Vehicle transmission

Microorganisms are transmitted through a contaminated substance, surface or equipment.

Examples include cholera infection through contaminated water and hepatitis B from a contaminated multi-dose vial or needle.

## Vector transmission

Microorganisms are introduced by another living creature (eg Ross River virus and malaria from mosquito bites).

## Infection and disease

Whether transmission of microorganisms causes clinical infection depends on the pathogenicity of the microorganism (ie its ability to cause disease) and the susceptibility of the person exposed. Some people may be colonised by such microorganisms but remain asymptomatic. If they are able to transmit these microorganisms to others, they are known as 'carriers'.

Other factors that determine relative risk and whether infection develops include the number of microorganisms transmitted (the dose) and contact with a cell type that the microorganism can replicate in (target cells). For example, a staff member may regularly use a pen handled by multiple infectious patients, while patients will only use the pen once. The relative risk of infection (through indirect contact) is therefore potentially higher for staff.

Numerous microorganisms live on the skin and in the gastrointestinal tract of all people. Most of the time these microorganisms are harmless but occasionally these 'resident' microorganisms may cause infection. This can occur due to:

- an imbalance, for example, *Candida* can reside in the female genital tract without causing a clinical problem until after a course of antibiotics kills symbiotic resident bacteria and allows the *Candida* to overgrow and become symptomatic
- transfer from one part of the body to another, for example, *E. coli* bacteria of the gastrointestinal tract can cause urinary tract infection
- interruption of normal defences, for example, a skin wound can become infected by resident skin flora such as *Staphylococcus aureus*.

## Section 1.3. Hand hygiene

Effective hand hygiene, using soap and water, antiseptic hand wash or alcohol-based hand rubs or wipes, has been proven to reduce the spread of infection.

Gloves are not a substitute for hand cleaning.

Easy access to hand-hygiene facilities enables staff to clean their hands more reliably. Selecting the correct hand-hygiene product is essential in ensuring the hands of staff members are adequately cleaned and disinfected if necessary.

Hands need to be thoroughly dried following washing with liquid soap and water.

Staff need to be educated on effective hand hygiene and hand care.

Any pathogenic microorganism transmitted by contact or droplet can potentially be transmitted by touch. Hand hygiene refers to any action of hand cleansing that reduces the number of microorganisms on hands. Effective hand hygiene is an essential element of all infection prevention and control policies. Methods of hand hygiene are outlined in *Table 1.2*.

Gloves are not a substitute for hand hygiene.

Practices should assess appropriate moments for patient hand hygiene and provide suitable facilities, such as alcohol-based hand rubs at the reception desk and in the waiting room.

Table 1.2. Methods of hand hygiene

Type of hand hygiene	Technique	Duration	Drying	When
Routine hand cleaning for soiled hands	<b>Washing:</b> <ul style="list-style-type: none"> <li>wet hands</li> <li>wash with neutral liquid soap</li> <li>rinse thoroughly</li> <li>use paper towel to turn off taps if not 'hands free'</li> </ul>	10–15 seconds	Paper towel or Clean, dry, single use cloth towel or Clean section of roller towel	<ul style="list-style-type: none"> <li>Before eating</li> <li>After going to the toilet</li> <li>Before and after patient contact</li> <li>After removing gloves</li> </ul>
	<b>Skin disinfectants:</b> <ul style="list-style-type: none"> <li>remove soil first, using hand wipes or soap and water</li> <li>apply alcohol-based hand rub</li> <li>rub over all surfaces in the same manner as washing hands</li> </ul>	10–15 seconds, or until dry	Rub hands until dry, without wiping	<ul style="list-style-type: none"> <li>Before eating</li> <li>After going to the toilet</li> <li>Before and after patient contact when hands are not visibly soiled</li> <li>After removing gloves</li> </ul>
Hand washing for standard aseptic (clinical) procedures	<b>Method:</b> <ul style="list-style-type: none"> <li>wet hands</li> <li>wash with neutral liquid soap or antimicrobial cleaner</li> <li>rinse thoroughly</li> <li>use paper towel to turn off taps if not 'hands free'</li> <li>alcohol-based hand rub can be used in emergency situations outside the practice, provided hands are not visibly soiled</li> </ul>	1 minute	Paper towel or Clean, single use cloth towel	Before any procedures requiring a clean or 'no touch' technique
Hand washing for surgical aseptic procedures	<b>Method:</b> <ul style="list-style-type: none"> <li>remove jewellery</li> <li>wet hands and forearms</li> <li>wash with antimicrobial cleaner (4% chlorhexidine or 0.75% detergent-based povidone or 1% aqueous povidone)</li> <li>clean under nails only if needed (do not scrub hands with nail brush as they can break the skin and be a source of infection)</li> <li>rinse carefully, keeping hands above elbows</li> </ul> <b>To turn off taps if not hands free:</b> <ul style="list-style-type: none"> <li>ask another staff member to turn off taps or use sterile towel</li> </ul>	First wash of day: 5 minutes Subsequent washes: 3 minutes	Sterile towels	Before significant invasive surgical procedures

## Why hands need to be cleaned

The hands of healthcare workers are a common source of transmission of microorganisms. Many of these microorganisms are acquired during patient care activities. Improved hand hygiene can reduce the

healthcare-associated infection rate, including those involving multiresistant organisms.

As patients frequently touch items and surfaces within the practice (such as pens, chairs, magazines and door handles), they are a potential source of infection. Encouraging hand-hygiene practices among patients can decrease microorganism transfer and the risk of healthcare-associated infection.

## When hands need to be cleaned

Hand hygiene must be performed before and after every episode of patient contact and after activities that may cause contamination. These include:

- before and after eating
- after routine use of gloves
- after handling any used instruments or equipment
- after going to the toilet
- when visibly soiled or perceived to be soiled
- between procedures
- before performing procedures (eg removal of moles, suturing lacerations, wedge resections, drainage of cysts)
- before examining neonates and patients who are immunocompromised.

'5 moments for hand hygiene' is a simple strategy developed by the World Health Organization and adopted by Hand Hygiene Australia to:

- protect patients from transmission of infectious agents from the hands of healthcare workers
- help to protect patients from infectious agents (including their own) entering their bodies during procedures
- protect healthcare workers and the healthcare surroundings from acquiring patients' infectious agents.

The '5 moments' state that hand hygiene should be undertaken:

1. before touching a patient
2. before a procedure
3. after a procedure or body fluid exposure risk
4. after touching a patient
5. after touching a patient's surroundings.

Hand Hygiene Australia has further information on its website ([www.hha.org.au](http://www.hha.org.au)), including a free online course and information on handwashing techniques.

## Fingernails and jewellery

Each practice should develop policies on jewellery, artificial nails and nail polish based on risk assessment.

The length and type of fingernail can affect hand hygiene. Areas under the nail can harbour high concentrations of bacteria even after handwashing, hence nails should ideally be kept short (not past the tip of the finger pad) and clean. False fingernails may harbour microorganisms, especially Gram-negative bacilli and yeasts, even after handwashing. Freshly applied nail polish on natural nails does not increase the microbial load if fingernails are short.

Jewellery (including rings, watches and other wrist jewellery) can also affect hand hygiene, however there is less evidence concerning its impact. The skin under rings may be more heavily colonised than comparable skin without rings and rings can interfere with hand-hygiene techniques. Hence, jewellery should be kept to a minimum when at work.

## Facilities for hand cleaning

Easy access to hand-hygiene facilities enables staff (and patients) to clean their hands more reliably.

Hand-hygiene facilities need to be accessible in all patient management areas (treatment areas, consulting areas). Provide hand gels, rubs or wipes in all examination and treatment areas to encourage effective hand hygiene. Treatment rooms should have handwashing facilities.

If handwashing facilities are not readily accessible (eg working offsite), use skin disinfectants (alcohol-based hand gels, rubs, wipes) preceded by a detergent wipe if required.

When building new premises or upgrading existing premises, consideration should be given to installing hands-free or elbow-operated handwashing facilities in all patient treatment areas, and ideally in all consulting areas and toilets.

## Hand-hygiene product selection

Selecting the correct product is essential. The person with the designated responsibility for infection prevention and control needs to consider:

- the type of hand-hygiene/wash routine required
- the location of the product
- compatibility of agents used to clean, wash and condition hands
- the need for hand-hygiene products to contain moisturisers and emollients to protect the hands (supermarket products are designed for intermittent domestic use and often do not contain these ingredients and can dry hands)
- safety issues (eg alcohols are flammable and may also cause irritation if splashed into the eyes).

Indications for the use of the selected products, and their location, needs to be included in the policy and procedure manual so that staff unfamiliar or new to the practice will follow the agreed protocols.

If hands are visibly soiled, hand hygiene should be performed using soap and water. Plain soaps with moisturiser and emollients may be used in toilets for routine handwashing. Soaps containing 2% chlorhexidine (a skin disinfectant) may also be used in toilets. Soaps containing 4% chlorhexidine should be used in treatment room areas where surgical handwash is required. If a staff member has an allergy to chlorhexidine, an alternative antimicrobial product such as triclosan (clinical setting) or povidone-iodine (in surgery and for VRE) should be considered.

## Soap bars

Bar or cake soaps, left wet, can harbour microorganisms and must not be used in general practices and other office- and community-based practices.

## Liquid hand cleaners

These may be plain or contain antimicrobial agents such as chlorhexidine, triclosan or povidone-iodine. Antimicrobial soaps, however, are associated with increased skin care issues and may not be necessary for use in everyday clinical practice.

Liquid handcleaning agent dispensers with an integrated container and dispensing nipple are recommended. The whole container and dispensing nipple should be disposed of when empty.

If this type of system is not available, consider a pump pack. It is best practice to dispose of pump packs when empty. If a pump pack is to be reused, the container needs to be emptied and both the container and pump device thoroughly cleaned before adding a fresh handcleaning agent (not just 'topped up'). Topping up refillable containers can increase the risk of contamination and microbial growth occurring in the contents that thicken and dry around the top of the pump.

Plain or antimicrobial (liquid) soap and water-based hand hygiene is preferred when *Clostridium difficile* or non-enveloped viruses (such as norovirus) are known or suspected, as alcohol-based hand rubs have been shown to be less effective.

## Alcohol-based hand rubs

Alcohol-based hand rubs (liquid or gel) are designed to be used without water and are easily accessible at point of care. They are suitable in circumstances where hand-hygiene facilities are not available or are inadequate (eg home visits, outreach clinics).

Alcohol-based hand rubs are not suitable if hands are visibly dirty. If significantly soiled and handwashing facilities are unavailable, clean hands first using detergent-based wipes.

Alcohol-based hand rubs are more effective than plain or antiseptic soap and water against many pathogenic microorganisms on hands. However, efficacy is affected by the type and concentration of alcohol used, contact time, volume of product used and whether hands are wet when the product is applied.

For routine hand-hygiene practices, use alcohol-based rubs that contain between 60% and 80% v/v ethanol or equivalent and meet requirements of European Standard EN 1500.

Always use hand rubs and hand wipes according to the product directions.

Fragrance, colour, emollient agents, drying characteristics, risk of skin irritation and accessibility can affect acceptance of alcohol-based hand rubs. Having them available throughout the practice, including at reception, encourages use by staff and patients.

## Drying hands

Hands need to be dried following washing with liquid soap and water. Incomplete drying can cause chapping and damage to skin. This can lead to colonisation with potentially pathogenic microorganisms and increased numbers of bacteria, raising the risk of transmission to patients during procedures.

## Drying hands after routine handwashing

Single use paper towels should be used for drying hands in treatment, consulting and reprocessing areas.

In toilets only, the use of hot air driers is acceptable.

Hot air dryers are unsuitable for clinical use. Jet dryers, while have quicker drying times resulting in less microorganism growth on hands, increase the spread of microorganisms through the air. Slower hot air dryers reduce the spread of microorganisms through the air, however the slower drying times result in more microorganism growth on hands.

## Drying hands for standard aseptic procedures

For standard aseptic procedures, disposable paper towels for drying are acceptable.

## Drying hands for surgical aseptic procedures

For surgical aseptic procedures, hand drying should be by sterile cloth or sterile disposable paper towels.

## Hand care

Staff need to care for their hands to prevent the risk of infection to themselves and others. Intact skin is an effective natural defence against the entry of pathogens and subsequent infection. Broken skin can be the site of bacterial growth and may facilitate the transmission of infection.

Drying hands after washing, use of compatible handcreams and attending to breaks in the skin are essential aspects of hand care. All hand-hygiene products should be compatible. Consider obtaining all hand-hygiene and hand-care products from a range by a single manufacturer.

Skin drying and dermatitis can occur due to too-hot or too-cold water, too much handwashing solution, or ineffective rinsing and drying. Gloves and latex allergy may also contribute.

## Hand-care techniques

To combat the drying effects of regular hand cleaning, use suitable aqueous-based handcreams that are compatible with the selected hand-hygiene products. These can be applied at meal breaks and when going home. Creams and ointments cannot, however, be used before wearing gloves (oil-based preparations may cause latex gloves to deteriorate and can contaminate instruments and equipment).

Cover cuts and abrasions with water-resistant dressings. These need to be changed if they become soiled or loose.

Doctors and other health professionals experiencing dermatitis or other skin disorders should seek medical advice before undertaking any activity that could potentially pose a risk to themselves or to patients.

Nailbrushes can abrade skin and are not recommended.

## Glove use

Hand-hygiene procedures need to be performed before putting on gloves and after removal of gloves.

Gloves do not provide complete protection against hand contamination. Microorganisms can be transmitted to and from the hands through small defects. Gloves also cause hands to sweat and facilitate resident microorganism growth.

## Section 1.4. Precautions

Standard precautions must be taken by all staff involved in patient care or who may have contact with blood or other body substances, secretions and excretions (except sweat), regardless of the known or perceived infection status of the patient.

Standard precautions are work practices that consistently achieve a basic level of infection prevention and control.

Use transmission-based precautions when a patient is known or suspected to be infected or colonised with microorganisms that cannot be contained by standard precautions alone.

Where transmission-based precautions are used, this is always in addition to standard precautions.

Standard aseptic technique refers to work practices used by doctors and other health professionals to minimise the risk of introducing and transmitting infection during clinical procedures.

All staff involved in procedures should be familiar with and use the standard aseptic technique as required.

Surgical aseptic technique refers to work practices that result in prevention or minimisation of microorganisms entering sterile body areas.

Standard precautions must be taken by all staff involved in patient care or who may have contact with blood or body fluids (including secretions and excretions but excluding sweat) regardless of the known or perceived infection status of the patient. 'All staff' includes doctors, other health professionals, practice staff and external contractors (eg cleaners).

The blood and body fluids of all patients are considered potentially infectious at all times.

Transmission-based precautions:

- are used when a patient is known or suspected to be infected or colonised with microorganisms that cannot be contained by standard precautions alone
- are always used in addition to standard precautions
- provide additional barriers between practice staff at risk and the infected patient, according to the route of transmission.

It is important that patients understand their role in infection prevention and control, and that precautions are in place to protect everyone from infection.

## Standard precautions

Standard precautions are work practices that are used consistently to achieve a basic level of infection prevention and control. They help protect doctors, health professionals and practice staff from infection, and help prevent infection transmission.

Standard precautions include:

- hand hygiene
- personal protective equipment as appropriate (eg mask, goggles, face shield, gloves, gown)
- respiratory hygiene and cough etiquette
- standard aseptic technique

- safe management of sharps and other clinical waste
- environmental controls such as design and maintenance, cleaning, and spills management
- support services such as waste disposal, laundry and cleaning services
- effective reprocessing of reusable equipment and instruments and appropriate use of cleaning products.

## When are standard precautions used?

Standard precautions are used when staff are likely to be in contact with:

- blood
- other body fluids, secretions or excretions, except sweat (eg urine and faeces)
- non-intact skin
- mucous membranes.

## Transmission-based precautions

Transmission-based precautions are used with standard precautions to further reduce transmission opportunities arising from specific transmission routes of microorganisms.

Patients should be encouraged to report any potential infectious disease to practice staff as soon as possible. For example, while patients are on hold they can listen to a message asking them to tell reception if they are experiencing any particular symptoms or have travelled to any particular areas. Practice websites may also be used to convey this message. Patients should be advised why particular measures are needed to protect all patients and staff from infection.

Transmission-based precautions include the use of:

- contact precautions
- droplet precautions
- airborne precautions.

## Contact precautions

Contact precautions should be used if there is a risk of direct or indirect contact transmission of pathogenic microorganisms (such as MRSA and *Clostridium difficile*) that are not effectively contained by standard precautions alone. To prevent contact transmission, the following items and actions are required:

- Wear gloves for all manual contact with patients, associated equipment and the immediate environment.
- Wear a water impermeable apron or gown if your clothing could be in substantial contact with the patient or their immediate environment.
- If a splash is likely during the procedure, use a fluid-repellent surgical mask and goggles or a face shield to protect the face.
- When removing personal protective equipment, remove gloves first and clean hands, then remove goggles, gown and mask.
- Clean hands immediately after attending to the patient and before leaving the area.
- Ensure all equipment in contact with the patient is single use or reprocessed before use on the next patient.
- Depending on the situation and space constraints, segregate patients with these types of infectious diseases (social distancing) – move the patient from the general waiting area to a spare room.
- Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg the practice nurse or ambulance and emergency department staff if being transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained.

## Droplet precautions

Droplet precautions should be used if there is a risk of infectious microorganisms being transmitted by droplets generated by coughing, sneezing or talking (eg patients with influenza). To prevent droplet transmission, the following items and actions are recommended:

- Offer staff appropriate immunisation for vaccine-preventable diseases.
- If not immune, use a fluid repellent surgical mask to protect the mouth and nose.
- Clean hands immediately after attending patient and removing mask (and face shield if used) before leaving the area.
- Segregate patients (social distancing) with these types of infectious diseases if possible – move the patient from the general waiting area to a vacant area, or maintain a 1-metre gap between the infectious patient and other patients in the waiting area.
- Ask the infectious patient to wear a surgical mask. In this instance, advise patients how to remove and dispose of the mask safely.
- Ask the patient to attend to respiratory etiquette (see *Chapter 5, Section 5.2*).
- Consider explaining the situation to nearby patients.
- Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg ambulance and emergency department staff if the patient is transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained.
- Staff known to be immune to particular infectious diseases do not need to use a mask and goggles when exposure is possible.

## Airborne precautions

Airborne precautions should be used where there is a risk of transmitting microorganisms generated by coughing, sneezing or talking that remain infectious over time and distance when suspended in air (eg measles, varicella, tuberculosis). To prevent airborne transmission, the following items and actions are recommended:

- Offer staff appropriate immunisation for vaccine-preventable diseases.
- If not immune, staff can use a P2/N95 close-fitting, high-efficiency filtration mask. Standard surgical masks are not particularly effective for this purpose.
- In order to minimise exposure time to other patients, consider:
  - consulting the patient ahead of others in the waiting area or schedule the appointment at the end of the session
  - segregating into a separate area such as a spare room
  - asking the infectious patient to wear a surgical mask
  - explaining the situation to patients waiting nearby
  - visiting the patient at home.
- Use goggles/face shield to protect the face if splash is likely.
- Clean hands immediately after attending the patient and removing mask (and face shield if used) before leaving the area.
- Ensure all equipment in contact with the patient is single use or reprocessed before use on the next patient.
- Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg ambulance and emergency department staff if transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained.
- Staff known to be immune to the infectious disease do not require P2/N95 masks.

## Other relevant information

Diseases such as pandemic influenza, measles and invasive meningococcal disease may require tracing of people that have been in contact with the infected patient (ie contact tracing). Contacts could include the patient's other household members, their work colleagues and other acquaintances, as well as other patients and staff in your practice. Your state or territory health department should be contacted for advice and direction (see *Appendix 2*).

*Appendix 3* is a table of transmissible diseases and suitable precautions.

*Table 1.3* describes personal protective equipment for transmission-based precautions.

**Table 1.3. Use of personal protective equipment for transmission-based precautions**

Requirement	Airborne transmission	Droplet transmission	Contact transmission
Gloves	No	No	For all manual contact with patient, associated devices and environmental surfaces
Impermeable gown, apron	No	No	Use when health professional's clothes are in substantial contact with the patient (including items in contact with the patient and their immediate environment)
Mask	Yes	Yes	Protect face if splash is likely
Goggles/face shield	Protect face if splash is likely	Protect face if splash is likely	Protect face if splash is likely
Special handling of equipment	Single use equipment or reprocess after patient use (includes all equipment in contact with patient)	No	Single use equipment or reprocess after patient use (includes all equipment in contact with patient)
Other	<ul style="list-style-type: none"> <li>Encourage patient to use respiratory etiquette</li> <li>Segregate patient if possible</li> <li>Give patient a mask to wear if segregation is not possible</li> <li>Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg ambulance and emergency department staff if transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained</li> </ul>	<ul style="list-style-type: none"> <li>Encourage patient to use respiratory etiquette</li> <li>Segregate patient if possible</li> <li>Give patient a mask to wear if segregation is not possible</li> <li>Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg ambulance and emergency department staff if transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained</li> </ul>	<ul style="list-style-type: none"> <li>Encourage patient to use respiratory etiquette</li> <li>Wash hands after removing gloves and gowns</li> <li>Communicate the patient's infectious status to other doctors and health professionals involved in the care of the patient (eg ambulance and emergency department staff if transferred to another healthcare facility) so that appropriate transmission-based precautions can be maintained</li> </ul>

## Standard aseptic technique

Standard aseptic technique refers to work practices used by doctors and other health professionals to minimise the risk of introducing and transmitting infection during clinical procedures. Standard aseptic technique is used during treatment of wounds such as lacerations and ulcers, minor operative procedures such as removal of moles and biopsies and venipuncture.

All staff involved in procedures should be familiar with, and use, the standard aseptic technique as required.

Standard aseptic technique is achieved by:

- using standard precautions, including hand hygiene and personal protective equipment where necessary
- using barriers (eg clean single-use gloves)
- using water or saline to clean ulcers or lacerations
- using skin disinfectants to prepare operative sites
- using clean environmental surfaces
- using a no-touch technique – that is, no direct contact between the health professional's hands and the patient during the procedure, such as using forceps during dressings or clean single-use gloves if no-touch technique is not possible (eg probing a penetrating wound)
- using drapes to form a 'clean field' dependent on situation and risk
- using sterile instruments and equipment
- reprocessing reusable instruments and other equipment between each patient.

## Surgical aseptic technique

Surgical aseptic technique refers to work practices that result in preventing or minimising microorganisms entering sterile body areas such as through surgical incisions during a procedure. Elements of this technique may be used in some settings for more invasive procedures (eg skin flaps).

Surgical aseptic technique involves:

- using a sterile operating field where everything within a defined radius is clean and sterile
- using sterile gloves, gowns, drapes and instruments
- using skin disinfection on the patient (see *Appendix 4*)
- taking care to ensure that nothing unsterile comes within the sterile field.

## Section 1.5. Personal protective equipment

Personal protective equipment is to be used by staff who are at risk of exposure to another person's blood or other body fluids.

Gloves should be worn by staff who are at risk of blood or body fluid exposure, or at risk of a disease transmissible by contact.

Goggles or face shields need to be used by staff where there is a risk of splashing or spraying of blood or body fluids such as during surgical procedures, venipuncture or cleaning of instruments.

Staff should wear aprons or gowns when there is a risk of soiling clothing from splashes of blood or body fluids, or when there is a risk of contact transmission of microorganisms.

Surgical masks may be used by unimmunised staff when there is a risk of droplet spread of disease. Surgical masks may also be worn by patients to prevent the spread of a disease (suspected or known) that is transmissible by droplet spread.

Applying and removing personal protective equipment in the correct order is essential to prevent transmission of disease to the staff member.

Personal protective equipment (PPE) refers to a variety of barriers (eg gloves, water impermeable aprons/ gowns, masks, glasses, goggles, face shields, footwear) used to protect mucous membranes, airways, skin and clothing from contact with blood and body substances.

The use and type of PPE depends on the situation and the risk. Factors to consider are probability of exposure, type of body substance involved, and probable type and route of transmission of microorganisms. For example, examination gloves are used as a standard precaution for low-risk procedures where there is a likelihood of exposure to a patient's blood or body fluid, while additional and more specialised PPE is added as required (eg P2/N95 masks) to prevent transmission of pandemic influenza and tuberculosis.

### Gloves

As for all PPE, the need for and type of gloves selected is based on risk assessment and the type of activity. Choosing gloves that fit properly and are appropriate for the task is an important aspect of improving safety.

When gloves are worn with other PPE, they are put on last and removed first.

### Types of gloves

- Sterile gloves are used for sterile procedures.
- Clean single use gloves are used for procedures where there is a risk of exposure to patient blood or body fluids, or contact with non-intact skin and mucous membranes: for example, venipuncture, vaginal or rectal exam, and minor procedures such as wound dressing, suturing and removal of minor skin lesions.
- Nonsterile gloves are available in a range of materials such as natural rubber latex and synthetic materials (eg vinyl, nitrile). Latex gloves enable the wearer to maintain dexterity, but sensitivity and allergy can occur. Practices need to document staff members and patients with latex allergy and provide alternative glove types.
- General purpose utility gloves (eg kitchen gloves) are used for nonpatient care activities such as cleaning surfaces.
- Heavy duty, puncture-resistant gloves must be used for instrument cleaning. These gloves can be reused.

## Fitting protective gloves

If wearing a gown, pull gloves on over the cuffs of the gown.

## Changing gloves

When wearing gloves, gloves need to be changed:

- after contact with each patient
- in between procedures on the same patient
- if gloves are damaged during a procedure
- on completion of tasks
- before handling notes, telephones.

## Removing and disposing of protective gloves

Correct handling of used gloves is important to reduce the risk of infection to the staff member. Remove gloves inside out and hold by the edge to minimise contamination of hands. Dispose of gloves into the appropriate waste stream as soon as they are removed. Perform hand hygiene after removing gloves.

## Latex sensitivity/allergy

Latex allergy is a reaction to proteins in latex rubber. Latex allergy appears to develop over time with frequent exposure to latex proteins (it mostly affects practice nurses, doctors, dentists and patients who have had multiple operations). Powdered latex gloves should not be used: they increase the risk of allergy as the powder concentrates the latex allergen.

Symptoms of latex allergy usually begin within minutes of exposure, although symptoms can also occur hours later. Symptoms range from mild itching and hives to more severe respiratory symptoms. Life-threatening symptoms are rare.

If latex sensitivity/allergy has occurred or if latex allergy is suspected, the staff member must be referred for medical assessment. Risk management strategies such as latex-free work areas should be implemented.

The risk of latex allergy is absent with the use of nonlatex gloves such as nitrile, vinyl and neoprene gloves. These gloves must be used when treating patients with latex allergies and by staff with latex allergies.

## Goggles/face shields

Goggles provide eye protection for staff performing procedures where there is a risk of splashing or spraying of blood or body fluids (eg surgical procedures, venipuncture, cleaning of instruments).

Face shields may be used to provide additional face and mouth protection.

Goggles/face shields need to be clear, antifogging, distortion free, close fitting and, ideally, closed at the sides. Goggles or face shields are fitted over the top of regular prescription glasses if worn. Newer styles of goggles fit over prescription glasses with minimal gaps.

When wearing goggles or a face shield, it is important not to touch the goggles or face shield.

When removing and disposing of goggles:

- take care to remove using the stems only
- if disposable, discard into the appropriate waste stream
- if reusable, wash with soap and water, disinfection with a hospital grade disinfectant can then follow, and dry before reuse.

Correct handling of used goggles/face shields is important in preventing the risk of infection to the staff member.

## Aprons and gowns

Aprons or gowns should be worn by practice team members when there is a risk of contamination of skin or clothing with blood, body substances, secretions or excretions. The type of apron or gown should be appropriate to the task and the degree of risk. They should be worn for a single procedure or episode of patient care and removed in the area where the episode of care takes place.

When wearing a gown or apron, do not touch the front or sleeves.

Perform hand-hygiene procedures after removing the gown or apron.

### Aprons

Single-use plastic aprons are suitable for general use when there is a risk that clothing may be exposed to blood or body substances during low-risk procedures and where there is a low risk of contamination to the arms. Aprons can be worn during contact precautions.

### Gowns

Gowns are worn to protect skin and prevent soiling of clothing. The choice of gown depends on the activity – for example, a full body gown (used in combination with other PPE) should be worn when there is a possibility of extensive splashing of blood and body substances such as vomit and uncontrolled faecal matter.

If it is anticipated that there will be heavy exposure to blood or body fluids, a waterproof apron may be worn between the wearer's clothes and the gown.

Gowns may be:

- disposable or reusable
- short or long sleeved
- cuffed
- secured at the back
- sterile pre-packaged.

### Fitting a protective gown

Put on the gown with the opening at the back. Secure the tapes to prevent the gown opening and clothes becoming contaminated.

### Removing aprons and gowns

Remove aprons and gowns in a manner that prevents contamination of clothing or skin. Undo tapes and remove the gown inside out, taking care not to touch the outside of the gown. Roll the gown into a bundle and, if disposable, dispose of it into the appropriate waste stream. If reusable, place the gown into a designated linen container so it can be washed and dried appropriately before reuse.

## Masks

Masks may be used by unimmunised staff when there is a risk of droplet or airborne spread of disease. Masks may also be worn by patients to prevent the spread of a disease (suspected or known) that is transmissible by droplet or airborne spread.

There are two types of masks: surgical and P2/N95 respirators.

The correct type of mask must be chosen according to the situation.

All masks need to be fluid repellent and disposable. Precautions include:

- Do not touch the front of the mask while being worn.
- Remove and replace the mask if it becomes wet or soiled.
- Do not wear a mask around your neck.
- Do not reapply a mask after it has been removed.

Hand hygiene should be performed upon touching or disposing of a used mask.

Masks with elastic loops have a use-by date as the elastic perishes with time: masks past their use-by date need to be replaced even if unused.

## Surgical masks

A surgical mask is intended to prevent the release of potential contaminants from the user into their immediate environment. It also protects the wearer from large droplets, sprays and splashes of body fluids. They can protect unimmunised staff and patients where there is a risk of droplet transmission of disease. Surgical masks have strings to be tied at the back of the head or elastic straps.

### Fitting a surgical mask

Masks need to be fitted correctly to be effective. To fit a surgical mask:

- apply the mask by tying the tapes above and below the ears, or placing the elastic around the ears
- spread the folds of the mask so that the mask covers the mouth and nose comfortably
- mould the area over the bridge of the nose to produce a snug, comfortable fit.

### Removing and disposing of a surgical mask

Correct handling of used masks is important to prevent the risk of infection of the staff member and patients. When removing a mask, handle by the strings or loops only. Dispose of the mask as soon as possible into the appropriate waste stream.

## P2/N95 masks

P2/N95 masks, also known as respirators or particulate filter masks, are special masks designed to filter out small particle aerosols and large droplets. P2/N95 masks must comply with AS/NZS1716:2012 *Respiratory protective devices* and need to be fitted correctly to be effective. Wearers need to be appropriately trained in their use. A risk-management approach should be applied to ensure that staff performing high-risk duties are fit tested and aware of how to perform a fit check.

Correct handling of used masks is important to prevent the risk of infection to the staff member and patient. When removing the mask, handle only the elastic or strings. Dispose of the mask into the appropriate waste stream.

### Fit testing and checking a P2/N95 mask

A fit test identifies the correct size and style of P2/N95 mask suitable for an individual. Ideally, testing should be performed at the start of employment for practice team members working in clinical areas where a significant risk of airborne transmission of infectious agents could arise.

Fit testing may need to be performed again where there is a significant change in the wearer's facial characteristics (eg growth or removal of facial hair, weight change) and at regular intervals – AS/NZS1715:2009 *Selection, use and maintenance of respiratory equipment* recommends annual fit testing.

Employers must ensure that their employees have the medical ability to wear a respirator.

Fit checking must be performed every time a P2/N95 mask is put on. Fit checks ensure the mask is sealed over the bridge of the nose and mouth and that there are no gaps between the mask and face. Fit checking should be performed as per the manufacturer's instructions.

## Applying and removing PPE

Applying and removing PPE in the correct order is essential to prevent transmission of disease to the staff member.

Before putting on PPE, explain to the patient that it is a routine part of infection prevention and control and done for everyone's safety.

Hand hygiene must be performed before putting on PPE and after removing PPE.

### Applying PPE

PPE should be applied in the following order:

1. long-sleeved gown, tied up at the back
2. mask
3. goggles
4. gloves, taking care to tuck the cuffs of the gown into the gloves.

Gloves must always be put on last.

### Removing PPE

PPE needs to be removed in the following order:

1. Remove gloves inside out. Dispose of into the appropriate waste stream.
2. Perform hand hygiene.
3. Remove goggles. Place disposable goggles into the appropriate waste stream. Reusable goggles are cleaned and disinfected before reuse.
4. Remove gown, taking care not to touch surfaces exposed to contamination.
5. Dispose of disposable gown into the appropriate waste stream. Reusable gowns are placed into a linen bag marked 'contaminated'.
6. Remove mask, taking care to handle by the strings only. Dispose of mask into the appropriate waste stream.
7. Perform hand hygiene.

The types of equipment used and method of disposal will vary with the situation – not all situations will require a mask or disposal into a biohazard bag. If PPE is not contaminated with pathogenic microorganisms, it may be disposed of into the general waste stream. If contaminated with a pathogen, it may require disposal into a biohazard bag and clinical waste stream.

## Footwear

Enclosed footwear should be worn to protect against injury if sharps or contaminated material are inadvertently dropped.

## Chapter 2. Protecting the health of staff

### Section 2.1. Staff immunisation

Doctors, other health professionals and practice staff need to be recommended immunisations appropriate to their duties.

While the employer is not required to vaccinate staff working in the practice, the employer is responsible for advising staff of the risks of infection and recommend that staff be covered for the vaccine-preventable diseases to which that staff member may be exposed.

It is important for the practice to keep an up-to-date record of the immunisation status of their employees.

Doctors, other health professionals and practice staff need to be recommended (and potentially offered) immunisations appropriate to their duties to ensure they are protected from vaccine-preventable infectious diseases. The exact requirements will vary, and need to be assessed according to the risk presented by the type of practice and the duties performed by the staff member.

Practices should refer to the current edition of *The Australian immunisation handbook* for comprehensive information regarding vaccination (refer to *Resources*).

### Employer responsibilities

Employers are not required to vaccinate staff working in the practice. However, where staff are at significant occupational risk of acquiring a vaccine-preventable disease, employers should implement a comprehensive vaccination program, which includes:

- a vaccine policy
- up-to-date staff vaccination records
- provision of information about relevant vaccination-preventable disease
- management of vaccine refusal.

A vaccination policy should incorporate individual assessments for practice team members. Attention to correcting any deficiencies in the immunisation status of staff will help ensure the 'herd immunity' of the practice community. Special consideration needs to be given to the vaccination status of staff born overseas and those where pregnancy or the possibility of pregnancy exists.

New staff should receive the vaccines they require before, or within the first few weeks of, employment (except influenza vaccine, which is given annually between March and May). Generally, if there is doubt about the adequacy of immunisation then serological testing should be performed if available, otherwise vaccination should be repeated. Practices should consider supplying new employees with a list of recommended vaccinations that they can take to their own GP to sign confirming their vaccination status. This signed list would then be included in the staff records.

Note: If a nonimmune person is exposed to a vaccine-preventable disease, employers should ensure that PEP is administered where indicated.

## Staff records

Staff records can assist in identifying nonimmune staff and excluding them from contact with patients during disease outbreaks.

Employers need to keep an up-to-date record of the immunisation status of their employees. Staff personnel files should include:

- advice given regarding the need for appropriate vaccination suitable for the type of practice and their duties
- the staff member's response
- details of vaccinations and serological results before present employment
- details of the vaccinations received subsequent to employment (date given, type and brand, batch number, and antibody response if appropriate)
- any refusal of the health professional to be appropriately vaccinated or have antibody levels assessed
- education given regarding infectious diseases and the use of standard and transmission-based precautions including effective use of PPE
- any additional counselling.

Refer to *Appendix 5* for an example of a staff immunisation record.

## Vaccinations for health professionals

*The Australian immunisation handbook* (refer to *Resources*) recommends the following vaccinations additional to the standard immunisation for all healthcare workers:

- hepatitis B (if nonimmune)
- influenza
- measles, mumps and rubella (MMR) (if nonimmune)
- diphtheria, tetanus and pertussis (dTpa)
- varicella (if nonimmune).

Other vaccinations, such as hepatitis A and polio, may be recommended based on risk assessment of the individual practice.

## Hepatitis B

All staff directly involved in patient care and/or the handling of human blood or tissue should be vaccinated against hepatitis B.

Serological antibody testing for anti-HBs should be done 4–8 weeks after the final dose of hepatitis B vaccine. An anti-HBs level of  $\geq 10$  mIU/mL indicates immunity. No further routine doses (ie booster doses) or testing are indicated for immunocompetent individuals. Even though vaccine-induced antibody levels may decline with time and may become undetectable, immune memory persists and is thought to result in a protected immune response on re-exposure.

Booster doses are recommended for persons who are immunocompromised. The time for boosting in such persons should be decided by regular monitoring of anti-HBs levels at 6- to 12-monthly intervals.

If healthcare workers were not tested for anti-HBs within 4–8 weeks after completion of a documented primary course, they should undergo serological testing. Again, if their anti-HBs level is  $\geq 10$  mIU/mL, the person can be regarded as immune. However, if they have an anti-HBs level of  $< 10$  mIU/mL, they should be given a single booster dose (fourth dose) of vaccine. Persons with immune memory established from effective prior vaccination should respond to this booster dose. Anti-HBs should be checked 4 weeks later, and if the anti-HBs levels remains  $< 10$  mIU/mL, the possibility of hepatitis B virus (HBV) infection should be investigated (and, if excluded, the person should be managed as a nonresponder to vaccination).

See *The Australian Immunisation Handbook* for information about nonresponders to primary vaccination.

Completion of a full course of hepatitis B vaccination is strongly recommended for any nonimmune healthcare worker who has sustained a needle-stick injury or other potential hepatitis B exposure. Healthcare workers who are nonresponders should be advised about the need for administration of hepatitis B immunoglobulin (HBIG) within 72 hours of a potential exposure to hepatitis B.

When vaccination against both hepatitis B and hepatitis A is indicated, the combined vaccines may be used.

## Influenza

Seasonal influenza vaccination offered annually may be appropriate to prevent transmission of influenza to other staff and patients, and to reduce work time lost due to influenza.

## Measles, mumps and rubella (MMR)

The MMR vaccine is generally used instead of the individual components.

No vaccination is required for staff born before 1966. All staff born during or since 1966 should have their vaccination records reviewed to ensure they have received two doses of MMR vaccine. Those who have not been vaccinated or have only received one dose of MMR vaccine should be vaccinated unless they have serological evidence of immunity on antibody testing.

See *The Australian Immunisation Handbook* for information about serological testing for immunity to MMR.

Rubella antibody testing needs to be considered for all healthcare workers born during or after 1966, for their own protection (especially potentially fertile female staff members) and to avoid the risk of transmitting rubella to pregnant women. Vaccination should be offered to those whose immune status is unknown or negative. Monovalent rubella vaccine is not available in Australia, so MMR should be used. Antibody testing to ensure immunity should follow a few months after immunisation and the second dose should be given to those who fail to seroconvert to the first dose.

## Diphtheria, tetanus and pertussis (dTpa)

Most Australian healthcare workers will have received a primary course of diphtheria and tetanus vaccine. Monovalent pertussis vaccination is not available in Australia. All healthcare workers should receive the combined dTpa vaccine due to significant risk of nosocomial transmission of pertussis from and to vulnerable patients. A booster dose of dTpa is recommended if the staff member has not received a booster vaccination within the past 10 years.

## Varicella

Varicella immunisation (documented two doses) or serology to confirm immunity is recommended for doctors, other health professionals, and staff with direct clinical contact in settings seeing paediatric cases (this may change when herd immunity from universal childhood immunisation is established).

Testing for seroconversion after vaccination is not recommended but can be used to check if vaccination is required.

Varicella vaccination is not 100% effective so practice staff need to be aware of the signs and symptoms of infection and how to manage them.

## Additional vaccinations

Inactivated polio vaccine may be offered to staff who may be exposed to polio and have not received a booster vaccination within the past 10 years.

Hepatitis A vaccination may be offered for practice staff in communities where hepatitis A is endemic, such as in some Indigenous populations. Seroconversion can be assessed by testing a few months following vaccination.

Meningococcal B and C are no more prevalent among health professionals than the general population. Staff members in the 'at risk' age group (up to 19 years of age) should be vaccinated for meningococcal C and consideration given to meningococcal B vaccination.

Tuberculosis (BCG vaccination) may be considered for healthcare workers likely to encounter patients with tuberculosis (eg chest clinic staff). Routine vaccination of healthcare workers is not recommended. BCG vaccination is by intradermal injection and should only be given by medical or nursing staff who are specifically trained in BCG vaccination procedures.

## Section 2.2. Safe sharps management

The safe handling, use and disposal of sharps is necessary to prevent injury and the possible transmission of disease.

It is important that staff with the responsibility for infection prevention and control in the practice assume an active role in sharps management.

Sharps are defined as 'anything that can penetrate the skin'. Healthcare workers face the risk of injury from needles and other sharps during many routine procedures. The safe handling, use and disposal of sharps is necessary to prevent injury and the possible transmission of disease to patients, doctors, other health professionals, practice staff and cleaning contractors.

Sharps may be contaminated by biological substances (eg blood, microorganisms) and other hazardous substances (eg medications, chemicals). All sharps, unless known to be sterile, should be considered contaminated.

### What sharps may be encountered?

Examples of sharps that may be generated in general practices and other office- and community-based practices are:

- needles
- scalpels
- stitch cutters
- glass ampoules and vials
- sharp plastic items
- punch biopsy equipment
- lancets
- wire cytology brushes
- razors
- scissors
- box cutters.

Staff who may come in contact with sharps need education regarding the safe use and disposal of sharps (*Box 2.1*).

## Box 2.1. Safe sharps management

### Do

Do think about safe disposal before generation of sharps. Sharps are best disposed of at the point of use. Strategically placed sharps containers need to be immediately available in all areas where sharps are generated.

Do accept responsibility for the safe disposal of sharps. The person who generates sharps is responsible for its safe disposal.

Do dispose of sharps correctly. Ensure that sharps are immediately placed into a sharps container after use, or placed into a kidney dish if not disposed of immediately.

Do ensure that sharps containers:

- are placed out of the reach of children
- are properly mounted to prevent falling over
- are closed and replaced as appropriate
- are compliant with Australian Standards.

Do ensure that:

- the opening of the sharps container is clearly able to be seen by the health professional when disposing of sharps to avoid accidental injury from protruding sharps
- scalpel blade removers are securely mounted to the wall
- full sharps containers are stored safely until collected.

### Don't

Don't resheath, remove or bend used needles. Most sharps injuries occur when attempting to manipulate a used needle.

Don't handle scalpel blades. When loading or removing scalpel blades, use artery forceps to hold the blade. Alternatively, used blades may be removed with a properly installed, approved scalpel blade removal device.

Don't pass sharps directly from person to person. When passing sharps such as scalpel blades or syringe and needle from one person to another, use a sterile kidney dish to contain the sharp.

Don't overfill sharps containers. The practice of compacting sharps by shaking the container, or forcing more sharps into an already full container can lead to a sharps injury.

Don't reopen a full sharps container: attempting to reopen a full container can lead to a sharps injury.

Don't hold 'hands free' scalpel removal devices by hand. Mount according to the manufacturer's instructions securely on a wall.

The risk is not just theoretical; sharps injury has resulted when these practices are not followed.

## When do sharps injuries occur?

Sharps injuries occur most often:

- during use of a sharp device on a patient
- after use and before disposal of a sharp device
- during or after disposal of sharp devices.

Sharps injuries can be significantly reduced when the person who is using or generating the sharp takes responsibility for its safe management and immediately disposes of it into an appropriate container.

## Dropped sharps

When managing dropped sharps:

- standard precautions should be taken (including wearing gloves)
- use tongs, artery forceps or a brush and pan (do not handle sharps manually)
- immediately discard sharps into a sharps container.

## Employer responsibilities

A fundamental principle of work health and safety legislation is eliminating workplace hazard and risk. While risk of sharps injury will vary between practice team members, it will never be eliminated for all members. Therefore risks must be strategically managed. Staff with the responsibility for infection prevention and control in the practice need to assume an active role in sharps management to successfully reduce risk without compromising patient safety or quality of care.

An organisational approach to sharps management includes training and education on the risks associated with procedures and devices, as well as implementing safer working practices. This may mean reducing the use of sharps where possible or using available safety advances that significantly reduce the risk of sharps injury. Examples include:

- self-retracting single-use lancets for blood glucose testing
- self-retracting cannula insertion devices
- vacuum blood collection tubes
- properly installed scalpel blade removal devices (if scalpel blade removal devices are not available use artery forceps to remove the blade)
- plastic ampoules replacing glass
- appropriately mounted sharps containers meeting Australian Standards.

## Section 2.3. Managing blood and body fluid exposure

All staff need to be familiar with the practice's policy regarding management of blood and body fluid exposure.

The blood and body substances of all persons are to be considered potential sources of infection, regardless of diagnosis or perceived risk.

All staff need to be aware of how to prevent exposure to blood or body fluids.

The employer is responsible to ensure that staff receive training adequate for the tasks they are expected to perform.

The risk of acquiring hepatitis B, hepatitis C or HIV infection through blood and body fluid exposure from known positive donors ranges from 6–30%, 0–7%, and 0–0.3% respectively in different studies, dependent on the amount of blood or body fluid injected.

The blood and body substances of all persons are to be considered potential sources of infection, regardless of diagnosis or perceived risk.

All staff need to know how to prevent exposure to blood and other body substances. Staff also need to know what immediate treatment needs to be instigated. Staff should be encouraged to report occupational exposures immediately to a designated person for advice and further treatment if available. All testing procedures and follow up treatment should be fully documented.

## Employer responsibilities

The practice must have written policies and procedures to deal with accidental exposure to blood or body fluids and these should be relevant to the daily routines of the practice. These policies must be reviewed and updated regularly. All members of the practice team must know who is responsible for ensuring certain activities are carried out and who to report to in the event of an accident.

Employers must ensure that staff receive regular training and education appropriate for the tasks they are expected to perform. Practice team members involved in exposure-prone procedures (EPPs) must have access to appropriate information, training, counselling and vaccination programs.

EPPs are invasive procedures where there is potential for direct contact between the skin (usually finger or thumb of the healthcare worker) and sharp surgical instruments, needles, body parts (eg fractured bones) or spicules of bone or teeth in body cavities or in poorly visualised or confined body sites, including the mouth of the patient. During EPPs, there is an increased risk of transmitting bloodborne viruses between healthcare workers and patients.

If there is an exposure incident, the employer should analyse the cause and modify procedures as required to reduce the risk of recurrence and protect staff. See the RACGP's patient safety resources for suggestions on assessing and analysing problems (refer to *Resources*).

Healthcare workers have a responsibility to know their infectious status regarding bloodborne diseases such as hepatitis B, hepatitis C and HIV. Practices should encourage self-disclosure by ensuring confidentiality and, where practical, counselling and modification of work practices or redeployment.

## Policies and procedures

Each practice must have clear policies and procedures to provide guidance to staff on the following issues:

- safe handling and disposal of sharps
- safe handling and transport of specimens
- safe handling and disposal of waste
- environmental cleaning
- appropriate cleaning of blood and body substance spills
- safe handling and cleaning of reusable instruments
- exposure to blood and body substance spills.

## Preventing blood and body fluid exposure

Preventing blood and body fluid exposure is achieved by the use of standard precautions and implementation of safe work practices. All staff at risk of blood or body substance exposure need to demonstrate an understanding of the principles of standard and transmission-based precautions.

Depending on their role and duties, practice team members may also need to:

- use safety devices where available
- practise safe handling and disposal of sharps
- practise safe handling and transport of specimens
- practise safe handling and disposal of waste
- use standard precautions for environmental cleaning
- use appropriate cleaning methods for blood and body substance spills
- practise safe handling and cleaning of reusable instruments.

## Management of blood or body fluid exposure

Steps for managing an exposure to blood or body fluid include:

1. Decontaminate the exposed area and treat the wound.
2. Report the exposure to the infection prevention and control coordinator so that appropriate investigations and treatment are initiated immediately.
3. Test the source for HBV, hepatitis C virus (HCV) and HIV.
4. Test the exposed person for HBV, HCV and HIV.
5. Assess risk of transmission of infection to the exposed person.
6. Initiate treatment according to risk.
7. Document exposure to allow investigation of the cause to take place.
8. Refer to an infectious diseases consultant if the exposure is high risk.

Refer to *Table 2.1* for a summary of actions relating to blood and body fluid exposure. For a full discussion of the management of blood and body fluid exposure, refer to *Appendix 6*.

Table 2.1 Summary of actions relating to blood and body fluid exposure

	Exposed person	Doctor	The practice
Pre-exposure	<ul style="list-style-type: none"> <li>• Use standard precautions</li> <li>• Implement safe work practices</li> </ul>	Ensure that knowledge base regarding management of blood and body fluid exposure is current	Staff education and policies on: <ul style="list-style-type: none"> <li>• safe handling and disposal of sharps and waste</li> <li>• safe handling and transport of specimens</li> <li>• environmental cleaning, including appropriate management of blood and body substance spills</li> <li>• safe handling and cleaning of reusable instruments</li> </ul>
Exposure	<ul style="list-style-type: none"> <li>• Decontaminate exposed area, (eg wash wound, rinse eyes if splashed)</li> <li>• Report exposure</li> <li>• Ensure incident is documented</li> </ul>	<ul style="list-style-type: none"> <li>• Test source</li> <li>• Test the exposed person</li> <li>• Initiate appropriate treatment (counselling, PEP)</li> </ul>	<ul style="list-style-type: none"> <li>• Facilitate immediate treatment of the exposed person</li> <li>• Ensure that the incident is documented</li> </ul>
Post-exposure	Ensure that all instructions are followed	If necessary, referral to infectious disease specialist	<ul style="list-style-type: none"> <li>• Perform a risk analysis to determine any need for a change to systems</li> <li>• Make any changes necessary</li> <li>• Reassess to ensure changes are effective in preventing recurrence</li> </ul>

## Chapter 3. Managing the practice physical environment

### Section 3.1. Cleaning policy for the practice

Practices need to have a current cleaning policy.

The cleaning policy should identify practice team member responsibilities, work health and safety issues, procedures for routine scheduled cleaning, unscheduled cleaning and monitoring of effectiveness.

Risk analysis determines the methods, frequency and thoroughness of cleaning and the products used.

Cleaning is an important part of the standard precautions to achieve a basic level of infection prevention and control.

Specific cleaning requirements will vary for each practice. However, all practices need a cleaning policy that includes both:

- routine, scheduled cleaning of all surfaces and equipment to reduce dust and dirt which can harbour microorganisms
- unscheduled cleaning for blood, body fluid and other spills.

All staff should be included in the cleaning policy.

Risk analysis determines the methods, frequency and thoroughness of cleaning and the products and equipment used. Products have been developed for the healthcare environment for spot cleaning and disinfection so that practices can select an option to suit rather than having to dilute and change solutions daily.

Practice cleaning policies need to outline:

- the person(s) with overall responsibility for infection prevention and control and for cleaning in the practice
- work health and safety issues
- scheduled cleaning
- unscheduled cleaning
- monitoring of outcome.

All staff members who have responsibility for cleaning, including contract cleaners, must adhere to the practice cleaning policy. Where a practice engages contract cleaners, the policy should be included in any contract.

### Responsible person

Each practice needs to appoint a person responsible for ensuring implementation of practice cleaning policies. All practice team members and any contract cleaners need to be able to identify this responsible person, be aware of the responsibilities of the person and should report to them any problems or events associated with cleaning (eg exposure to blood or body fluids).

## Work health and safety issues

The cleaning policy should address work health and safety issues relevant to environmental cleaning, including:

- the use of standard precautions
- the use of PPE in particular circumstances
- blood or body fluid exposure protocol
- correct product use and the location of material safety data sheets in the event of chemical exposure
- contact details for the relevant jurisdictional poisons authority.

## Scheduled cleaning

Practices need to have a cleaning schedule that ensures that the practice is systematically and appropriately cleaned. The cleaning schedule outlines the staff who are responsible for cleaning, the surfaces that need cleaning, the frequency of cleaning, the cleaning method and the products to be used. Refer to *Table 3.1* for an example of a cleaning schedule.

### Scheduled cleaning duties

The cleaning schedule should identify the staff who have responsibility for cleaning and their specific duties. This will also enable task-specific education and training.

Contract cleaners need to clearly understand their role in the practice's infection prevention and control, including when, how and why they need to clean specific surfaces and equipment.

### Surfaces that need scheduled cleaning

All environmental surfaces within the practice should be included in the cleaning schedule to ensure that the practice is systematically cleaned. The level of cleaning should be determined based on the risk of transmission of contamination or infection. Risk assessment considers the frequency of traffic or bodily contact of each surface.

Surfaces in frequent use and likely to become soiled over a day include carpets, toilet/bathroom fixtures, consultation room furniture and equipment (examination couch, desk and medical equipment).

Surfaces with minimal contact include windows, walls, doors and general furniture.

Some frequently touched items are unreasonable to clean after each use (eg pens, charts, handles, phones, keypads, computer keyboard, mouse) and should be considered always contaminated. A practice's risk assessment should consider if and when frequently touched items should be cleaned. Hand hygiene should be performed before patient contact if the health professional has had contact with these items.

### Toys

Toys are a particular surface item that can present a risk of both cross-infection and choking. If practices choose to have toys, they should consider toys that are:

- age appropriate and safe
- made of nonporous material such as plastic or intact lacquered wood and easily disassembled for cleaning. Alternatively, 'disposable' items (eg colouring-in sheets) can be considered for use
- not soft or stuffed or made of cloth
- not able to retain water, as moisture is a potential source of infection.

Toys need to be cleaned regularly in water and detergent and then dried. If toys are soiled or if staff observe a child 'mouthing' a toy, they should be immediately removed for cleaning.

Consider removing all toys during a disease outbreak.

## Frequency of scheduled cleaning

The cleaning schedule should allow for more frequent cleaning of surfaces that are subject to frequent contact (eg heavy traffic or high use areas). Frequently touched surfaces should be cleaned:

- at least daily
- when visibly soiled
- after every known contamination by a likely pathogen.

Surfaces that are subject to less frequent contact can be cleaned less frequently.

## Scheduled cleaning method

Effective cleaning consists of a combination of the use of mechanical action, detergent and water. Following cleaning, drying needs to occur as moisture encourages the growth of microorganisms (eg surfaces need to dry rapidly, instruments need to be dried after cleaning).

Most hard surfaces can be cleaned adequately with water and detergent.

On surfaces where there is a higher risk of contamination with infectious agents, a disinfectant solution can also be used. The disinfectant should be used after physical cleaning with water and detergent if a combined cleaning/disinfectant product is not used.

Detergent or disinfectant solutions should be prepared by the practice in accordance with the manufacturer's directions. The practice should date the container and develop a policy in regards to storage and shelf life.

## Products to be used for scheduled cleaning

Practices need to decide on the products that will be used for cleaning in various situations. The products need to be appropriate to the proposed use. For ease of convenience, safety, and to improve compliance, practices may consider standardising and minimising the number of products available in the practice.

Employers have an obligation to obtain the relevant material safety data sheets (MSDS) and keep them in a location easily accessible by staff for referral before use and in the event of a product exposure incident. An MSDS is prepared by the manufacturer of a hazardous substance and describes a chemical's properties, uses, health hazard information and precautions for use and safe handling.

### Detergents

In most instances, the detergent used for instrument cleaning is also satisfactory for most environmental cleaning; however it may be significantly more expensive. Mildly alkaline detergents in the pH range of 8.0–10.8 are preferred over neutral pH detergents in most applications as alkalinity improves the detergent's cleaning efficacy. Detergent products selected for general cleaning can have combined disinfecting abilities.

Detergent wipes are useful for spot cleaning and are disposable. There are many brands of suitable detergent wipes in varying sizes available to practices. These should be conveniently placed to increase the timely cleaning of surfaces by staff (eg dressing trolleys). These eliminate the need for preparing daily solutions.

### Surface disinfectants

Disinfectants can reduce the number of microorganisms on a surface, but they are not a replacement for thorough cleaning. The cleaning process determines the effectiveness of any disinfectant.

Disinfectants have been shown to fail where prior cleaning is nonexistent or ineffective.

Disinfectant use is not mandatory but may be used following cleaning with detergent and water, and can be combined with detergent in some products. Disinfectants should be considered when there is a risk of contamination with infectious agents and can be combined with detergent in some products.

The Therapeutic Goods Administration now regulates all chemical disinfectants. Higher categories have an AUST R or AUST L number listed on the label, indicating that the claims have been approved. There are differences in chemical composition of different products and it is important to use the correct product and follow the manufacturer's instructions.

Alcohol-based disinfectants can cause rubber to swell, plastic to harden and glues to weaken, and are highly flammable when used in high concentrations. However, in general terms they are effective and useful products. Alcohol-based disinfectants can be used on semicritical and noncritical equipment such as thermometers, tape measures and stethoscopes after use.

Chlorine-based disinfectants have limited application in general practices and other office- and community-based practices. They have work health and safety related issues (eg lung and skin irritation), cause instruments to rust, bleach soft fabrics and have an unpleasant odour.

Quaternary ammonium compounds have detergent as well as disinfectant properties. They can be used for surface cleaning as long as the user understands that disinfection is achieved by cleaning followed by re-application of the product for sufficient contact time. They are deactivated by soaps and anionic detergents and can cause contact dermatitis of the hands.

## Cleaning tools

Part of a cleaning protocol involves reducing contamination of cleaning tools.

Buckets and mop heads need to be washed then rinsed clean in hot water after use, and the mop heads wrung out and hung to dry. Wet mops can develop unacceptable levels of contaminating bacteria so consider having a spare mop or a spare detachable mop head so that only a clean, dry mop is used. Single-use mop heads are available but carry an added cost.

Reusable cleaning cloths need to be cleaned (washed) and dried (hung out or mechanically dried) after use, when wet or soiled. Sponges do not dry easily and their use should be avoided. Practices should consider eliminating cleaning cloths, instead cleaning the clinical areas and toilets with either detergent wipes or water and detergent with paper towel.

Brooms should not be used in any healthcare area as they disperse dust and microorganisms into the air.

## Monitoring of outcome

Monitoring of cleaning is usually done through visual inspection. This often means a spot check of a surface that was scheduled for cleaning the day beforehand. Routine microbiological sampling of the practice environment is not recommended due to considerable limitations.

Adherence to the cleaning schedule can also be monitored by having cleaning staff make entries into a cleaning record.

Discrepancies in the cleaning record or any observed problems in cleaning can be reported to the responsible person (*Table 3.1*).

Table 3.1. Example of cleaning schedule

Surface	Product	Method	Frequency	Person responsible
<ul style="list-style-type: none"> <li>Smooth surfaces, (eg bench tops, couches, sinks, toilets and floors)</li> <li>High touch surfaces (eg door handles, light switches)</li> </ul>	Detergent and water, damp cloth or Disposable wipes	<ul style="list-style-type: none"> <li>Wiping/rubbing with a damp cloth, or use disposable wipes</li> <li>Dry the surface with a clean cloth</li> </ul>	As determined by the practice (eg bench tops, sinks, toilets and treatment room floors daily, other floors every second day)	
Smooth floors	<ul style="list-style-type: none"> <li>Detergent and water</li> <li>Mop and bucket</li> </ul>	Damp mopping to ensure dust is captured and not dispersed into the air (Note: mops need to be cleaned and left to dry after use, not left wet in a bucket)	As determined by the practice	
Carpet (regular vacuum cleaning)	Vacuum cleaner	Vacuum	As determined by the practice (eg daily)	
Carpet (spot cleaning)	Spill kit or carpet cleaning solution recommended by manufacturer or Vacuum cleaner	<ul style="list-style-type: none"> <li>Use spill kit to blot up excess moisture and other matter (eg vomit)</li> <li>Clean according to directions for use</li> <li>Assist carpet to dry quickly (ventilation/heating) and quarantine until dry</li> <li>Use carpet cleaning solution for other spills</li> <li>Use vacuum cleaner for solid objects</li> </ul>	As determined by the practice (eg when soiled)	
Carpet (steam/dry cleaning)	Usually performed by a carpet cleaning contractor with suitable equipment and products	<ul style="list-style-type: none"> <li>Perform out of hours if possible</li> <li>Assist carpet to dry quickly (ventilation/heating) and quarantine until dry</li> </ul>	As determined by the practice (eg when soiled or yearly)	
Fabrics (eg furniture)	Fabric cleaner recommended by the manufacturer or Detergent and water	Clean according to directions for use and quarantine until dry	As determined by the practice (eg when soiled)	
Toys	Detergent and water	Clean thoroughly	As determined by the practice (eg when soiled or immediately after use if young children are observed 'mouthing' toys, or quarterly)	
Other items (eg stethoscopes, tape measures)	Detergent and water, alcohol wipes	Clean thoroughly, wipe over with alcohol wipe but avoid on stethoscope tubing	As determined by the practice	

## Section 3.2. Managing blood and body fluid spills

Blood or body fluids need to be treated as potentially infectious substances that can transmit disease should contact occur.

Blood and body fluid spills need to be managed promptly.

Managing spills depends on the type of spill, possible microorganisms present, type of surface and the area where the spill occurs. Spills may be vomit, blood, urine or any other body substance. Blood or body substances (except sweat) need to be treated as potentially infectious materials that can transmit disease should contact occur.

All members of the practice team need to be familiar with the practice's policy and procedure for managing blood and body fluid spills.

Blood and body fluid spills need to be treated promptly to reduce the potential for contact with other patients, staff or visitors, and to reduce the damage done to surfaces.

### Spills kit

Practices need to have a kit readily available to manage spills. The spills kit can consist of a suitable rigid-walled labelled container (eg bucket or plastic sealable box) containing:

- a laminated guide with a list of spill kit contents and the management procedure
- nonsterile or utility gloves
- goggles/face shield
- masks
- disposable aprons
- plastic (clinical and general) waste bags
- kitty litter, polymerising beads or other absorbent material
- paper towels
- scrapers (eg two small pieces of cardboard)
- detergent to be made up when needed or detergent wipes
- hazard sign to quarantine area.

The spills kit may be combined with an infection prevention and control kit (see *Appendix 7*).

## Method for cleaning spills

Standard precautions apply including PPE appropriate to the task (eg gloves, goggles/face shield, apron – which are put on well away from the spill).

The method for cleaning spills will depend on the volume of the spill and where it occurs.

1. Wipe up and safely remove any solid matter and excess material.
2. If the spill is on a hard surface:
  - clean with detergent and water
  - dry the surface
  - consider further treatment such as disinfection if site is large or in contact with skin
  - dispose of contaminated material including PPE as per local requirements.
3. If the spill is on nonremovable soft fabric or carpet:
  - do not use liquid on the spill as this will spread the spill
  - use kitty litter, polymerising beads or other absorbent material
  - scrape up residue safely without causing material to disperse
  - damp-pat surface (do not wipe or scrub) to remove further material
  - dispose of contaminated material including PPE as per local requirements
  - clean fabric or carpet with damp cloth (detergent and water) or recommended carpet cleaning agent
  - quarantine the area until the soft fabric or carpet is dry.
4. A disinfectant may be used after cleaning.
5. Hand hygiene should be performed after management of any spill.

## Products for cleaning spills

The detergent used for general cleaning is satisfactory for cleaning spills.

Where transmission-based precautions apply, a disinfectant should be chosen that has label claims against the microorganism of concern.

## Section 3.3. Linen

Staff need to be educated about when to change linen; the use of appropriate precautions during handling; and the washing, drying and storage of linen.

Staff may wish to consider alternatives to linen.

There is little evidence of disease transmission by linen in general practices and other office- and community-based practices. If linen is carefully handled and cleaned, any potential risk of cross infection is virtually eliminated.

Practices should have a policy on the management of linen. Staff need to be educated about when to change linen; the use of appropriate precautions during handling; and the washing, drying and storage of linen.

If practice policy is not to use linen, then the policy needs to indicate how alternatives are to be used.

### How often to change linen

Doctors and other health professionals need to assess the risk of infection to patients when considering when to change linen.

Linen needs to be changed if:

- a patient requires the use of contact precautions, for example, is known or suspected of having CAMRSA, scabies or lice
- there has been a blood or body fluid spill on the linen
- the linen is visibly soiled
- the linen has absorbed odour.

Other fabric items such as modesty sheets, blankets, pillow cases and towels all need to be similarly changed and cleaned. Cloth hand towels are a special case, and should only be used once before disposal as a single-use item or before being reprocessed.

There may be other circumstances where linen may be changed, such as before an operative procedure.

Appropriate use of reusable or disposable linen protectors can minimise linen usage.

### Precautions when changing linen

Practices should:

- use appropriate PPE as required. If soiled, use gloves, and if dripping with fluid or body substances, also wear a mask, apron and safety glasses
- check that sharps or other items are not caught up in linen. Never shake linen
- place used linen into a covered, lined container while awaiting cleaning
- store used-linen containers away from clean linen, preferably in a 'dirty' utility area.

Linen that contains expressible blood or body fluids needs to be collected into a plastic bag before being placed in the used linen receptacle.

The examination or treatment couch should also be cleaned with detergent wipes or diluted detergent solution and paper towel if the linen was contaminated with blood or body fluids or in contact with patients requiring contact precautions. This may be followed by a disinfectant wipe or solution after contact with patients with conditions such as CAMRSA.

## Using offsite linen services

Laundry services in some areas of Australia will process linen on behalf of health services. Other services such as hospitals or nursing homes may also provide laundry services to general practices and other office- and community-based practices.

## Processing linen onsite

### Pre-wash stain treatment

Appropriate PPE should be worn when undertaking the immediate treatment of blood and other stains. This can be by rinsing the blood or contamination off, applying an oxygenated stain remover or placing the item in a bucket of water with detergent or oxygenated stain remover to prevent the spill drying before washing.

### Washing

Either a hot or cold wash cycle with appropriate detergent should be used. Activated oxygen-based laundry detergents provide antimicrobial activity in addition to their stain-removing properties and are a good addition to the wash cycle. Chlorine bleach is also an economical, broad-spectrum chemical germicide but is not an appropriate laundry additive for all fabrics.

### Drying

Mechanical drying in a tumble dryer is the preferred method because of the effects of thermal disinfection. Regardless of whether hot or cold water is used for washing, the temperatures reached by this drying method provide additional significant antimicrobial action. The materials dictate dryer temperatures and cycle times but linen needs to emerge dry from a hot cycle.

### Storage

Clean linen should be stored in a clean, dry and dust-free environment.

## Section 3.4. Waste management

Practices need to have a current waste management policy.

Staff need education and training in handling and disposal of wastes.

Waste needs to be safely and appropriately segregated into clinical (and related) waste and general waste at the point of generation.

Management of waste must conform to state or territory regulations and AS/NZS 3816.

Effective and safe waste management is important not only to reduce the risk of infection to staff and patients, but also to reduce the impact on the environment and reduce costs. The three 'waste management goals' of recycling – reduce, reuse and recycle – can all be brought into play in general practices and other office- and community-based practices to help minimise waste, but have limitations due to the infection prevention and control issues and the single use nature of many items.

Practices need to have a waste management policy that covers:

- the correct segregation of waste into three streams: general waste, clinical waste and related waste
- storage of waste
- disposal of waste
- work health and safety procedures
- responsible person (monitoring, education of staff).

### Waste segregation

Waste needs to be segregated into clinical and related waste and general waste at the point of generation. Proper waste segregation allows for appropriate disposal of different forms of waste. Waste segregation also assists in waste reduction and recycling.

A separate bin is required for each waste stream. The correct packaging is the responsibility of the practice and practice team members must have training in the handling and disposal of wastes.

Waste transport and disposal companies are required to notify practices in writing of waste segregation requirements, and may refuse to collect incorrectly segregated or unsafely presented waste.

### Clinical and related waste

Clinical waste is waste that has the potential to cause infection, sharps injury or public offence. There is no current national definition of clinical waste.

Practices need to check their relevant state or territory environmental protection agency definition of clinical waste and the related requirements as this can differ between jurisdictions.

In general, clinical waste includes:

- discarded sharps
- human blood, fluids and tissue (excludes teeth, hair, nails, urine and faeces)
- any waste from patients known to have, or expected of having, an epidemiologically significant communicable disease (eg influenza) or are suspected or known to be colonised/infected with an antibiotic resistant organism (eg MRSA)
- material that contains free flowing or expressible blood.

If appropriately segregated, only a small percentage of the total waste produced by a practice will be clinical waste.

Related waste includes pharmaceutical, chemical and cytotoxic waste.

Management of clinical and related wastes must conform to state or territory regulations and AS/NZS 3816 *Management of clinical and related waste*.

## Clinical waste containers

Clinical waste containers need to be:

- rigid walled
- sealable with a secure lid
- easily handled: ideally they should have hands-free operation
- appropriately labelled: yellow in colour, biohazard symbol displayed and be labelled as 'clinical waste'.

Liquid clinical waste should be absorbed using 'kitty litter' or polymerising beads, then bagged to avoid leakage and potential for splash.

Sharps containers are a particular type of clinical waste container that need to meet Australian Standards requirements.

## Cytotoxic waste containers

Cytotoxic waste containers should have the same properties as clinical waste containers. They should be purple, display the telophase symbol in white and be labelled 'cytotoxic waste'.

Unused or expired pharmaceuticals can be returned to pharmacies for safe disposal.

## General waste

General waste is any waste that does not fall into the clinical and related waste categories. It includes:

- office waste
- kitchen waste
- urine, faeces, teeth, hair, nails
- disposable nappies
- used tongue depressors
- non-hazardous 'pharmaceutical' waste (eg out-of-date saline)
- items contaminated with blood or body substances not to an extent considered clinical waste (ie not contaminated with expressible blood) – practices need to check their relevant state or territory environment protection agency definition and requirements.

General waste can further be divided into recyclable and nonrecyclable material.

Practices should consider their waste segregation and decide on what type of containers are required.

Practices may provide receptacles for disposal of:

- recyclables (eg separate waste and confidential waste bins under desk, glass and plastic recyclables bin in the kitchen)
- waste contaminated with blood or body fluids that is not clinical waste (eg for disposing of tongue depressors, using a small bin mounted on a wall inaccessible to small children).

## Storage of waste

Before collection and disposal, clinical and related waste should be appropriately stored as follows:

- The storage area should be dedicated to clinical and related waste storage (no mixing with other stored materials such as supplies).
- The storage area should be appropriately signed.
- Clinical waste needs to be double bagged, with the outer bag being yellow (or purple) to identify the contents for appropriate disposal.
- Bags need to remain within secure outer containers that are appropriately labelled.
- The waste storage area needs to be secure (not accessible to the public).

A spill kit should be located in the storage area or nearby.

General waste should be stored in covered receptacles such as a rubbish bins in a secure location. It may be co-located with the clinical waste bins.

## Disposal of waste

Clinical and related waste must be transported by a licensed transport and disposal company that will take it for appropriate treatment and disposal. The generator of the waste (the practice) is responsible for it until it has been rendered safe.

The transport/disposal company may refuse to collect from overflowing, wrongly segregated or unlabelled bins.

## Work health and safety

The waste management policy should consider:

- minimising human contact with waste (eg reducing double handling)
- standard precautions including appropriate use of PPE
- avoiding manual compaction of waste
- safe transfer of waste from clinical areas to storage area
- safe storage
- procedures to deal with spills
- a blood and body fluids exposure protocol.

## Responsible person

The practice should nominate a person responsible for waste management. The responsibilities of this person may include:

- monitoring for appropriate waste disposal (eg that waste is being appropriately segregated)
- being the contact person for waste transport/disposal companies
- providing task-specific waste management education for staff.

## Chapter 4. Processing reusable equipment

### Section 4.1. Risk assessment and processing reusable equipment

An appropriate risk assessment based on the Spaulding classification is required to determine the appropriate level of processing required for specific reusable medical devices.

Practices need to ensure that staff whose duties require them to process equipment for reuse have received adequate training and competency checking.

The practice infection prevention and control coordinator needs to ensure the level of processing for specific reusable medical devices and equipment is appropriate to the risk of infection posed by their reuse. The Spaulding classification (*Table 4.1*) should be used as a general basis for the risk assessment. The site of use (eg skin, mucous membranes, wounds) is a key determinant of level of risk to the patient.

Table 4.1. The Spaulding classification

Level of risk	Application	Process
Critical	Entry or penetration into sterile tissue, cavity or bloodstream	Sterility is required
Semicritical	Contact with intact nonsterile mucosa or nonintact skin	Sterilisation preferred where possible. If sterilisation is not possible then high-level chemical disinfection is required
Noncritical	Contact with intact skin	Clean as necessary with detergent and water

The practice needs to have policies and procedures describing every aspect of instrument and equipment reprocessing.

The RACGP believes that health professionals need to balance the following when determining what is reasonable in the processing of reusable equipment:

- the probability of harm to a patient
- the likely seriousness of the harm
- the feasibility of meeting all processing requirements in the practice
- complying with the manufacturer's instructions around the recommended use of equipment and products to ensure appropriate sterilisation.

In Australian general practice and other office- and community-based practice contexts, a risk-based assessment will result in some differences between primary care and hospitals. For example, it is the opinion of the RACGP that semicritical devices used on intact mucosa or intact skin require cleaning followed by low- or intermediate-level disinfection, whereas a strict interpretation of the *Australian guidelines for the prevention and control of infection in healthcare* (refer to *Resources*) would lead to the conclusion that semicritical items would require high-level disinfection.

## Section 4.2. Staff training

Practices need to ensure that staff involved in processing equipment for reuse have received adequate training and competency assessment. Training and competency assessment needs to be documented.

Aspects that require training and competency testing include:

- correct use of standard precautions, including hand hygiene and PPE
- cleaning of equipment and the reprocessing area, including correct use of detergents and other equipment used by the practice
- correct packaging of reusable medical devices and equipment
- correct loading of the steriliser
- choosing the correct cycle
- monitoring and recording the sterilisation cycle
- unloading the steriliser
- parameters for releasing reusable medical devices and equipment for reuse
- correct storage of equipment and reusable medical devices
- tracking of items used in critical procedures
- rotation of sterile stock
- ability to detect abnormalities in the process and take appropriate corrective action
- steriliser maintenance requirements:
  - daily, weekly, monthly, quarterly and annual maintenance
  - annual calibration and servicing
  - validation
- adherence to the practice's procedures regarding the processes for operation and maintenance of the steriliser.

## Section 4.3. The sterilisation process

Sterilisation is more than simply putting loads through a steriliser. It is a process that begins with prior cleaning of reusable medical devices and equipment and continues through to cycle monitoring and storage ready for reuse.

The processes of sterility assurance include all aspects of equipment reprocessing and staff education.

### Sterility assurance

A comprehensive sterility assurance program incorporates every aspect of equipment processing so that a sterile product is the result of a reliable and reproducible process.

The processes of sterility assurance include all aspects of equipment reprocessing and staff education.

### Summary of equipment reprocessing

Practices should follow a documented validated process, which includes:

- cleaning reusable medical devices and equipment
- packaging, sealing and labelling
- using Class 1 chemical indicators on every load to differentiate which packs have been through the steriliser, noting that colour change does not imply sterility, just that they have been subjected to some heat
- loading the steriliser
- monitoring the sterilisation cycle by printout of the parameter or use of a Class 5 or 6 chemical indicator or data logger
- unloading the steriliser
- before releasing the load for use, checking the printout, data logger or the Class 5 or 6 chemical indicator
- recording the following:
  - load description and load number
  - results of cycle monitoring
  - unloading
  - pack condition (dry, intact seals, chemical indicators have the correct colour change)
  - date and signature of staff member authorising release of the items for use or rejection of the load
  - details of the issues causing the rejection, where appropriate
  - detection of abnormalities in the process and appropriate corrective action, where appropriate
- storage, distribution and handling to the point of use
- daily, weekly and annual steriliser maintenance
- annual servicing, calibration and validation.

Appendix 8 provides a nine-step summary of the reprocessing cycle.

## Section 4.4. Equipment processing area

Use a designated area for processing all instruments and equipment for reuse.

Practices must establish a workflow pattern systematically moving from 'dirty to clean' within the designated area.

### Design of the equipment processing area

It is essential to establish a workflow pattern systematically moving from 'dirty to clean' within the designated area.

A one-way workflow will ensure that dirty reusable medical devices do not come into contact with clean reusable medical devices.

### Hand hygiene

Hand hygiene should be performed:

- when moving from dirty to clean areas
- after handling soiled equipment
- before handling or packaging clean equipment.

Appropriate gloves (eg utility or puncture resistant, heavy duty) should be worn when handling contaminated reusable medical devices at all times.

### Sinks

The equipment processing area needs to have two sinks: one 'dirty' sink designated for washing and one 'clean' (or cleaner) sink for rinsing washed reusable medical devices. If separate sinks are not available for washing and rinsing then a clearly labelled, suitably sized container may be used.

All sinks and any containers used need to be cleaned after use with water and detergent as well as regularly cleaned and dried to reduce contamination.

A sluice or laundry sink can be considered for disposing of waste water from cleaning, rinsing bloody linen and cleaning buckets and mops. The sluice or laundry sink is best located in the practice laundry or utility room.

### Single sink operation

Where only one sink is available:

- obtain and label a suitably sized container to act as the 'dirty' sink
- use the container to wash the used reusable medical devices
- use the physical sink as a 'clean' sink to rinse reusable medical devices.

Use the single sink to dispose of the water from the 'dirty' container and rinsing items.

## Two sink operation

Where two separate sinks are available:

- use the first as a 'dirty' sink for washing used reusable medical devices
- use the second as a 'clean' sink for rinsing the washed reusable medical devices

## Three sink operation

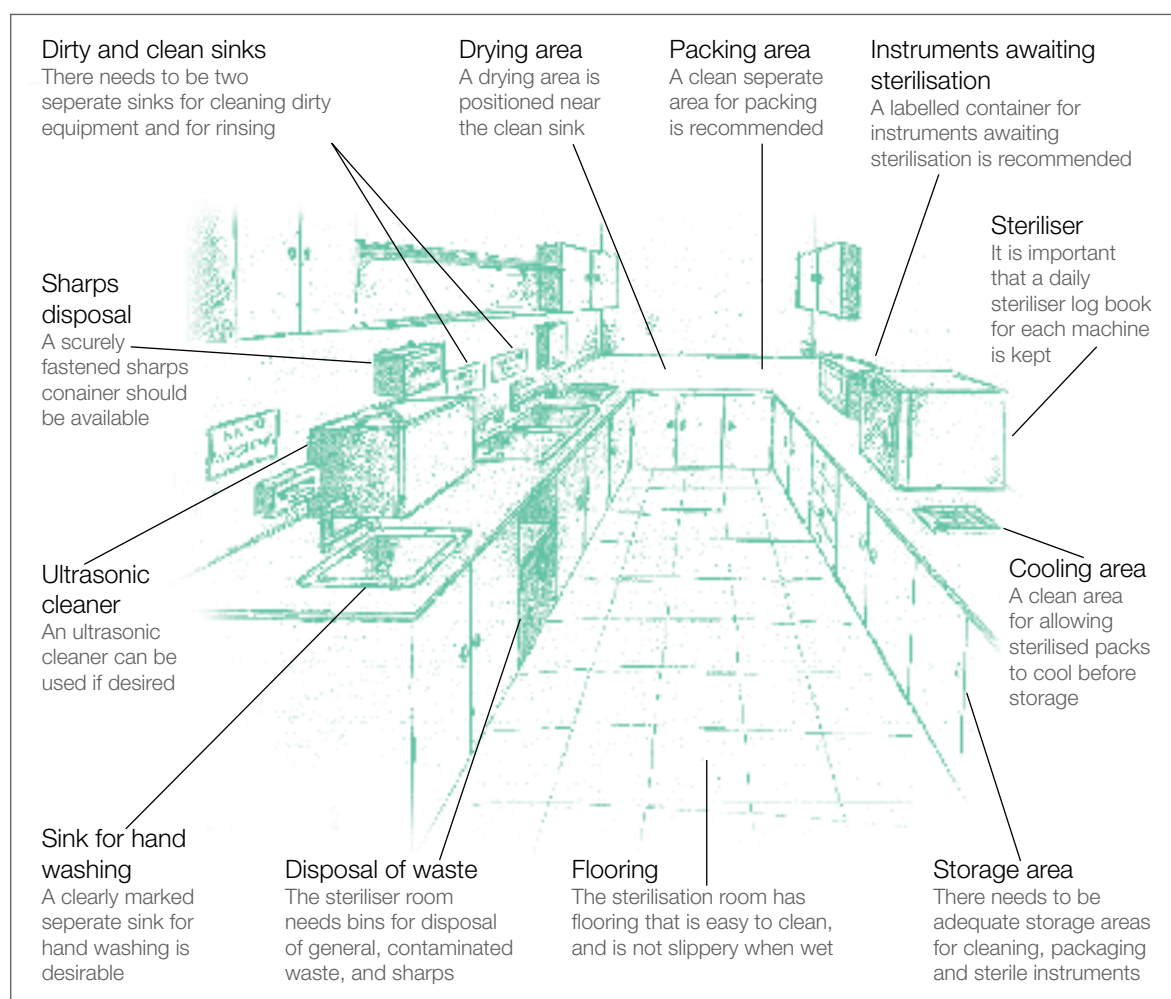
Where three separate sinks are available, or when remodelling/designing a practice, consider having a 'dirty' sink, a 'clean' sink and a separate sink for hand washing.

## Bench tops

Bench tops should be regularly cleaned and kept clean. If space is restricted, an area can be made temporarily clean by placing a sheet of disposable plastic-backed paper or a suitably labelled tray or container in the area.

Packaging of items must take place on a clean, dry surface away from contaminated items. The bench top must be cleaned and dried between uses.

**Figure 4.1 Suggested processing area design and layout**



## Section 4.5. Reprocessing equipment

All staff expected to operate and monitor equipment must be appropriately trained and assessed for competency and their ability to detect malfunction and take corrective action.

Ultrasonic cleaners clean but do not sterilise or disinfect reusable medical devices.

Automatic washer disinfectors clean and disinfect but do not sterilise reusable medical devices.

Steam under pressure is the most reliable way of sterilising cleaned reusable medical devices and is recommended as the method of choice for sterilisation of reusable items in general practices and other office- and community-based practices.

Small steam sterilisers may be grouped by class of cycle and method of steam introduction.

- Class N cycles are those without an active drying cycle. They are not suitable for sterilising packaged items as they cannot effectively dry the load and must not be used.
- Class S cycles have an active drying cycle and may use some vacuum to assist air removal.
- Class B cycles have an active drying cycle and use a vacuum to assist steam penetration and are suitable for sterilising very long, narrow, cannulated devices.

Practices should consider the manufacturer's instructions relevant to the reusable medical devices which the steriliser claims to be capable of sterilising.

All staff who are expected to operate and monitor equipment must be appropriately trained and assessed for competency and their ability to detect malfunction and take corrective action. Additional education needs to be provided when new procedures or equipment are introduced.

## Washing and drying equipment

### Ultrasonic cleaners

Ultrasonic cleaners are efficient and effective at cleaning (and are safer for the user than manual cleaning) but they do not sterilise or disinfect reusable medical devices.

Ultrasonic cleaners use ultra-high frequency sound waves that pass through water, creating cavitation. Cavitation is the implosion of microscopic bubbles causing high-energy vacuum and movement. This pulls dirt and contaminants from the surfaces being cleaned.

Practices that use ultrasonic cleaners should refer to the manufacturer's instructions.

### Advantages

- Ultrasonic cleaners clean surfaces and cavities without scratching, brushing or scraping.
- They are efficient as they have short cleaning times.
- They can reduce the work health and safety hazards of instrument cleaning by staff as compared with manual cleaning.
- They are very simple and easy to use.
- Concentration of chemicals required for ultrasonic cleaning can be less than that in conventional cleaning.
- Smaller models are available, providing a cost-effective option.

### Disadvantages

- Ultrasonic cleaners require monthly aluminium foil testing.
- Not all items can be ultrasonically cleaned.
- They don't clean large loads as quickly as small loads due to energy absorption.
- Large, heavy parts can 'shadow' each other or themselves, resulting in poor cleaning.
- Items must be rinsed as soon as the cycle stops or debris will settle back onto the items.

Note: for small numbers of easy-to-clean instruments, ultrasonic cleaners may not be necessary.

### Automatic washer disinfectors

Automatic washer disinfectors clean and disinfect but do not sterilise. The high temperatures and very alkaline detergents clean reusable medical devices by thermal and chemical means.

Practices that use washer disinfectors should refer to the manufacturer's instructions for their appropriate use.

Domestic dishwashers, while similar, are not suitable for washing reusable medical devices and must not be used for this purpose.

### Advantages

- Automatic washer disinfectors clean, disinfect and dry items ready for packaging and subsequent sterilisation.
- They reduce the work health and safety hazards of instrument cleaning by staff.
- They remove the need for manual drying.

### Disadvantages

- Automatic washer disinfectors are expensive due to their high capital and running costs and maintenance requirements.
- Cycles can take a long time – approximately 1 hour (*Table 4.2*).

**Table 4.2. Time-temperature relationship for thermal disinfection**

Surface temperature	Minimum disinfection time
90°C	1 minute
80°C	10 minutes
70°C	100 minutes

## Sterilisers

In general practices and other office- and community-based practices, sterilisation can be achieved by dry heat or by steam sterilisation under pressure (autoclaves). Systems of ionising radiation, ethylene-oxide, peracetic acid or hydrogen peroxide plasma sterilisation are not generally applicable due to cost, size or complexity.

Routine cycle monitoring and validation are required for all sterilisers to ensure sterility. Care must also be taken to ensure the steriliser is operated and maintained according to the practice's documented procedures based on the manufacturer's instructions.

Under Therapeutic Goods Administration regulations, all new devices sold in Australia must perform the essential functions of their intended purpose.

### Dry heat sterilisers

Dry heat destroys microorganisms by charring the carbon compounds of their structure. This takes high temperatures and a considerable period of time (eg 120 minutes plus penetration time at 160°C). Forced-air dry heat sterilisers are fan assisted so the heat is evenly distributed.

The use of dry heat sterilisers is extremely limited in general practices and other office- and community-based practices. In addition to the relatively long sterilisation times, the 160–80°C temperature range may cause damage to materials. Dry heat sterilisation should only be used for materials that might be damaged by moist heat or are impenetrable to moist heat. It is reasonable to say their use is not recommended.

Note: Domestic ovens, while similar, are unsuitable for sterilising reusable medical devices and must not be used for this purpose.

### Small steam sterilisers (autoclaves)

Steam under pressure is the most reliable way of sterilising cleaned reusable medical devices and is recommended as the method of choice for sterilisation of items in general practices and other office- and community-based practices.

Steam under pressure works by transferring the latent heat of condensation to the microorganisms on the surfaces of the reusable medical devices. This results in coagulation of the microorganism's protein structures, resulting in their death.

All manufacturers and suppliers of bench top and portable sterilisers must lodge applications for their products to be listed on the Australian Register of Therapeutic Goods: all bench top and portable sterilisers are now required to be listed on the register. Purchasers should also ensure that the manufacturer has obtained pressure vessel compliance relevant to the practice's state or territory.

Australian Standards have begun a move to harmonise with European Standards (EN 13060:2004 *Small steam sterilizers*). In Europe, there has been a reclassification of steam sterilisers according to the size and type of sterilisation cycle they are capable of performing. This differs from previous standards, which classified sterilisers according to location and the method of steam introduction. For example, a typical bench top steriliser of the gravity displacement type with an active drying cycle will now be described as small steam steriliser capable of Class S cycles.

In addition, European Standards have seen a phasing out of gravity displacement sterilisers and a push towards more technologically advanced sterilisers incorporating the use of vacuum pumps. The European Standards recognise the variety of practice settings and items requiring sterilising. This will dictate the different performance requirements of the sterilisation cycles.

The European move away from gravity displacement units is based on the belief that the mechanism of air removal in these machines is obsolete because the process cannot be fully validated (some guidance documents state this type of steriliser is only suitable for sterilisation of unwrapped, nonporous items).

However, there is no compelling evidence that, in the usual Australian general practice and other office- and community-based practices, the use of gravity displacement units with an active drying cycle should be abandoned. The European changes highlight the need for practices to give careful consideration to the capabilities of their steriliser, irrespective of the method of steam introduction.

Downward displacement sterilisers without a drying cycle are not capable of anything more than Class N cycles (discussed immediately below) and cannot be used to provide wrapped or packaged items for storage and later use.

In most general practices and other office- and community-based practices, small steam sterilisers are still of the downward displacement type with an active drying cycle capable of providing Class S cycles (discussed immediately below).

## Steriliser classification

Sterilisers are classified according to the types of cycles they can run. The Australian Standard (AS/NZ 4815:2006) governing autoclave use in general practice and other office- and community-based practice assigns three different classes for sterilisation cycles: Class N, S and B. Some advanced sterilisers are capable of switching modes and run different classes of cycle but they are not in general use.

*Appendix 9* describes how practices may choose a steriliser.

### Class N cycles

These are cycles without an active drying cycle. They are used for sterilising unwrapped, solid items.

They are not suitable for sterilising packaged items as they cannot effectively dry the load. They cannot be used to process porous or hollow items. The use of such cycles is limited to:

- emergency situations (eg to quickly resterilise a dropped instrument during a procedure)
- disinfecting unwrapped items
- reprocessing items requiring sterilisation following use, but not required to be sterile at the time of reuse.

Routine use of Class N cycles is not appropriate in the general practice and other office- and community-based practice setting to sterilise reusable medical devices for reuse as sterile items.

### Class S cycles

For most general practices and other office- and community-based practices, the use of Class S cycles provided by gravity displacement sterilisers is adequate. These sterilisers remain the most efficient in terms of cost and monitoring.

These cycles are provided by sterilisers that have an active drying cycle and are capable of sterilising unwrapped solid goods and at least one of the following:

- porous products
- small porous items
- type A hollow items
- type B hollow items
- single wrapped products
- multiple wrapped products.

Class S steriliser types in increasing order of cycle capability are:

- Gravity (downward displacement) and active drying
  - air removal in this traditional type of steriliser is by a relatively slow process relying partly on displacement of the air by steam, and partly on mixing of chamber air with steam generated by water boiling within the chamber. During the air removal phase of operation, air is gradually removed as the air/steam mixture is continually being released via the chamber drain line, often back to the steriliser's internal water reservoir.

- Purge under pressure (assisted air removal)
  - air removal is by alternating inflow and outflow of steam.
- Single vacuum pulse (pre-vacuum, preliminary vacuum, vacuum assisted)
  - air removal in this type of steriliser is greatly assisted by an air removal pump before the sterilisation stage. The pump is often also used as part of the active drying stage ('post-vacuum') to assist in the removal of steam at the beginning of the drying cycle to speed the drying process.
- Multiple vacuum pulse (fractionated) but not 'B' type.

### Note on hollow load items

**Type A hollow load:** one open end in which  $1 \leq L/D \leq 750$ , where D is the diameter of the hollow and L is the length, with  $L \leq 1500$  mm, or an open space at both ends in which  $2 \leq L/D \leq 1500$ , with  $L \leq 3000$  mm, and which is not a B-type hollow load (eg handpiece, turbine)

**Type B hollow load:** one open end in which  $1 \leq L/D \leq 5$ , where D is the diameter of the hollow and L is the length, with  $D \leq 5$  mm, or an open space at both ends in which  $2 \leq L/D \leq 10$ , with  $D \geq 5$  mm, and which is not a A-type hollow load (eg operating cup, surgical aspirator tips).

Most, if not all, Class S sterilisers are incapable of sterilising hollow load A items.

Further explanation of these terms is available in the *Glossary*.

## Class B cycles

These classes of cycles are capable of sterilising:

- all packaged items (single and double wrapped)
- hollow items that do not exceed the specifications of hollow type A
- solid and porous items.

Air removal in this type of steriliser utilises one or more vacuum stages causing repeated venting of air together with positive incursions of steam under pressure (fractionated vacuum system). There are various systems utilising varying chamber pressures above and below atmospheric pressure (trans-atmospheric), above atmospheric pressure (supra-atmospheric) or below atmospheric (sub-atmospheric).

Class B cycles are suitable for sterilising very long, narrow, cannulated devices (eg trocars, tubing).

Sterilisers with Class B cycles (fractionated vacuum) are the most expensive to buy and operate and may require onsite supply of deionised water.

In dental practice, the use of long hollow reusable medical devices and the need for fast turnaround favours the use of Class B cycles.

## Consumables

### Instrument detergent

Practices should choose instrument detergents that are:

- mildly alkaline as they are more effective at removing blood and fatty substances (neutral detergents can also be considered as most reusable medical devices used in general practices and other office- and community-based practices are not heavily soiled and are easy to clean)
- free rinsing to avoid leaving a film which could harbour microorganisms
- low foaming (high-foaming detergents make items more difficult to see when washing and generate aerosols, increasing the risk of staff injury).

Practices should avoid:

- abrasive cleaners such as steel wool, domestic cleaning powders and pastes, as these may damage the surfaces of reusable medical devices or leave a residue
- normal household detergents, as they are generally high foaming and often leave a film that is hard to rinse away
- strongly alkaline detergents for manual cleaning; although they are more effective, they are caustic and are only safe for use in washer disinfectors
- chlorine-based products such as bleach, as they can corrode and rust reusable medical devices and sterilisers.

Enzymatic detergents can be used for soaking and cleaning heavily soiled reusable medical devices but are generally not required in general practice and other office-based and community-based settings. These detergents are generally more expensive than regular instrument detergents and require a contact time as advised by the manufacturer.

### No-lint or low-lint microfibre cloth or disposable paper towel for dryings

Residual lint on instrument surfaces can harbour microorganisms and contaminate wounds. A simple check to ensure the cloth or towel is low lint or lint free is by wetting it and wiping a window. If any lint is obvious on the window, do not use this type of cloth or towel to dry the reusable medical devices. Low-lint or lint-free microfibre cloths can be washed, dried and reused. Disposable kitchen wipes or tea towels are not suitable because of the amount of lint they leave.

### Sterile barrier systems (packaging)

Sterile barrier systems include:

- bags made of paper that require tape for sealing
- self-sealing bags made of paper backed with clear plastic (lamine) on the other
- rolls requiring heat sealing, wrapping material made of cloth or nonwoven material.

Sterile barrier systems need to be suitable to their purpose. Single-use nonwoven material such as 'Kimguard' is used for large packs and has replaced reusable linen wraps in general practices and other office- and community-based practices.

Tape containing a Class 1 chemical indicator in the form of stripes can be used to seal wrapped items and steriliser bags. It is important to ensure these are fully sealed.

Lamine rolls require a heat sealer (spare elements should be kept as they can burn out) or tape to seal the ends.

### Distilled water

Most new sterilisers capable of Class S or B cycles have significant requirements for distilled water, especially as water is often not recycled, as in older gravity displacement sterilisers. Practices can consider a small distiller (7 hours = 4 litres) or a suitable reverse osmosis system.

Water that is discharged from any steriliser is not suitable for reuse.

## Section 4.6. Cleaning reusable medical devices

If an item cannot be cleaned, it cannot be further processed or reused.

PPE must be used at all times when handling used reusable medical devices until items are placed into a sterile barrier system.

Preliminary cleaning begins at the end of the procedure in which the reusable medical device is used.

After preliminary cleaning, all items require thorough cleaning in the equipment reprocessing area before sterilising.

## Chemical indicators

See Chapter 4, Section 4.10.

Items must be clean before being subjected to a disinfection or sterilisation process. Effective cleaning to remove all foreign matter is an important step towards ensuring successful sterilisation.

If items to be sterilised are not cleaned thoroughly and foreign matter remains, microorganisms can be protected from the action of the sterilisation cycle. Therefore, if an instrument or other item cannot be cleaned due to physical reasons (eg narrow lumen) or safety concerns (eg acupuncture needles), effective disinfection or sterilisation cannot be guaranteed. If foreign matter is allowed to dry or harden on this item, the cleaning process will be more difficult and possibly be compromised.

PPE must be used at all times when handling used reusable medical devices.

## Preliminary cleaning

Visibly soiled reusable medical devices need preliminary cleaning before processing for reuse. Preliminary cleaning begins at the end of the procedure in which the instrument is used.

Preliminary cleaning to remove gross soil can be achieved by the following (singly or in combination):

- safely wiping off gross soil at point of use
- rinsing under gently running warm water in the 'dirty' sink – avoid very hot or very cold water as fats solidify in cold water and proteins coagulate and may fix onto surfaces in hot water
- immersing items in a 'holding container' with water and detergent as soon as possible after use. The item should be free of gross visible soil or the solution may become heavily contaminated and pose an unnecessary extra risk to staff when handling. This prevents organic matter from drying out if cleaning is delayed. Reusable medical devices should not be left to soak in this solution for long periods (more than a few hours) as any residual microorganisms can multiply and rusting may occur.

Avoid splashes because these can contaminate nearby surfaces and other people nearby.

Wash all contaminants down the sink with a slow running tap. Remove larger contaminants, if present, with a paper towel.

## Cleaning – manual

After preliminary cleaning, all items require thorough cleaning in the equipment reprocessing area before sterilising. This should take place as soon as practicable after use.

The staff member requires brushes of various sizes and is to carefully inspect the item for remaining matter.

## Procedure for manual cleaning

Use standard precautions including PPE: gloves, goggles and apron. A mask or face shield may be worn.

### Preparation for manual cleaning

- Fill the 'dirty' sink/container with sufficient tepid water to wash the items.
- Measure out the correct amount of detergent (according to the manufacturer's directions) and add to the water. It is useful to mark the water line with a permanent marker and pre-measure the volume of detergent delivered by pump pack to facilitate the correct detergent:water ratio each time.
- Open or disassemble reusable medical devices to be cleaned.

### Wash reusable medical devices

- Wash reusable medical devices under the waterline to minimise aerosol production and prevent splashing.
- Wash items thoroughly by scrubbing with a clean, firm bristled (nylon or brass) brush. Use a thin brush (eg cytology brush) to clean items with lumens, holes or valves.

### Rinse reusable medical devices

- Rinse items in the 'clean' sink in gently running warm to hot water. It is important that the temperature of the water is not so hot as to cause injury to staff.
- Visually inspect each surface to ensure all foreign matter is removed.
- Allow items to drain off excess water on the sink drain board, a rack, or low-lint paper towel.

### Dry reusable medical devices

- Dry with a low-lint or lint-free microfibre cloth or paper towel and, if items are not going to be further processed immediately, place items in a clean labelled container for storage before packaging. If items are going to be processed immediately after drying place in, or onto, the sterile barrier system (eg pouch or Kimguard wrap) in the one action to save double handling.
- Do not leave to air or 'drip-dry' as the microorganisms on instrument surfaces can multiply if there is a delay in drying, packaging and processing.

### Manage dirty water, containers and cleaning equipment

- Water used for cleaning dirty reusable medical devices needs to be treated with due care as it is contaminated and a potential biohazard.
- If in a container, contaminated water should be carefully discarded in the sink, directly down the plughole.
- Once drained of contaminated water, sinks should be rinsed with gently running water. It is important not to let contaminated water remain pooled in sinks as this can create a biofilm containing microorganisms.
- Clean the brushes and reusable cloths used for cleaning and drying with detergent and tepid water, rinse thoroughly and hang to dry after use. Practices can consider putting these items through a sterilisation cycle to disinfect them.
- Wash the 'dirty' and 'clean' sinks/containers with water and detergent and rinse with hot water daily. Dry the sink and any containers with a disposable towel.
- Remove the PPE. Clean reusable PPE such as goggles and aprons by washing with detergent and water and wiping dry.

## Remove utility gloves and perform hand hygiene

- Gloves are to be removed and hands to be cleaned before moving on to other tasks.

## Cleaning – ultrasonic

### Work health and safety aspects

When using ultrasonic cleaners, standard precautions are required. Other precautions to be taken include:

- Following cleaning of soiled reusable medical devices, the instrument bath containing used detergent and water needs to be treated with due care as a potential biohazard.
- The lid of the ultrasonic cleaner needs to be in place to prevent the emission of aerosols and hearing damage to the operator.
- Hands should not be immersed in operating ultrasonic machines as injury may occur.

### Appropriate use of the ultrasonic cleaner

Ultrasonic cleaners can be used for cleaning jointed and serrated stainless steel reusable medical devices.

Ultrasonic cleaners are not suitable for cleaning:

- internal surfaces of cannulated reusable medical devices
- plastics and other similar materials
- cemented glass syringes
- mirrors and lenses (these will be damaged if repeatedly subjected to this process)
- fine-pointed reusable medical devices (the vibration caused by the process can blunt fine points).

### Procedure for ultrasonic cleaning

Always operate the ultrasonic cleaner according to the manufacturer's directions. The general procedure for ultrasonic cleaning is as follows:

- Ensure that gross contamination is first wiped or rinsed off items before immersion into the ultrasonic cleaner.
- Fill the water tank with water (not temperature critical) and add a measured amount of detergent of the recommended type and volume for ultrasonic use. Operate the machine for a short time to 'degas' the solution.
- Immerse items (opened and disassembled) in the basket supplied (usually this has a perforated solid base) in the ultrasonic cleaner.
- A cassette system, compatible with ultrasonic cleaning baths, may be used to minimise the handling of sharp reusable medical devices.
- Close the lid.
- Commence the cycle (for length of cycle, refer to the manufacturer's instructions).
- After the specified time, remove the instrument basket and rinse the reusable medical devices in clean, warm to hot running water.
- Visually inspect reusable medical devices after rinsing and repeat the process if necessary. Manual cleaning may still be necessary as some surfaces may be 'shadowed' from the ultrasound waves and therefore not cleaned.
- Dry reusable medical devices ready for packaging (as for manual cleaning).

## Maintenance of the ultrasonic cleaner

Always maintain the ultrasonic cleaner according to the manufacturer's directions.

Daily maintenance and monitoring is required. Change the water and detergent daily or more frequently, depending on usage and thoroughness of preliminary wiping or rinsing.

A monthly efficacy test – the aluminium foil test or 'pencil' test – needs to be performed. Such a test should also be performed if the ultrasonic cleaner's operation is not evident (vibrations are not seen or felt) or if inspection of reusable medical devices after cleaning reveals remaining contamination, raising doubts as to its effectiveness.

### Procedure for aluminium foil test

1. Cut a strip of thin aluminium foil slightly narrower than the width of the tank and slightly longer than the depth.
2. After the tank of the ultrasonic cleaner has been filled, switch on and lower the foil into the tank vertically until almost touching the bottom; hold in position for at least 10 seconds.
3. Remove the foil and observe the distribution of perforations and pitting. The indentations should be fine and evenly distributed. Unsatisfactory performance is indicated by:
  - no pitting (failed operation)
  - asymmetric distribution (uneven ultrasonic field)
  - tears or large pits (abnormal ultrasonic wave generation).

### Procedure for 'pencil' test

1. With a lead pencil, densely mark several discs or coins.
2. Drop into the ultrasonic cleaner in different locations.
3. Operate the cleaner.
4. Remove the discs and observe that all the pencil markings have been removed.

After performing either of these tests, ensure that the tank is emptied and refilled to remove pieces of aluminium/lead, etc.

## Section 4.7. Sterile barrier systems (packaging) for sterilisation

Placing reusable medical devices in a sterile barrier system takes place in a 'clean' area.

Items contained in a sterile barrier system and porous materials must only be processed in sterilisers capable of Class S or B cycles with a functioning active drying cycle.

Correct sterile barrier systems are important as they ensure reusable medical devices are able to be sterilised and remain sterile.

All sterile barrier systems should be labelled. This enables appropriate stock rotation and the identification of other affected items if a problem with a processed item is identified.

Reusable medical devices required to be sterile at the time of use must be protected by a sterile barrier system.

The placing of reusable medical devices into sterile barrier systems takes place in a 'clean' area adjacent to the cleaning area after the reusable medical devices have been dried (refer to *Chapter 4, Section 4.4*). If space is restricted, an area can be made temporarily 'clean' by placing a sheet of disposable plastic backed paper or a suitably labelled tray or container in the area to create this space.

A sterile barrier system that contains reusable medical devices to be sterilised must only be sterilised using the appropriate Class S or B cycle in sterilisers with a functioning active drying cycle.

Gloves (eg clean nonsterile utility) should be worn when placing items into a sterile barrier system in order to minimise contamination of the items (and contamination of the staff member if the items have been manually or ultrasonically cleaned and not thermally disinfected in a washer disinfectant).

### Purpose of using sterile barrier systems

The purpose of using sterile barrier systems is to:

- provide an effective barrier against sources of potential contamination during storage
- permit aseptic removal of the contents of the sterile barrier system at the time of subsequent use.

### Choosing an appropriate sterile barrier system

Sterile barrier systems need to allow for air removal, steam penetration, removal of steam and drying of the contents. Using the correct sterile barrier system ensures that reusable medical devices are sterilised and remain sterile.

The type of sterile barrier system chosen depends on the:

- type of steriliser used (dry heat or steam)
- size and contents of the sterile barrier system (eg laminate pouches come in a limited range of sizes)
- type of reusable medical devices/equipment to be placed in the sterile barrier system.

Annual validation confirms the suitability of the sterile barrier system. Some materials may melt (eg Kimguard) if contact with the outer wall of the steriliser occurs. This may also occur during the drying stage. Cellulose materials are more resistant to damage during drying.

## Sterile barrier system preparation requirements

### Class 1 chemical indicator

All items placed in a sterile barrier system must incorporate a Class 1 chemical indicator on the bag or pouch or on the tape used to seal the item (AS/NZS 4815:2006).

Class 1 chemical indicators are designed to demonstrate that the sterile barrier system has been exposed to the physical conditions of the sterilisation process (but does not guarantee sterility).

### Labelling

All sterile barrier systems should be labelled with a permanent marker or a self-adhesive label before loading.

Sharp-tipped pens (eg ballpoint pens) should be avoided as they can perforate paper packaging and nonwoven wraps. They can be used on noncritical areas such as the tags at the ends of pouches. Water-soluble markers should be avoided as the details of the load can be washed away by steam.

Self-adhesive labels often incorporate an additional chemical indicator strip (eg Class 4), which provides additional surety to the process.

Minimum labelling includes the date of sterilisation and the load number. This enables appropriate stock rotation and the identification of other affected items if a problem with a processed item is identified.

If appropriate, additional labelling may include:

- steriliser identification (in practices using more than one steriliser)
- identification of the contents if items are not clearly visible (eg when using paper bags or wraps or if reusable medical devices within a kidney dish are sterilised in laminate pouches, as the hollow side faces the paper)
- identification of the person responsible for cleaning and placing items in the sterile barrier system (only in practices with several staff preparing items, as this allows staff counselling should cleaning or the sterile barrier system be found to be defective)
- location of storage post-sterilisation (this may be applicable in larger practices to enable storage of different packs in different locations – ‘downstairs plastics set’, ‘small treatment room suture pack’).

Practices can use various codes to record this information, which varies in complexity. For example, 12/01/06 2–207 2 7 STR SP for a pack sterilised on 12 January 2006 in steriliser 2, load no. 207, cleaned by staff member 2, placed in a sterile barrier system by staff member 7 for storage in small treatment room and containing a suture pack. Some practices use mechanical labellers for this task.

## Packaging reusable medical devices

When placing reusable medical devices in a sterile barrier system:

- Ideally unlock and open all reusable medical devices to allow steam penetration to all surfaces. Scissors should only be loosely opened, not to the maximum extent, as they may present work health and safety risks. Artery forceps and similar items can be closed on the loosest ratchet to enable them to fit into pouches.
- Tip protectors can be used to prevent sharp reusable medical devices from perforating the sterile barrier system. Tip protectors that allow exposure to steam are available from medical suppliers.
- Place reusable medical devices with the handle towards the end of the sterile barrier system to be opened (when using laminate pouches or paper bags). This allows ‘sterile’ removal and decreases the possibility of injury from the instrument tip when the bag is opened.
- Do not exceed the parameters of the validated ‘challenge pack’ (the hardest to sterilise). Photographs of the validated contents and their arrangement within the sterile barrier system are useful as a valuable ready reference.

If reprocessing items from a failed sterilisation cycle, they must be repacked in a new sterile barrier system, but do not require recleaning unless they have been contaminated (eg dropped on the floor).

## Placing hollowware in a sterile barrier system

Place hollowware (eg kidney dishes, gallipots and bowls) in a sterile barrier system with the open side against the paper to avoid condensation on the inside of the item if being sterilised in paper/laminate rolls or pouches.

If placing several items of hollowware together in a sterile barrier system, ensure that all openings are facing the same way and that each item can move freely. This allows adequate steam penetration and drying. Use spacers between tightly fitting identical items (eg when sterilising two or more identical and stackable kidney dishes).

## Sealing sterile barrier systems

Correct sealing of sterile barrier systems is important to ensure sterile reusable medical devices at the end of the sterilisation process. While many practices use adhesive pouches, some use continuous roll pouches that require adhesive tape.

When sealing a sterile barrier system:

- If using tape, use one that is specific to the type of steriliser and compatible with the packing/wrapping material used (there are different tapes for paper and nonwoven materials).
- Do not use pins, staples, string or nonadhesive tape to seal sterile barrier systems as these items can compromise its integrity and sterility.
- Ensure that sterile barrier systems are sealed in such a way that air cannot enter after removal from the steriliser.
- If using a self-sealing pouch, precisely fold seals along the 'dotted' line.
- If sealing wrapped items with tape, double fold joins and use several short strips across the join rather than a long length of tape along the joint. This ensures that when this type of sterile barrier system is opened, the tape can be broken across the join line, thus preserving the integrity of the sterile barrier system.

## Wrapping sterile barrier systems

Wrapping sterile barrier systems requires special techniques outside the scope of this document. Staff advice or training may be available from a local hospital sterilising department, primary healthcare organisation or infection prevention and control provider.

## Sterile barrier systems and packs containing mixed materials

Sterile barrier systems containing reusable medical devices and textiles such as gauze, cotton wool, towels or drapes can be difficult to sterilise as the various contents heat at different rates. If a practice wishes to sterilise mixed items in a sterile barrier system, it is crucial to:

- establish the penetration time
- validate the sterilisation cycle physically and microbiologically
- validate the drying time.

## Section 4.8. Loading the steriliser

Correct loading of the steriliser is important to ensure air is removed and steam can penetrate the load.

It is important that the load does not exceed the practice's validated parameters.

Correct loading of the steriliser is important to ensure steam can penetrate and sterilise every surface of the load and to prevent sterile barrier systems from damage.

It is important that the load does not exceed:

- the practice's validated parameters, that is, the load is not more difficult to sterilise than the 'challenge load' (the hardest to sterilise load) tested at time of validation. Any new load configurations assessed as possibly exceeding that of the validated 'challenge load' require validation, or use of a Class 5 or 6 chemical indicator in emergency situations until validation is able to be performed as soon as possible.
- the maximum specified by the manufacturer.

## Equipment needed to load the steriliser

The correct equipment needs to be used to load the steriliser to prevent compromise of the sterilisation cycle. This equipment can be obtained through the steriliser manufacturer or medical supply company.

### Load separators

Load separators are used to space items (eg identical kidney dishes that would stack closely together and hinder air removal or steam penetration between them).

### Trays

Trays used in the steriliser must be perforated to allow steam penetration and condensation drainage during the sterilisation cycle. Use trays specifically designed for that steriliser.

Solid trays must not be used as they inhibit steam movement and steam can condense on them, leaving pools of moisture and possibly wetting packs.

### Racks

Racks (horizontal or vertical) may be used to separate sterile barrier systems and enable larger loads to be sterilised by allowing effective steam penetration (eg stainless steel load separators, commonly referred to as 'toast racks', allow effective separation of sterile barrier systems containing reusable medical devices).

Use racks specifically designed for that steriliser. Domestic toast racks made of plated steel or low-grade stainless steel are not suitable as they will rust and corrode.

## Method of loading

Follow the loading instructions provided by the manufacturer. General principles of loading a steriliser include:

- Ensure adequate space between each sterile barrier system (eg using load separators, racks) to allow steam penetration.
- Load the steriliser so that no items touch the walls (eg use trays or racks).
- Load trays loosely to capacity – only one layer of sterile barrier systems can be loaded onto a tray (or use racks).

Loading of the steriliser follows the same pattern of loading described in the validation protocol. Photographs or diagrams of the validated loading pattern and any lesser loading patterns used are useful as a ready reference.

## Bags and pouches

When loading bags or pouches:

- ideally load vertically (on edge)
- separate regular-shaped bags and pouches with a rack; irregular-shaped bags and pouches can be placed against each other
- face multiple bags and pouches the same way (the paper side of a laminated bag or pouch should face the laminated side of the next bag or pouch)
- face pairs of bags or pouches paper to paper
- if loading a laminate pouch horizontally on a tray, position with paper side down to enable air removal and steam penetration.

## Wrapped linen packs

If drapes, towels or gauze are being sterilised, position them on their edge if possible to provide the least resistance for the passage of steam.

## Hollowware

Tilt hollow items and place hollowware items such as bowls, kidney dishes and jugs on their sides (in a draining position), whether packed in a sterile barrier system or not. This allows steam to displace the air and adequate drainage of condensation.

## Section 4.9. Sterilisation cycle parameters

The time selected for sterilising a load is a critical factor in ensuring sterility of the load. The total processing time is the sum of the penetration time and the holding time.

The density of the 'challenge pack/load' determines the penetration time.

Holding time is the time required at the desired temperature to kill all microorganisms.

### Processing time

The time selected for sterilising a load is a critical factor in ensuring sterility of the load. The total processing time is the sum of the penetration time and the holding time.

Often manufacturers preset the processing time on sterilisers. These times must be checked and altered if necessary to ensure adequate time at temperature to kill all microorganisms.

### Penetration (equilibration) time

Penetration time is the time it takes for the hardest to reach part of the load to achieve the required temperature once the chamber has reached that temperature. The hardest to reach part is usually the centre of the 'challenge pack' within the 'challenge load'. This time difference will vary depending on the type of steriliser and each type of challenge pack/load. It is important not to exceed the maximum load specifications of the manufacturer.

The density of the challenge pack/load determines the penetration time. For example, laminate pouches containing up to four small reusable medical devices can be safely assumed to have a penetration time of zero. Wrapped packs and packs containing gauze or other textiles are denser and more difficult for steam to penetrate and require formal assessment of the penetration time by a service technician. This can be done when commissioning the steriliser or at validation.

See *Appendix 12, Tables A12.2 and A12.3* for an example of a challenge pack and challenge load.

### Method for determining penetration time

The person with responsibility for infection prevention and control needs to select the practice's worst-case scenario – the most difficult to sterilise package (the challenge pack) and the most difficult to sterilise load (the challenge load) that the practice intends to sterilise. The details of this 'challenge pack/load' need to be documented. The use of photographs or diagrams can be of great assistance in addition to the written description for future reference.

The service technician places a thermocouple probe close to the centre of the challenge pack, which is then placed in the most difficult to sterilise position within a challenge load. The penetration time determined by the service technician should be recorded with the description of the challenge pack/load.

Significant penetration times of more than 5–10 minutes can indicate air entrapments and/or inadequate steam penetration due to:

- inappropriate sterile barrier system
- excessive density of the challenge pack
- chamber overloading
- incorrect steriliser type.

The cause of prolonged penetration time needs to be investigated.

Penetration time only needs to be determined once for any particular challenge pack/load and does not need to be repeated unless:

- alterations to the challenge pack/load are made which could adversely affect (lengthen) the sterilisation time – that is, alterations to challenge pack contents, sterile barrier systems or chamber loading details (in this event, validation of the sterilisation cycle will also need to be repeated), or
- the steriliser itself undergoes a major repair or refit.

This is easily measured during time at temperature testing and should not be an additional expense.

## Holding time

The holding time is the time the whole load must be held at the sterilising temperature. The holding time includes a safety factor (*Table 4.3*).

The holding time depends on the temperature selected (eg 121°C for 15 minutes holding time or 134°C for 3 minutes holding time).

**Table 4.3. Recommended temperature, pressure and holding times in a steam steriliser**

Temperature (°C)	Pressure (kPa)	Pressure (psi)	Pressure (Mb)	Holding time (mins)
121	103	1030	15	15
126	138	1380	20	10
132	186	1860	27	4
134	203	2030	30	3

Source: Adapted from AS/NZS 4815:2006

## Drying time

Drying time needs to be established for all the different challenge pack/loads the practice intends to sterilise.

## Heat distribution

A heat distribution study is required in large sterilisers to ensure that monitoring reflects the temperature in the coldest part of the chamber. This requirement is not relevant in small steam sterilisers as, unlike large commercial sterilisers, they rarely have significant cold spots. This study is only required once and may be available either from the manufacturer, a previous validation, or can be determined by the service technician.

This can be checked during routine calibration and should not be an additional expense.

## Section 4.10. Monitoring the sterilisation cycle

It is vital that the efficacy of the sterilisation cycle be checked to ensure the correct temperature, pressure and time have been attained for each cycle.

All sterilisers should produce evidence that the selected cycle parameters have been met for every cycle.

Chemical indicators are used in addition to physical monitoring as part of routine sterilisation cycle monitoring. A Class 1 chemical indicator must be used on every sterile barrier system of every load, or in the tray of unwrapped items, as evidence that the load has been subject to the sterilisation process.

Biological indicators consist of a predetermined number of microorganisms. They are designed to measure the killing power of the sterilising process.

Biological indicators are not designed to be used for routine monitoring or as a substitute for validation.

Incomplete removal of air can jeopardise the effectiveness of the sterilisation cycle.

## Methods of monitoring

Sterilisation efficacy depends on temperature, (steam) pressure and time – these parameters must be monitored. There are three methods for monitoring the sterilisation cycle:

- mechanical/physical indicators (eg time at temperature monitoring, either manually or by automatic printout or computerised data logger which must be checked before use of that load)
- chemical indicators
- biological/enzymatic indicators.

### Mechanical/physical monitoring

Sterilisers should be fitted with devices (gauges/timers/digital readout) that provide visible monitoring of the time and temperature during a cycle. Additional pressure monitoring is an advantage. Results should be automatically recorded by printout or a data log, which must be viewed after each cycle.

### Leak tests

Leak tests are not required in simple gravity downward displacement sterilisers.

All sterilisers providing Class B cycles and most sterilisers providing vacuum-assisted Class S cycles are capable of performing a leak test cycle.

Incomplete removal of air can jeopardise the effectiveness of the sterilisation cycle. Refer to the steriliser operating instructions for required (leak test) checking if any. Many newer sterilisers have automatic systems to detect leaks and other process failures with appropriate error messages.

Leak testing frequency, if not otherwise specified by the manufacturer, should be performed as follows:

- Sterilisers with an air detector fitted require a weekly leak ('vacuum') test cycle.
- Sterilisers performing Class B cycles without an air detector fitted require a daily leak ('vacuum') test cycle.
- Sterilisers performing Class S cycles not fitted with an air detector but capable of performing a leak test cycle require a weekly leak test.

## Steam penetration/air removal tests

Steam penetration/air removal tests are not required in gravity downward displacement sterilisers.

Sterilisers that provide Class B cycles may require tests of steam penetration and air removal in between validations if recommended by the manufacturer (eg a Bowie-Dick-type test, helix device or other appropriate process challenge device).

The RACGP recommends that practices perform a risk assessment based on the frequency of use of Class B cycles, with reference to the manufacturer's instructions. A steam penetration test (eg Bowie-Dick-type test, helix or appropriate process challenge device) is then performed at intervals established by the risk assessment. For example, a helix device may be used to test daily, weekly or monthly in a steriliser performing Class B cycles to sterilise hollow load A reusable medical devices.

Steam penetration tests may be used in vacuum-assisted sterilisers providing Class S cycles if recommended by the manufacturer.

Very few vacuum-assisted sterilisers providing Class S cycles can successfully perform a Bowie-Dick-type test and virtually none can successfully perform a helix test.

## Process challenge devices (PCDs)

An example of a simple PCD is the challenge pack used during the validation process. A Class 4, 5 or 6 chemical indicator is placed in the hardest-to-sterilise location within the challenge pack and placed in the hardest-to-sterilise challenge pack location (usually the centre) in order to check the steriliser functioning between validations.

Various manufactured process challenge devices now exist to mimic particular challenges or worst-case scenarios (eg helix devices consisting of long lengths of thin tubing capable of holding a Class 4, 5 or 6 chemical indicator). The helix device must be used to check the efficacy of Class B cycles in their ability to remove air from long, thin, cannulated reusable medical devices (hollow load A items), on a regular basis. For all other cycles the use of PCDs is optional.

## Printouts and data logs

All sterilisers should produce evidence – automatically recorded – that the selected cycle parameters have been met for every cycle. This can be a printout (where a printer is fitted) or a downloaded data log that must be viewed after each cycle. The printout or data logger should show the temperature and pressure at critical points during the sterilisation cycle as well as the drying time. Results of the cycle (pass/fail) must be entered into the steriliser log. The printout or electronic data logger record may be kept.

Unless practices are prepared to download and check data from each cycle, it may be better to purchase a steriliser with fitted printer.

The RACGP recommends the following:

### Sterilisers with a printer attached

- The designated staff member reviews the printout or download after each cycle.
- The result (success or failure of the cycle) must be recorded in the steriliser log at the end of each cycle. The printout may be kept (eg for a month) for evidence and to assess trending temperatures and pressure.
- The steriliser logbook is retained with the same requirements as a medical record – 7 years from the last entry.

### Sterilisers attached to a data logger

- The designated staff member reviews the data log after each cycle.
- The result (success or failure of the cycle) must be recorded in the steriliser log at the end of each cycle. The data may be kept.
- The steriliser log is retained with the same requirements as a medical record – 7 years from the last entry.

**In emergencies while waiting for repairs to a faulty printer or data logger**

Until repairs can be effected, if the printer is faulty or out of paper or if the data logger is inoperative or its data is unable to be viewed, for each cycle practices must either:

- use a Class 4, 5 or 6 chemical indicator in the tray of every cycle and its colour change noted in the steriliser log as evidence of the cycle achieving the required parameters, or
- manually record the time at temperature every 30 seconds during the sterilising time in the steriliser log.

Note: Sterilisers without a printer or data logger are obsolete and should not be used.

**Chemical indicator monitoring**

An understanding of the different types and functions of chemical indicators is essential for correct selection and use.

Chemical indicators are used in addition to physical monitoring as part of routine sterilisation cycle monitoring. They are used to detect when one or more sterilisation process conditions have reached predetermined levels, that is, the monitoring of time at temperature. They provide immediate results.

There are six classes of chemical indicator (classes 1–6). The higher the class, the more information and greater specificity of the chemical indicator.

The colour of the chemical indicator change cannot be guaranteed to remain constant over time – the colour may fade or change. Therefore it is not appropriate to store these chemical indicators or read them at the time of pack use as a ‘proof of process’.

**When to use chemical indicators****Every load**

A Class 1 chemical indicator must be used on every pack of every load or in the tray of unwrapped items as evidence that the load has been subject to a heat process. Self-sealing pouches and some sealing tape incorporate Class 1 chemical indicators.

**When additional assurance is required or if printer or data logger is absent or fails**

A Class 4, 5 or 6 chemical indicator can be used for monitoring the success of cycles or as additional assurance or proof of process in the tray with every load. They can also be placed inside particularly challenging packs (eg linen bundles or dense gauze packs) that are intended for use within days or weeks and in process challenge devices.

**When validation cannot be performed**

A Class 5 or 6 chemical indicator must be used with the challenge pack (judged the most difficult to sterilise) in every load if validation of the sterilisation cycle cannot be performed (eg due to remoteness or while awaiting revalidation). *Table 4.4* summarises the types and uses of the various chemical indicators available on the Australian market.

## Microbiological indicator monitoring

There are two types of microbiological indicators: biological and enzymatic.

- Biological indicators consist of a predetermined number of microorganisms. They are designed to measure the killing power of the sterilising process. They require incubation.
- Enzyme tests are similar to biological indicators but do not require an incubator. The indicator, containing an enzyme from a micro-organism, rapidly changes colour when a drop of solution is added after the cycle.

At the time of publication there were no rapid enzymatic tests suitable for gravity displacement sterilisers sterilising at 134°C on the Australian market.

Biological indicators are the 'gold standard' for checking the effectiveness of the sterilisation process. They are not commonly used for testing regular cycles in the general practice and other office- and community-based practice setting because of the need to incubate, resulting in a 48-hour delay in providing results.

A biological indicator should be used:

- to validate a sterilisation cycle and load
- as a quality assurance activity
- to investigate cycle failures
- on running any load type that exceeds the previously validated worst case parameters. In this case, it is important not to release the load for use until the results are available.

Biological indicators are not designed to be used for routine monitoring or as a substitute for validation.

### How to use a biological indicator

Place the biological indicator on the tray with unwrapped items or within the sterile barrier systems of the load to be sterilised. After the cycle is complete, the indicator is incubated in an annually calibrated incubator according to the manufacturer's instructions. This can be done onsite in practices that own or have access to a loaned incubator or offsite by another practice, pathology laboratory or other provider.

Practices should then read the results and record the results in the steriliser logbook before releasing the load.

Table 4.4. Types of chemical indicators and their use

Class	Description	When used	Steriliser type or cycle class of steam steriliser	Advantages	Disadvantages
1	Process indicator (eg steriliser indicator tape)	<ul style="list-style-type: none"> <li>On every pack in every load</li> <li>On the tray of every unpacked load</li> </ul>	All classes	Can assist in easily distinguishing between processed and unprocessed loads	Designed to reach their endpoint after an exposure to a cycle that may be less than adequate for sterilisation
2	Specific test indicator (eg Bowie-Dick-type tests)	According to practice risk assessment	Class B cycles	Designed to show air removal and the rapid and even penetration of steam	Designed to reach their endpoint after an exposure to a cycle that may be less than adequate for sterilisation
3	Single-parameter indicator (eg temperature)	<ul style="list-style-type: none"> <li>On every pack in every load</li> <li>On the tray of every unpacked load</li> </ul>	Mainly in dry heat sterilisers	Designed to reach their endpoint after exposure to a sterilisation cycle at a stated value of the chosen parameter (eg when the temperature in the chamber reaches 160°C)	Checks only one parameter necessary for sterilisation (time or temperature or pressure)
4	Two-parameter indicators (eg time and temperature)	<ul style="list-style-type: none"> <li>For extra assurance of successful completion of a sterilisation cycle</li> <li>Can be used in the absence of a printout</li> </ul>	All classes	<ul style="list-style-type: none"> <li>Designed to reach their endpoint after exposure to a sterilisation cycle at the stated values of the chosen parameter (eg 134°C for 3 minutes)</li> <li>Provide more assurance of a successful sterilisation cycle than that provided by either process (Class 1) or single-parameter (Class 3) indicators and can be used in the absence of a printout</li> </ul>	Failure to reach the endpoint may not allow identification of the specific parameter or parameters that have failed
5	Integrating indicators (eg time, temperature and pressure)	To provide high-level assurance of successful sterilisation cycle and can be used in the absence of a printout	All classes	Provide as much information as a biological indicator by mimicking the conditions necessary to destroy microorganisms and can be used in the absence of a printout or validation in certain situations	Failure to reach the endpoint may not allow identification of the specific parameter or parameters that have failed
6	Emulating indicators (eg 134°C for 3.5 minutes in steam under pressure)	To check that all critical conditions of the sterilisation cycle are met, based on the settings of the selected sterilisation cycles	All classes	Provides a very high level of assurance of a successful sterilisation cycle and can be used in the absence of a printout or validation in certain situations	Failure to reach the endpoint may not allow identification of the specific parameter or parameters that have failed

## Section 4.11. Unloading the steriliser

Correct handling of the sterile load when it is taken out of the steriliser is vital to ensure items remain sterile.

If an item contained in a sterile barrier system emerges from the steriliser wet or damaged in any way, it cannot be considered sterile.

### Method

To correctly unload the steriliser:

1. Remove the load from the steriliser as soon as the cycle has finished. Do not place hot rack or tray on a cold surface.
2. Allow the load to cool in an area away from high levels of activity before being handled, as hot packs are easily contaminated or damaged.
3. Visually check that the load is dry (do not touch until cool).
4. Check sterile barrier system(s), chemical indicator(s) and printouts. Log the results.
5. Report any failures. All items in a failed load must be rejected, the fault identified and corrected, and the entire load reprocessed in a new sterile barrier system.
6. Store the contents of a successful load for later use.

Any sterile barrier systems that are wet, dropped, torn, damaged, or have broken seals are considered unsterile and must be reprocessed. This reprocessing involves repackaging in a new sterile barrier system. Recleaning is required only if the reusable medical devices have been contaminated. Any reprocessing must be recorded.

### Emergency unloading

Occasionally there is a need for practices to sterilise an item for immediate use (eg when an important item is dropped during a procedure). In this case, the drying cycle may be bypassed – run a Class N cycle.

If it is essential to unload after the sterilisation function of the cycle but before the drying cycle:

- on completion of the sterilisation function of the cycle, check the results of routine cycle monitoring and for colour change of the Class 1 chemical indicator in the tray
- record result in the steriliser log (as for any other cycle), indicating that the drying cycle was interrupted
- take measures to ensure sterility is maintained to the point of use
- remove sterilised items using a previously sterilised instrument
- allow items to cool on a sterile surface such as an opened sterile wrap, or by pouring sterile water over them in a sterile kidney dish
- avoid burn injury by not touching or using item before fully cooled.

Items sterilised in this way cannot be stored for later use.

## Section 4.12. Storing sterile stock

Maintaining integrity of sterile stock is crucial to ensuring sterility of reusable medical devices at the time of use. Correct storage and handling of sterile stock is critical to the maintenance of sterile barrier system integrity.

Sterility is 'event related', so if reusable medical devices are stored and handled correctly, there is considered to be no time limit on storage.

Unwrapped sterilised reusable medical devices processed in a Class N cycle cannot be stored for later use as sterile supplies.

### Requirements for sterile stock storage

All sterile stock must be stored in a way that keeps it:

- dry
- clean
- dust free
- away from sources of moisture (eg not next to or below sinks or above sterilisers).

Clean cupboards, drawers or plastic containers are generally suitable. Sterile barrier systems can be further protected in protective packaging such as plastic dust covers, bags or containers.

Sunlight can affect the integrity of some types of sterile barrier systems. Manufacturer instructions should be consulted if items are to be stored in direct sunlight. Sterilised laminate can become brittle over time and unused laminate packs need to be checked after 2–3 months.

### Duration of sterility

Sterility is 'event related', so if items contained within a sterile barrier system are stored and handled correctly, there is no time limit on storage.

Repeated or rough handling, the use of rubber bands, wet hands and other exposure to moisture can compromise sterility by damaging sterile barrier system. If water is splashed onto sterile barrier systems this renders them 'unsterile' and the items must be placed in a new sterile barrier system and resterilised.

Unwrapped sterilised reusable medical devices processed in a Class N cycle cannot be stored for later use as sterile supplies.

Sterile barrier systems used infrequently can be wrapped in plastic or stored in sealed plastic containers when cooled, before storage. This will further protect the sterile barrier system from dust and damage.

### Rotation of stock

Ensure the practice has a procedure for sterile stock rotation such as 'use from the left, restock from the right' or 'use from the front, restock from the rear'. Use the dates on the items within the sterile barrier system to assist.

If frequent handling takes place, consider implementing a reprocessing protocol (eg quarterly re-sterilisation in a new sterile barrier system).

## Section 4.13. Documenting the cycle

Documenting the entire process is important for quality assurance and review purposes so that any doubts about the sterility of a particular item or load can be identified.

### Types of logbooks

Practices may develop their own logbook or take advantage of suitable commercial logbooks available, some of which incorporate tracking and tracing functions. There is an example of a steriliser log in *Appendix 10*.

Logbooks should be retained with the records of validation and maintenance details, and treated as a 'medical record'.

### Information required

For every cycle, record the following information in the steriliser logbook:

- cycle date
- steriliser identity (if the practice has more than one steriliser)
- load number
- load contents
- identity of the person who prepared the load
- results of the cycle monitoring (pass/fail). The printout of the cycle can be attached to the logbook and verified as correct in the logbook. If a data logger is used, verify in the logbook that the data logger recording was viewed and is correct. If manual recording is used, record temperature versus time.
- Class 1 chemical indicators change
- results of any other indicators used (eg chemical or biological)
- condition of the sterile barrier systems (ie dry, seals intact and no damage)
- signature of the person releasing or rejecting the load. In larger practices it may be necessary to record the name of each person involved in cleaning the items, placing them in a sterile barrier system and loading to enable follow up of any problems
- comments regarding fault identification and corrective action taken.

## Section 4.14. Steriliser maintenance

Maintenance is essential to ensure sterility of the equipment processed and assist prolong the life of the steriliser.

The practice needs to have a written policy and procedure to cover all steriliser maintenance issues.

Maintenance is essential to ensure sterility of the equipment processed and longevity of the steriliser.

Maintenance needs to be performed according to the manufacturer's instructions. Refer to the steriliser operating instructions for details.

### Changing the water

Deionised or distilled water must be used as it minimises scale build up and corrosion. Sterilisers utilising Class B cycles and some Class S cycles do not recycle water and have larger requirements for distilled or deionised water. Sterilisers that have a reservoir and recycle water need to be topped up as required and the water drained and changed weekly.

Many automatic Class S sterilisers are connected to a water supply and do not need manual water changing.

### Cleaning the steriliser

Regular cleaning of the chamber, trays and racks is required. The steriliser should be cleaned with the agent recommended by the manufacturer. Check the manufacturer's instructions for details.

Scale is often removed using commercially prepared products containing phosphoric acid (check and carefully follow the manufacturer's recommendations) or a solution of citric acid (made up from citric acid powder available at supermarkets). Other cleaners may cause damage to water tanks, filters or hoses.

Tape, label debris and glue may have to be removed from the trays with stainless steel cleaner and a nylon scourer.

The drain holes need to be checked to ensure they are clear of debris.

### Servicing the steriliser

Routine daily/weekly/monthly/quarterly scheduled maintenance such as checking the seal and filter changes and hinge oiling as recommended by the manufacturer needs to be performed as appropriate by practice and service personnel.

### Frequency

Calibration and a full service must occur at least annually and should be done more frequently if there are any problems with the steriliser or if recommended by the manufacturer. Validation is usually also scheduled at this time.

### Service personnel

A suitably qualified service technician needs to perform annual calibration and servicing. Technicians need to have access to appropriate manuals, equipment and software in order to measure and correct inaccuracies and to ensure correct calibration. Servicing needs to be in accordance with the manufacturer's instructions. To locate a qualified technician, contact the manufacturer or distributor.

## What needs to be checked

The service technician checks the temperature, pressures and time achieved during a full sterilisation cycle as well as the gauges, recording devices, seals and filters.

## Documentation

Documentation of all maintenance (apart from routine cleaning) and servicing is part of the monitoring process and is required as evidence of the correct operation of the steriliser.

Documentation of maintenance includes:

- maintenance performed by staff as per the manufacturer's instructions (eg changing water, daily cleaning and checking door seal)
- annual (or more frequently if required by heavy usage) servicing and calibration by a qualified technician. The service reports need to be retained along with the steriliser log.

The practice needs to have a written policy and procedure to cover all maintenance issues regarding the steriliser.

## Section 4.15. Validating the sterilisation process

Validating the entire sterilisation process is essential to ensure that loads are sterile when they come out of the steriliser.

Validation is managed by the designated staff member with overall responsibility for the practice's sterilisation process.

Validation should be performed onsite.

Validation is a documented procedure for obtaining, recording and interpreting results required to establish that the sterilisation procedures will consistently yield sterile reusable medical devices and equipment.

Ensuring sterility following validation depends upon exactly the same procedure being followed for every part of each sterilisation process.

There should be a periodic review of sterilisation procedures within a practice to ensure that current approaches are adequate to practice needs. For example, if the number of procedural GPs at a practice has reduced, the practice may no longer need to perform its own sterilisation.

### The validation process

Validation involves:

- reviewing the practice's documented procedures from preliminary cleaning through to point of use
- performing all of these procedures
- checking the efficacy of the results
- recording the results.

### When to perform validation

Validation of the entire process (all aspects of reprocessing, not just the sterilisation cycle) must be performed at installation and then annually, including when sterilisers without an active drying stage are only used to disinfect reusable medical devices.

For most practices, validation of the sterilisation cycle will involve only a single steriliser, cycle time, temperature and 'challenge pack/load'. However, for some practices it will be more complex as there is a need to validate each:

- steriliser used, if practices use more than one
- different cycle temperature the practice intends to use
  - the practice may have to sterilise some special items at a lower temperature (eg at 121°C for 15 minutes) but still require higher temperatures for the majority of their reprocessing (eg at 134°C for 3 minutes)
- different sterilisation and/or drying time the practice intends to use
  - the practice may wish to use longer sterilisation/drying times for a small number of packs (eg 10 minutes at 134°C, including 7 minutes' penetration time and 15 minutes' drying time) but select a shorter time for most reprocessing (eg 3 minutes at 134°C, 0 minutes penetration time and 7 minutes drying time). This will require different 'challenge pack/load' and chamber loading details.

If any part of the sterilisation process is altered that could adversely affect the sterilisation outcome between annual validations, then that part must be validated. For example:

- installation of an ultrasonic cleaner (cleaning)
- return of the steriliser after repair offsite (sterilisation cycle)
- after major onsite repairs (sterilisation cycle)
- after significant changes to the sterile barrier systems or chamber loading (sterilisation cycle).

## Who is responsible for validation

Validation is managed by the designated staff member with overall responsibility for the practice's sterilisation process. Note this responsible person may not be the person with designated responsibility for the practice's infection prevention and control processes.

## Where validation should take place

All aspects of validation should be performed onsite. Validation of the sterilisation process outside the practice may not be reflective of practice conditions, and transport of the steriliser back to the practice constitutes reason for validation of the sterilisation cycle to be repeated after reinstallation and commissioning.

However, it is recognised that in many areas of Australia, general practices and other office- and community-based practices cannot reasonably access onsite technical support. In cases where annual servicing and calibration occurs offsite, the practice should send a complete 'challenge pack/load' with the steriliser to allow:

- checking of penetration time and appropriate selection of sterilisation times
- physical checking of 'time at temperature' of the steriliser.

Provided appropriate transport back to the practice has occurred and the steriliser is not grossly mishandled, the validation process can then be completed onsite. The microbiological checking using appropriate biological or enzymatic indicators must be performed onsite by the practice. The service technician should send a copy of the printout results of a sterilisation cycle of the 'challenge pack/load' to the practice to confirm the parameters that were tested and for comparison when the practice runs its microbiological checking to further lessen the risk of adverse changes having occurred in transport.

In the absence of full onsite validation or the compromise outlined above, alternative checking of every cycle must take place (refer to 'Alternative to validation of the sterilisation cycle' below).

## How validation is achieved

Reviewing each sterilisation cycle used is crucial to the sterilisation cycle process. The temperature, pressure and challenge pack/load must be validated according to the manufacturer's instructions, and include:

- heat distribution studies conducted on an empty chamber: available from the manufacturer, a previous validation or determined by the service technician
- a description of the challenge pack and load and chamber loading details, including a diagram or picture
- penetration time of the challenge pack of each load to be validated, as determined by the service technician at this or a previous validation (provided no alterations have been made to the pack contents, packing, sterile barrier system or loading of the chamber) or when assumed to be zero
- physically qualifying (checking) the sterilisation cycle:
  - time at temperature testing
  - microbiologically qualifying (checking) the sterilisation cycle.

## Indicators used for microbiological qualification

- Biological or enzymatic indicators must be used.
- Indicators need to be stored, used and incubated or treated according to the manufacturer's instructions.
- Most enzymatic indicators on the Australian market are not suitable for sterilisation validation in steam, gravity displacement bench top sterilisers at 134°C. If enzymatic indicators are used, they need to be equivalent to the spore count of biological indicators and be suitable for both the type of steriliser and temperature of operation.
- Indicators used for validation need to be from the same brand and batch
- Indicators should have a spore count of or equivalent to 10<sup>5</sup>.
- Dry heat sterilisers use biological indicators that contain *Bacillus atrophaeus* (formerly known as *Bacillus subtilis*).
- Steam sterilisers use biological indicators that contain *Geobacillus stearothermophilus* (formerly known as *Bacillus stearothermophilus*).

## Validation method

Refer to Appendix 11, 12.

## Alternative to validation of the sterilisation cycle

A Class 5 or 6 chemical indicator must be used within an appropriate PCD within every load:

- if validation of the sterilisation cycle cannot reasonably be expected to be performed on time (eg due to extreme remoteness)
- after major repairs or after changes to the challenge pack/load while awaiting revalidation
- if there is a delay in completing annual validation
- in emergency situations.

The PCD must provide at least an equivalent challenge to the sterilisation cycle as would the practice's most difficult-to-sterilise pack and be placed in the most difficult-to-sterilise location (near any identified cold spot or in the centre of the load if none). The PCD may be a commercially manufactured device or made by the practice.

The results of the chemical indicator change must be observed and recorded before other items from the load can be released for use. If the load is contained within a sterile barrier system so that the chemical indicator is not visible, this will require that the PCD be unwrapped or disassembled to view the chemical indicator. This is because chemical indicator colour change is not necessarily maintained over time. It also follows that, in the absence of colour fastness of chemical indicators, it is not acceptable to put a Class 5 or 6 chemical indicator in every sterile barrier system and read the chemical indicator at time of use.

In emergency situations, the PCD may be used if it is a required instrument sterile barrier system (eg a sterile barrier system known or suspected to exceed the practice's validated challenge pack/load), provided the chemical indicator change is checked and recorded and is close to the time of sterilisation (ie the sterile barrier system has not been stored for any length of time).

## Section 4.16. Dry heat sterilisers

Dry heat sterilising follows the same process as steam sterilising, with some additional factors to take into account.

The process for sterilising reusable medical devices in a dry heat steriliser should generally follow that for steam sterilisation. In addition:

- reusable medical devices must be completely dry before sterilising in a dry heat steriliser to prevent them from becoming dull, spotted or rusted
- powders, waxes, oils, ointments and liquids cannot be sterilised in a dry heat steriliser
- the holding time commences when the reusable medical devices to be sterilised have reached the required temperature. This does not include the time taken for the chamber to reach the required temperature
- the holding time for sterilisation at 160°C is 120 minutes (AS/NZS 4815:2006).

## Section 4.17. Instrument disinfection

Instrument disinfection has little place in the general practice and other office- and community-based practice setting.

The use of steam sterilisation to process equipment is the preferred method for all items that can withstand the process.

Items that are not clean cannot be effectively disinfected.

Instrument disinfection has little place in the general practice and other office- and community-based practice setting. In most cases, sterilisation or the use of single-use equipment has taken the place of disinfection of reusable medical devices. Steam sterilisation is the preferred method for all items that can withstand the process.

Items that are not clean cannot be effectively disinfected (refer to *Chapter 4, Section 4.3* for discussion on risk assessment as it applies to instrument and equipment disinfection).

### Thermal disinfection

Thermal disinfection can be achieved by the use of washer disinfectors specifically designed for cleaning and disinfecting reusable medical devices.

Boiling reusable medical devices in general practice and other office- and community-based practices is unacceptable as a means of disinfection because of the uncertainty of the temperature kinetics on the surface of items due to cavitation (bubbles forming). This process may be employed in the domestic environment.

### Chemical disinfection

Chemical disinfection of reusable medical devices has very limited application in general practice and other office- and community-based practices.

The minimum treatment recommended for reprocessing reusable medical devices and devices that cannot be sterilised for use in critical and some semicritical sites is by use of high level disinfectants (eg glutaraldehyde). This requires automated or manual processing systems with strict work health and safety requirements.

Practices that use equipment requiring high-level disinfectants (eg endoscopy equipment) need to refer to the manufacturer's instructions, Australian Standard AS4187 and state/territory work health and safety guidelines.

The minimum treatment recommended for reprocessing reusable medical devices used in low-risk semicritical sites and devices of a semicritical nature is intermediate-level disinfectant, such as by wiping with a 70% isopropyl alcohol wipe.

The minimum treatment recommended for reprocessing reusable medical devices and devices in noncritical sites (eg glucometers, stethoscopes) is by cleaning with detergent and water solutions or detergent wipes after use. However, low-level disinfectants such as quaternary ammonium compounds or intermediate level disinfectants such as alcohol wipes can also be used.

Alcohol can stiffen and damage some stethoscope tubing and fix matter to the surface. Therefore it is not recommended for disinfecting stethoscopes.

## Section 4.18. Tracking reusable medical devices and patient tracing

Tracking reusable medical devices and patient tracing may be important in the event of a sterilisation process failure or medicolegal issue relating to sterilisation in the practice.

The need to track reusable medical devices or trace patients on whom they have been used should not be necessary if the validated sterilisation process is strictly adhered to and monitored.

Practices need to assess the risk relevant to their practice and decide on the need and extent of tracking and tracing activities, if any, required in their setting.

Tracking of reusable medical devices and patient tracing may be important in the event of a sterilisation process failure or medicolegal issue relating to sterilisation in the practice.

At the time of publication, tracking and tracing measures are not requirements of the Australian Standards but are considered best practice. This issue is driven by the risk of prion-contaminated items getting into the reprocessing chain in hospitals. However, general practices and other office- and community-based practices are coming under increased pressure to add this activity to their infection prevention and control procedures.

The need to track reusable medical devices or trace patients on whom they have been used should not be necessary if the validated sterilisation process is strictly adhered to and monitored.

Practices need to assess the risk relevant to their practice and decide on the need and extent of tracking and tracing activities, if any, required in their setting.

### Methods of tracking the sterility of reusable medical devices

The ability to 'look back' to the details of the sterilisation process in any individual case to prove that the reusable medical devices were sterile at the time of use could be helpful if medicolegal issues arise.

This level of tracking can be achieved by entering into the patient's medical record the sterilisation load number from the sterile barrier system which the reusable medical devices was contained in, or sticking a removable label with these details into a paper record.

Should an issue arise later, the practice can use this load number to refer back to the sterilisation log (and corresponding printout if retained) to recheck the results of that particular cycle.

### Methods of tracing of patients

If a process failure is identified after the release of items for use, it could be helpful to trace all patients on whom they were used. This can be done by recording patient identifiers (eg name and/or record number or date of birth) for each patient next to each item or pack listed in the load details in the steriliser log (*Appendix 10*).

## Section 4.19. Single-use items

Single-use devices must not be reprocessed.

Single patient use devices may be reprocessed for use on the same patient provided the manufacturer's instructions are followed.

Practices must have stock control policies to ensure a ready supply of single-use stock is available as required.

Single-use devices must not be reprocessed.

A manufacturer may classify its product as single use for several reasons including:

- cleaning difficulties posed by sharp or narrow lumen reusable medical devices
- materials used in the manufacture of the item may not withstand the cleaning and sterilisation process (eg some plastics in nebuliser sets, tubing, spacers and syringes may distort or melt, low-quality stainless steels in disposable sets may rust)
- significant work health and safety risks posed in reprocessing (eg needles for injections, neurological testing, acupuncture and suturing; scalpel blades; lancets; stitch cutters).

Even practices that reprocess their own equipment will still use many single-use items. Practices need to have stock control policies to ensure a ready supply of single-use stock is available as required.

It should be noted that specialised instruments are often unavailable in a disposable form and, as such, must be accompanied by an appropriate cleaning and decontamination process.

### Advantages

The advantages of single-use items are that they:

- minimise the risk of cross-infection
- reduce the staff time and financial burdens associated with onsite sterilisation in some practices
  - some practices, especially those that rarely perform procedures requiring sterile reusable medical devices, will often find it more economical to maintain a range of prepackaged, sterile items to manage all their anticipated needs
- reduce the work health and safety risks of reprocessing and sterilising.

### Disadvantages

The disadvantages of single-use items are that they:

- can be more costly
- may have a greater environmental impact
- may have quality issues (eg disposable needle holders may have very coarse teeth and may not grip fine suture materials)
- can be subject to potential supply chain problems and therefore require that practices keep larger amounts of disposable stock as a buffer
- may cause potential storage problems due to the need to hold larger amounts of commonly used disposable stock.

## Spacers, nebuliser masks and tubing

Most spacers, nebulising devices and masks are single patient use items and should be given to the patient for further use or discarded after use.

Tubing is for single patient use only, cannot be reprocessed and must be replaced.

Some items (eg sterilisable spacers) may be reprocessed in a steriliser and used on other patients. In these instances, practices should follow the manufacturer's directions for cleaning and processing.

In an emergency situation, washing in hot water and detergent will provide a level of decontamination and disinfection to spacers, masks and nebulisers, but the risk to the patient needs to be considered (ie the risk of reusing a single-use item versus the risk of inadequate treatment). This process is suitable for domestic single patient reuse but not advisable for routine management of these devices in the general practice and other office- and community-based practice setting

Spacers, nebulisers and masks do not have to be sterile at the time of use and should be stored in a clean and dry environment.

## Lancets for blood testing

Lancets should be of the spring-loaded, retractable, single-use variety for most applications. The main exception is disposable nonretractable lancets used multiple times for allergy testing on a single patient then discarded.

Plates or bases of reusable spring-loaded devices are a potential source of cross-infection and pose an unacceptable risk to patients in general practice and other office- and community-based practices. However, their use is appropriate for single patient home use where instructions on thorough cleaning are provided.

Changing the plates or bases and reloading with new but unprotected lancets poses a work health and safety risk.

## Auroscope tips

Cleaning auroscope tips and similar noncritical items can be difficult and is discouraged because fine brushes and extra time are required due to small lumens and wax contamination. Practices are advised that disposable tips be used.

## Spirometer and peak flow mouthpieces

Single-use mouthpieces must be used in practices.

Mouthpieces can incorporate a one-way valve to prevent reverse flow from the device or ideally can be filtered to prevent contamination of the device.

## Single patient use devices

Single patient use devices may be reprocessed for use by the same patient provided the manufacturer's instructions are followed.

In the domestic situation, spacers, nebulisers and masks need to be regularly washed every few weeks in hot water and detergent solution. All items except for spacers should be rinsed and dried. Spacers should be left to drain and dry without rinsing or drying (one of few exceptions to immediate drying) as this treatment minimises static charge and improves the performance of the device.

Single patient use, washable plastic mouthpieces are suitable only for use in peak flow meters in the domestic environment.

Infection prevention and control and risk management is discussed further in *Appendix 13*.

## Section 4.20. Offsite sterilisation

For many practices, offsite sterilisation may be more cost effective than purchasing and running a steriliser, or using disposable single-use equipment.

The practice must obtain appropriate documentation concerning the offsite sterilisation activities as evidence that sterilisation standards have been met.

A documented agreement between the practice and offsite sterilisation facility is helpful to detail the arrangements and responsibilities of each party.

The practice must keep a record of offsite sterilising in the practice's steriliser logbook.

For many practices, offsite sterilisation may be more cost effective than purchasing and running a steriliser, or using disposable single-use equipment.

As the turnaround time for the reprocessing of equipment is usually slower when performed offsite, more sets of reusable medical devices are required. The actual number of sets required depends on usage patterns and turnaround time.

## Documentation

### Accredited offsite sterilisation facilities

If the offsite sterilisation facility is accredited (eg an accredited general practice or Australian Council on Healthcare Standards accredited hospital), the practice needs to have a copy of the facility's accreditation certificate.

### Nonaccredited offsite sterilisation facilities

If the offsite facility is not accredited, the practice needs to assure itself that the facility would meet accreditation requirements for sterilisation and have copies of the facility's relevant documents, including:

- reprocessing
- sterilisation policies and procedures
- results of validation.

### Agreement between the practice and offsite sterilisation facility

A documented agreement between the practice and offsite sterilisation facility is helpful to detail the arrangements and responsibilities of each party (eg responsibility for washing and packaging used equipment, expected turnaround time, responsible contact personnel in the practice and the offsite sterilisation facility and contingencies for process failure).

## Steriliser logbook

The practice must keep a steriliser logbook which contains:

- the details of sterile barrier systems and loads
- the load number
- details of contents of the cycle performed offsite
- the condition of sterile barrier systems received back by the practice, and the identity of staff preparing loads for sterilising and releasing loads for use. Practices and offsite facilities should have an agreed method of reporting to each other any unacceptable loads received.

## Practice policies and procedures

The practice must have appropriate policies and procedures to ensure:

- sharps and contaminated disposable reusable medical devices are safely discarded
- dirty reusable medical devices undergo some preliminary cleaning (eg dry wiping, damp wiping or rinsing)
- standard precautions and personal protective equipment are used to prevent exposure to blood and body substances
- hand hygiene occurs
- maintenance of sterility during transport from the site (described below).

## Transportation of used but cleaned reusable medical devices

A labelled container is used for transportation of used reusable medical devices which have been cleaned and dried, whether placed in a sterile barrier system in the practice or not.

The container and lid need to be appropriately labelled (eg 'unsterile reusable medical devices') and standard precautions need to be used at all times when handling this container.

## Transportation of sterile reusable medical devices

Another labelled container is used to transport the reusable medical devices back to the practice after sterilisation.

The container and lid need to be appropriately labelled (eg 'sterile reusable medical devices').

Packs need to be checked for Class 1 chemical indicator change, intact seals and damage before being released for use in the practice.

## Section 4.21. Sterile equipment used outside the practice

Practices that perform procedures in other locations – such as aged care facilities, home visits and at sporting events – need to develop policies and procedures that ensure sterility of equipment in transport and safe handling of used equipment.

Practices that perform procedures outside the practice need to have appropriate risk-based policies and procedures that ensure:

- maintaining the sterility of reusable medical devices in transport to the site
- separation of sterile and nonsterile reusable medical devices using appropriately marked containers
- preliminary cleaning of used reusable medical devices at the offsite location by wiping or rinsing off gross soil
- safe management and disposal of sharps and used single-use reusable medical devices
- the use of standard precautions to prevent exposure to blood and body substances.

## Chapter 5. Disease surveillance

### Section 5.1. Disease surveillance

Staff need to be familiar with their statutory responsibilities in relation to monitoring for and reporting disease outbreaks to the relevant state/territory authorities, and responding with the institution of appropriate precautions at the practice level.

Systems must be in place to ensure the timely reporting of notifiable diseases to the relevant state/territory health department.

In addition to awareness and reporting of notifiable diseases, practices need to institute appropriate infection prevention and control measures to prevent the risk of spread of disease.

Systems must be in place to monitor for threats of outbreaks (eg varicella, measles, lyssavirus, hendravirus), bioterrorism (eg anthrax) and emerging diseases such as (SARS, Middle East respiratory syndrome (MERS), avian influenza and CAMRSA).

### Staff education

Staff need to be educated around awareness of patients presenting with suspected or confirmed infectious diseases.

Reception staff need to be able to identify the potentially infectious patient and to implement appropriate infection prevention and control measures (eg ask the patient to wear a mask, segregate the patient, explain to the patient why infection prevention and control measures are being implemented).

Staff should be trained in the use of an infection prevention and control kit (available at reception) to enable prompt initiation of appropriate measures when a patient with a suspected or confirmed infectious disease presents. An example of an infection prevention and control kit can be found at *Appendix 7*.

All members of the practice team should be able to demonstrate how risks of potential cross-infection within the practice are appropriately managed, including:

- hand hygiene
- the use of PPE
- triage of patients with potential communicable disease
- safe storage and disposal of clinical waste including sharps
- managing blood and body fluid spills.

The practice team member with delegated responsibility for staff education on infection prevention and control must ensure that the induction program for new staff covers the practice's infection prevention and control policy as relevant to their role. They must also ensure that requirements are met for providing ongoing staff education and assessing staff competency.

## Monitoring for threats

General practices and other office- and community-based practices need to have systems in place that allow for monitoring threats of outbreaks (eg varicella, measles, lyssavirus, hendra virus), bioterrorism (eg anthrax) and emerging diseases such as SARS, MERS, avian influenza, and CAMRSA (see *Appendix 14*).

To ensure that practices remain up to date with information, it is useful for a nominated staff member to have the responsibility for checking relevant federal and state/territory websites for relevant guidelines (refer to *Resources*) and for disseminating this information to other practice members.

The RACGP provides urgent information to practices through its newsletter network. Updates are sent as necessary to any doctor or practice that subscribes. To subscribe, email [friday.facts@racgp.org.au](mailto:friday.facts@racgp.org.au). It will be helpful to subscribe to other alert lists (refer to *Resources*).

The RACGP will endeavour at all times to ensure that all such information is coordinated with other alert lists – but if any information is conflicting then practices are advised to contact their local public health office.

## Notifying relevant authorities

General practices and other office- and community-based practices need to have systems in place to ensure the timely reporting of notifiable diseases to the relevant state/territory health department. A system of communication with local health authorities should be established and maintained. Some notifiable diseases require notification by telephone.

Each doctor and health professional has a responsibility to ensure that suspected or confirmed notifiable diseases are reported in a timely fashion.

Contact details for state/territory public health officers are in *Appendix 2*.

The Australian Government has a list of national notifiable diseases on the Department of Health's website ([www.health.gov.au](http://www.health.gov.au)).

## Contact tracing

Occasionally a patient may present at the practice, and later be known to have a transmissible disease (eg tuberculosis). State/territory health authorities need to be notified to enable tracing of contacts of the infected patient. In order to initiate appropriate counselling, quarantine and post-exposure prophylaxis, practices may need to identify staff on duty and other patients present at the time who may have been exposed to the infectious patient and be at risk. This may entail checking staff rosters, staff immunisation records and patient appointment records.

## Practice response to threats

In addition to awareness and reporting of notifiable diseases, practices also need to institute appropriate infection prevention and control measures (standard and transmission-based precautions) to prevent the risk of spread of disease. Refer to *Chapter 1, Section 1.4*.

Practices will benefit from having an infection prevention and control kit available at reception in order to initiate appropriate measures when a patient with a suspected or confirmed infectious disease presents. An infection prevention and control kit contains items for implementation of standard and transmission-based precautions, including personal protective equipment. The infection prevention and control kit may be combined with a spills kit. An example of an infection prevention and control kit can be found at *Appendix 7*.

## Section 5.2. Reception and triage

Transmission-based precautions should be routinely used for patients known or suspected to be infected with highly transmissible infectious agents (eg influenza).

It is essential that all staff are trained to recognise symptoms and signs of potentially infectious disease and to respond appropriately.

Staff need to know how and when to use standard and transmission-based precautions to protect themselves and other patients, especially in the event of a disease outbreak.

The practice team member delegated to staff education on infection prevention and control is responsible for ensuring that the induction program for new staff covers the practice infection prevention and control policy as relevant to their role, and for ensuring requirements are met for providing ongoing staff education and assessing staff competency.

It is important to educate patients to indicate to the reception staff that they have a possible infectious disease when they present.

It is essential that staff respond rapidly when confronted by a patient with a suspected or confirmed infectious disease.

Practices need to consider providing hand-hygiene products (eg alcohol-based hand rub, facial tissues, waste bins) in strategic locations around the practice to encourage patients to attend to respiratory and hand hygiene.

The use of masks (by both the patient and staff), segregation and social distancing may also be indicated.

It is advisable for the practice to have an infection prevention and control kit at hand.

It is important that all staff are trained to recognise symptoms and signs of potentially infectious disease and to respond appropriately. Role-appropriate education and training is the responsibility of the practice's infection prevention and control program coordinator.

It is useful to think of triage in general practices and other office- and community-based practices in three stages:

1. Routine questions asked of all patients.
2. Questions asked when the patient indicates signs or symptoms consistent with an infectious disease.
3. Questions asked of patients when the practice suspects a localised outbreak of an infectious disease (eg measles) or when the practice is part of a response to a (suspected) pandemic.

Staff need to know how and when to use standard and transmission-based precautions to protect themselves and other patients, especially in the event of a disease outbreak. Staff also need to know how to explain to patients why precautions are being taken and to reassure patients that precautions are for everyone's benefit.

## Booking appointments

Due consideration to patient privacy needs to be taken when asking questions, however, a small amount of information can be very useful in planning for the patient's arrival and care within the practice.

Reception staff can ask a general question when booking appointments for patients regarding the reason for the consultation. However, patients need to understand the reason that the question is being asked. An example of such a question is: 'So that our doctors can provide the best possible care, can you give me an indication of the nature of your visit?'

Where a patient indicates that they have a fever, a rash, a cough, diarrhoea or an infectious disease (eg the patient says they suspect they might have contracted MERS), then it is appropriate to ask further questions.

Again, it is important to tell the patient why you are asking: 'Would you mind if I asked a few more questions, as the information will help us care for you?'

Then, if the patient has not already told you, ask:

- Do you have a fever?
- Do you have a rash?
- Do you have a cough?
- Do you have diarrhoea?
- Have you been overseas recently and if so, where?
- Have you recently had contact with an infectious disease?

The answers should be recorded and conveyed to the doctor.

Practices may wish to consider a script or question sheet for the clerical staff to use for this purpose.

When the practice suspects a localised outbreak of an infectious disease or when the practice is part of a response to a (suspected) pandemic (eg avian influenza), the practice should have planning and policies in place, of which all staff are aware.

In these circumstances, it is essential to ask questions specific to the suspected disease. In a pandemic it is likely that the RACGP and/or public health authorities will provide advice about these questions. Again, it is important for reception staff to explain the reason they are asking the questions.

In this situation, it may be appropriate for staff to say to patients, 'Our doctors have asked us to ask all patients the following questions' and then ask relevant questions. For example:

- Have you been exposed to anyone with chicken pox in the past 3 weeks?
- Have you recently returned from overseas?

If the patient answers yes, staff need to consider the implementation of appropriate precautions when the patient attends. Such precautions should be part of planning and policies already in place.

When booking an appointment, consider booking appointments for patients with potentially infectious diseases at a time when there are fewer patients present (eg at the end of a session). In a pandemic, consider booking such patients to a designated doctor in a designated separate room – preferably with separate entrance/exit to the main surgery. It may be possible in a pandemic that such patients can be directed to a flu centre (where available) rather than being treated in the surgery. Even where flu centres are in operation, practices should anticipate that some patients with flu will prefer to be treated by their GP and refuse to attend a flu centre.

## Practice signage

Practices should consider:

- posting a sign at the entrance to the practice and another at reception requesting patients presenting with symptoms of infection to inform the receptionist
- displaying information on the practice notice board, the practice website or inserting it in the practice information sheet

- recording a telephone message for patients on hold, asking them to let the receptionist know if they think they may have an infectious disease.

In a pandemic, if patients are not being directed to a flu centre, consider having a properly protected staff member controlling the door who can explain to patients the precautions being taken and only let in patients who will, for example, wear a mask and agree to segregation, preferably in a designated room with a separate entrance/exit.

## Precautions to be taken with a potentially infectious patient

It is important that staff respond rapidly and with the appropriate precautions when confronted by a patient with a suspected or confirmed infectious disease. These precautions include:

- If possible, take the patient to a separate area (segregation) or have the patient wait outside away from the door (depending on the patient's condition).
- If it is not possible to physically segregate the patient, attempt to provide a gap of at least 1 metre between the potentially infectious patient and other patients in the waiting area (social distancing).
- For droplet and airborne spread disease:
  - instruct the patient on respiratory etiquette (described below)
  - consider instructing the patient to wear a mask. To date this has not been a common practice in Australia, and patients will need to be educated on the need to protect others
  - instruct the patient on the use of a mask, disposal of used tissues and hand hygiene
  - consider explaining to other patients waiting near the potentially infectious patient.
- For contact spread disease and any communicable disease:
  - instruct the patient to refrain from touching communal objects (eg toys) and to ensure their hands are cleaned with an alcohol-based hand rub kept by the staff and accessible to patients.

## Respiratory etiquette

Respiratory etiquette refers to practices that reduce the potential for transmission of diseases from coughing and sneezing and includes:

- covering the mouth and nose when coughing and sneezing
- using tissues to contain secretions, and disposing of tissues after use in bin provided
- attending to hand hygiene with soap and using water and disposable towels to dry hands, or using an alcohol-based hand rub.

It is useful and appropriate to have posters prominently displayed in patient and staff areas relating to respiratory etiquette. This becomes essential in pandemics.

## Infection prevention and control kit

It is advisable for the practice to have an infection prevention and control kit at hand for ease of use when a patient with a potentially infectious disease presents (*Appendix 7*). The kit should contain items that allow immediate implementation of standard precautions and some transmission-based precautions.

## Further reading

See the RACGP Pandemic flu kit for further information regarding pandemic influenza. This contains current evidence-based information about pandemic influenza and includes comprehensive information regarding prevention, preparedness, response and recovery principles and activities. It also provides a range of operational documents developed to support general practices in their preparedness and response efforts.

## infection prevention and control training

[illegible]

## Reprocessing medical equipment and instruments

[illegible]

## *Appendix 2. State and territory health department communicable disease contacts*

Australian Capital Territory	02 6205 2155
Northern Territory	08 8922 8044
Royal Darwin Hospital	08 8922 8888 (AH)
New South Wales	1300 066 055
Queensland	07 3234 1155
South Australia	08 8226 7177
Tasmania	0408 532 708
Victoria	1300 651 160
Western Australia	08 9388 4999
	08 9328 0553 (AH)

## Appendix 3. Transmissible diseases and precautions

It is important to remember that preventing the transmission of some infections may require the use of more than one type of precaution: for example, respiratory viruses generally require the implementation of both contact and droplet precautions.

Disease	Recommended precautions	Reportable to state/territory health departments
Acute bacterial conjunctivitis	Contact	Yes, if gonorrhoeal or chlamydial
Adenoviruses	Droplet	No
Amoebiasis	Contact	No
Anthrax – cutaneous	Contact	Yes
Anthrax – pulmonary	Airborne	Yes
Bronchiolitis	Contact and droplet	No
Croup	Droplet	No
Cytomegalovirus (CMV)	Contact	No
Ebola	Airborne	Yes
Enteroviruses	Contact	No
Extended spectrum beta-lactamase (ESBL )	Contact	No
Giardiasis	Contact	Yes
Hand, foot and mouth disease	Contact	No
Hepatitis A	Contact	Yes
Herpes simplex	Contact and droplet	No
Haemophilus influenzae type B (HIB)	Droplet	Yes
Impetigo	Contact	No
Influenza	Contact and droplet	Yes
Measles	Contact and airborne	Yes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	Contact	No
Meningitis	Droplet	Yes
Mumps	Droplet	Yes
Parvovirus B19	Droplet	No
Pediculosis	Contact	No
Pertussis	Droplet	Yes
Pinworm	Contact	No
Respiratory syncytial virus (RSV)	Contact and droplet	No
Rotaviruses	Contact	No
Roundworm	Contact	No

Ringworm	Contact	No
Rubella	Droplet	Yes
Salmonellosis	Contact	Yes
Scabies	Contact	No
Shigellosis	Contact	Yes
Slapped cheek disease	Contact	No
Staphylococcal infections	Contact	No
Streptococcus Group A	Droplet	No
Severe acute respiratory distress syndrome (SARS)	Contact and airborne	Yes
Tuberculosis	Airborne	Yes
Vancomycin resistant enterococci (VRE)	Contact	No
Varicella (chicken pox)	Contact and airborne	No
Varicella zoster (shingles)	Contact and droplet	No
Viral haemorrhagic fevers	Airborne	Yes

Adapted from: Victorian Government Department of Human Services, The blue book: guidelines for the control of infectious diseases. Melbourne, 2005.

## Appendix 4. Skin disinfection

Skin disinfectants kill, and temporarily reduce, microorganisms on the skin. They are appropriate for use in the following situations:

- to reduce the number of resident microorganisms on the skin (eg before surgery or intravascular or body cavity cannulation or injection)
- when the level of microbial contamination is high (eg 'dirty' wounds)
- when persistent antimicrobial activity is desired (eg during surgery)
- before intravascular or joint or body cavity penetration
- before intradermal, subcutaneous or intramuscular injection (eg vaccinations), however their use is not essential.

Table A4.1 provides further information about products used for skin disinfection.

Table A4.1 Products suitable for skin disinfection

Product	Use	Contraindications for use
Tap water	Wound/ulcer cleaning where disinfection is not required	Where quality of tap water is uncertain, use boiled, distilled water or sterile water or saline
Sterile water or saline	Wound/ulcer cleaning where disinfection is not required	–
Aqueous chlorhexidine	For disinfection of skin and mucous membranes	Cannot be used in middle ear or ocular surgery
Alcohol 70%	For skin disinfection	Cannot be used on broken skin, mucous membranes or where the use of diathermy or laser is anticipated
Iodine-based preparations	For disinfection of skin and mucous membranes	Cannot be used in ocular surgery

Adapted from: Department of Health and Ageing, Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting. Canberra, 2004.

### Using skin disinfectants

Skin disinfectants are regulated by the Therapeutic Goods Administration and are labelled according to their appropriate use.

Skin disinfectants must be used according to the manufacturer's directions.

Skin disinfectants need to be appropriate to the site. Some disinfectants are irritant to mucous membranes (eg alcohol) and some cause nerve damage (eg chlorhexidine can cause sensorineural deafness if used in the middle ear).

## Appendix 5. Staff immunisation record (example)

Name:				Date of birth:		
Address:						
Vaccinations required						
Vaccine	If completed, provide date	Pre-vaccination antibody status and date	Date received	Date received	Date received	Post-vaccination antibody status and date
Hepatitis B						
Influenza						
MMR						
Pertussis						
Varicella						
Hepatitis A						
Polio						
Risk of infection and benefits of vaccination explained						
Date:						
Signature of person providing advice:						
Signature of staff member acknowledging vaccination advice offered:						
Consent for vaccination obtained from staff member: YES / NO						
Further counselling and education provided:						

## *Appendix 6. Immediate action following blood and body fluid exposure*

It is important that any blood or body fluid exposure be assessed and managed immediately to reduce the possible risks to the exposed person.

### Caring for the exposed person

#### Decontaminate exposed area

- Skin: wash with soap and water or a skin disinfectant product (do not use caustic agents such as bleach as these may compromise skin integrity).
- Mouth, nose, eyes: rinse well with water or saline.
- Treat the wound as appropriate (eg suturing, dressing).

#### Report

Report exposure to a medical practitioner to ensure prompt and appropriate commencement of treatment.

#### Test the exposed person

- If the source is unknown, the exposed person needs to be tested and PEP needs to be considered.
- Perform baseline tests for HIV, HBV and HCV antibody levels. These baseline tests establish the immune status or previously acquired infection of the health professional.
- Request urgent testing and results from the laboratory.
- If HBV prophylaxis is required, it is important that the injured health professional returns within 48 hours of the incident to commence PEP.
- Maintain confidentiality of the health professional's status within privacy and public health guidelines. In order to protect their confidentiality, staff may choose to have these tests performed at a different general practice (eg hospital emergency department or sexually transmitted infection clinic).
- Advise the health professional to practise safe sex (eg use condoms) until their results and the patient's risk history have been reviewed.
- Give the health professional the phone number for the state/territory health department communicable disease office (see *Appendix 2*).
- Refer the health professional to an infectious diseases specialist if the injury is high risk or if the source patient has at-risk activities.

#### Assess risk of transmission of infection

The risk of the health professional getting a disease from a blood or body fluid exposure depends on the type of injury, the type of body fluid, and whether the source has infective blood.

An exposure that might place the health professional at risk for HIV infection is defined as a percutaneous injury (eg a needlestick or cut with a sharp object) or contact of mucous membrane or nonintact skin (eg exposed skin that is chapped, abraded or afflicted with dermatitis) with blood, tissue or other body fluids that are potentially infectious. In addition to blood and visibly bloody body fluids, semen and vaginal secretions are considered potentially infectious. Although semen and vaginal secretions have been implicated in the sexual transmission of HIV, they have not been implicated in occupational transmission from patients to health professionals.

The following fluids also are considered potentially infectious: cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluid. The risk for transmission of HIV infection from these fluids is unknown. The potential risk to health professionals from occupational exposures has not been assessed by epidemiologic studies in health care settings. Faeces, nasal secretions, saliva, sputum, sweat, tears, urine and vomit are not considered potentially infectious unless they are visibly bloody; the risk for transmission of HIV infection from these fluids and materials is low.

## Initiate treatment

For advice about appropriate PEP, consult the state/territory health department communicable disease contact (see *Appendix 2*).

- PEP needs to be commenced if it is anticipated that the source's blood test results will not be available within 24 hours and the source patient is likely to be HIV positive, or in the window period.
- PEP for HIV can be considered if the exposure was a high-risk injury from an unknown source.
- When test results become available, treatment may be reassessed.
- If the source's HBV result will not be available within 24–48 hours, and if the health professional's HBV status is not documented, then give, with the exposed person's consent:
  - hepatitis B immunoglobulin
  - hepatitis B vaccine (first dose)
  - adult diphtheria and tetanus (ADT) if necessary.

## Referral

The person exposed should be referred for immediate consultation with an infectious diseases specialist:

- if the injury is classified as high risk (*Table A6.1*)
- if the source has participated in at-risk activities
- if the source has a positive result for HIV, HBV or HCV.

## Possible patient exposure

If the incident occurred during a procedure, the possibility of the patient being exposed to the injured health professional's blood needs to be considered. If there is a risk of exposure of the patient to a health professional's blood, the patient needs to be advised to have the same screening and treatment.

## Caring for the source

### Reassure the source

- Explain to the source that a health professional was inadvertently exposed to their blood or body fluid, and that testing is required because:
  - every healthcare facility follows this protocol after an exposure of a health professional to blood or body fluids
  - all sources are tested and there is no discrimination
  - it would be of benefit to the exposed health professional.
- If relevant, reassure the source that they are not responsible for the accident and/or that they have not been exposed.
- Explain that the incident is being investigated to prevent a recurrence.
- Reassure the source that their confidentiality will be maintained, within privacy and public health guidelines.

## Arrange pre-test counselling

- Arrange pre-test counselling of the source. This is required by legislation in some states and territories.
- Counselling needs to be provided by a qualified person.
- Inform the source that, if they have had at-risk activities, a blood test might not show evidence of infection until 3–6 months after the at risk activity.

## Take a history

Taking a history from the source will help identify the likely risk of disease exposure to the exposed person. Take a history from the source about at risk activities or previous exposure, especially in the past 6 months such as:

- unprotected sexual intercourse
- sharing needles, or tattoos or body piercing
- sharing razor blades or toothbrushes
- blood or body fluid exposure of mucous membranes or nonintact skin
- blood transfusion before February 1990 (for HCV)
- infection with HIV, HBV or HCV.

## Test the source

Most patients will agree to a blood test if they are approached in a sensitive manner. In some states and territories there is legislation that includes mechanisms requiring testing if the source refuses or is unable to consent to testing.

Obtain informed consent from the source for testing for HBV, HCV and HIV.

Have the source's blood tested as soon as possible. Results can be available within 1 hour if received at an appropriate testing laboratory.

**Table A6.1. Classification of exposure to blood and body fluids**

Risk to exposed person	Description
High risk	Percutaneous exposure to blood AND large volume of high titre blood infected with HIV, HBV, HCV
Significant risk	Nonintact skin exposure to the above
Low or increased risk	<ul style="list-style-type: none"> <li>• Mucous membrane exposure (eg eyes, mouth)</li> <li>• Exposure to small amount of blood</li> <li>• Exposure to noninfective blood</li> </ul>
No risk	Percutaneous, mucous membrane or cutaneous exposure to non-bloodstained urine or saliva, or exposure to intact skin

## Document exposure

The following information should be documented:

- what procedure was being undertaken
- how the injury occurred
- the nature and extent of the injury
- exactly what caused the injury (eg specify the needle gauge)
- the nature of the body substance involved
- how much source blood/body fluid the health professional was exposed to
- what personal protective equipment was being used
- if possible, identify the source.

## Summary

Management of an occupational exposure ensures:

- immediate decontamination of the exposed area
- rapid testing of the exposed person and the source
- timely administration of PEP when appropriate
- full documentation of the incident to enable investigation
- counselling of the exposed person and source
- analysis of the cause of the exposure incident and modification of procedures as required to reduce the risk of recurrence
- staff education as required.

For further information regarding treatment and management of exposure to blood or body fluids, call the state/territory health department communicable disease contact (see *Appendix 2*).

## *Appendix 7. Infection prevention and control kit*

General practices and other office- and community-based practices need to have equipment appropriate to deal with possible or confirmed infectious diseases ready for use. It is useful for the practice to keep a kit containing the necessary equipment close to reception in a container with the contents clearly labelled, perhaps combined with the practice spill kit. The contents should be checked regularly.

A suggested infection prevention and control kit could contain adequate stocks of the following:

- nonsterile disposable gloves
- goggles
- gown: preferably disposable and long sleeved with cuffs
- masks: regular surgical masks for patient use and P2/N95 masks for use by doctors, health professionals and other staff for protection against airborne diseases
- tissues: for general use in promoting respiratory etiquette
- waste bin lined with a plastic bag: for disposing of used tissues
- alcohol-based hand rub or wipes for hand hygiene
- water and detergent spray and/or wipes
- alcohol wipes or disinfectant spray for treating surfaces after contact with an infectious patient
- yellow biohazard bags for disposal of contaminated items and to line the bin.

## *Appendix 8. Processing reusable equipment*

The following is a summary of the steps to processing reusable equipment. This document is designed to be an aid only and does not take the place of the full information found in *Chapter 4*. Staff need to be trained and assessed as competent for each step of the processing cycle that they perform.

### Step 1. Precleaning (in treatment/consultation room)

- Following the procedure, while still gloved, remove gross soil from used instruments (eg wiping or rinsing instrument).
- If practicable, transport instruments to the reprocessing area for immediate cleaning. Transport instruments in a container dedicated for that purpose.
- If immediate transport and cleaning is not possible, soak used instruments for short periods of time in water and detergent until cleaning is possible.

### Step 2. Cleaning (in the reprocessing area)

- Use personal protective equipment when handling soiled instruments. This includes the appropriate use of gloves, goggles/face mask and apron to protect against contact, droplet and airborne exposure to microorganisms.
- In the 'dirty' sink, wash all used instruments and equipment under tepid water with an appropriate detergent.

or

- Place used instruments in ultrasonic cleaner or instrument washer/disinfector and operate according to the manufacturer's instructions.

### Step 3. Rinsing and drying (for manual and ultrasonic cleaning)

- In the 'clean' sink, rinse all instruments and equipment in gently running HOT water.
- Drain on a clean surface (eg sink drain, cake rack or low-lint towel).
- Dry with a low-lint cloth.
- Check all instruments and equipment for cleanliness.

### Step 4. Preparing the load for sterilising

- Select packaging of appropriate size to match the item to be sterilised.
- Ensure each package has a Class 1 chemical indicator included.
- Seal the package to ensure there are no gaps through which air can enter.
- Label packages with date, load number and, if required, description of contents, and the signature of person responsible for packing.

## Step 5. Loading the steriliser

- Load hollowware (eg kidney dishes, gallipots) on their sides and separate to ensure adequate steam penetration.
- Use load separators and trays to ensure packages are separated and only loosely in contact.
- Ensure the load does not exceed the validated challenge load parameters (check validation record) and packages are not touching the sides of the steriliser.

## Step 6. Sterilising the load

- Check water level and add water if necessary, according to manufacturer's instructions.
- Select appropriate steriliser cycle parameters (check validation record) (eg 134°C for 3.5 minutes).
- Close door and start steriliser cycle.
- Record details of the load into the steriliser logbook (date, load description and load number, identification of the person who prepared the load).
- Do not attempt to open the steriliser door while the cycle is in operation.

## Step 7. Unloading the steriliser

- Do not attempt to open the steriliser door while the cycle is in operation.
- When the cycle is completed, remove trays and place in a clean area to cool. Take care not to touch hot packages.
- Check bags for moisture and damage.
- If packages are moist when they come out of the steriliser, chemical indicators do not have correct colour change or cycle monitoring parameters are not correct, fail the load, investigate the cause and resterilise the load. If packages are damaged, reprocess the affected item in new packaging.

## Step 8. Documenting the cycle

In addition to the detail previously recorded, record the following details into the steriliser logbook:

- Class 1 chemical indicators have changed colour
- results of any other indicators used (eg chemical or biological)
- correct time at temperature the sterilisation cycle was achieved
- condition of the packs (ie dry and intact)
- comments (eg action taken for failed cycle)
- identification of the person who released the load.

## Step 9. Storage

- When cool, store sterile instruments/equipment in clean area away from dust or moisture.
- Rotate stock so that instruments/equipment sterilised earlier are used first.

## Appendix 9. Choosing a steriliser

### Assessing the need for a steriliser

Practices must assess their requirements for sterile equipment (eg types of items to be sterilised, numbers required, turnaround time). This assessment will determine the need and type of steriliser required. The following points may assist:

- What types of sterile instruments and equipment are required?
- How often are they required?
- Comparative costs of onsite sterilisation:
  - initial purchase price
  - installation
  - training of staff
  - consumables (eg printer paper and ink cartridges, packaging, distilled water, spore tests for validation and Bowie-Dick tests for Class B cycles)
  - staff time for performing and recording leak rate tests and Bowie-Dick tests
  - staff time for reprocessing equipment
  - ongoing maintenance
  - validation costs.
- Comparative costs of offsite sterilisation:
  - cost of extra sets of instruments
  - sterilisation charges.
- Use of single-use disposable equipment:
  - cost of instrument sets
  - availability of appropriate sets.

#### Case study 1. Rural group practice

A rural practice does procedural work involving minor procedures such as IUD insertion, vasectomies and removal of lesions. There are several procedures of each type daily. There is also a dentist onsite with a high patient turnover and who needs to sterilise narrow cannulated handpieces.

The practice decided to invest in a new steriliser. They chose a steriliser that could undertake all cycle classes (including Class B) to deal with their need to disinfect some items such as hollowware (eg kidney dishes) and sterilise instruments and dental handpieces (hollow load A items). They chose a steriliser model with a large capacity chamber to deal with their larger loads and packs.

#### Case study 2. Small urban solo practice

A solo practitioner assessed the needs of the practice. The practitioner did very few procedures, such as occasional Pap tests, suturing of lacerations and dressings. The practitioner decided to use commercial dressing packs and single-use instruments. The local hospital agreed to process the few instruments that could be reprocessed. The practice purchased extra instruments to allow for the turnaround time using the hospital.

## Further considerations

### The practice owns a steriliser without an active drying cycle

Practices that own older style sterilisers without an active drying stage must decide whether to:

- purchase a new steriliser, or
- use prepackaged disposable sterile stock, or
- use offsite sterilisation facilities.

### The steriliser does not provide a printout of the sterilisation cycle

Monitoring the sterilisation cycle is essential for ensuring instrument sterility. The results of each cycle must be checked before the instruments are released for reuse. Sterilisers without a printer do not provide the user with the details of the cycle and are not suitable for use in general practices and other office- and community-based practices without additional monitoring. If the steriliser has a data logger, the log must be checked for each cycle before processing items are used and the details recorded into the sterilisation logbook.

If details of the sterilisation cycle are not available because there is no printer or data logger, or if the printer breaks down or runs out of consumables, or the data logger or its computer fails, the practice must decide on one of the following:

- have a printer retrofitted, or
- purchase a new steriliser, or
- use a Class 4, 5 or 6 chemical indicator in the tray with every load, or manually record the time at temperature readings every 30 seconds throughout the sterilisation cycle and drying cycle.

## Appendix 10. Steriliser/maintenance logbook (examples)

Date	Load no.	Person preparing load (name or ID)	Load contents description	Time and temperature printout or Class 4, 5 or 6 chemical indicator	Class 1 chemical indicator change	Packs dry and intact	Person releasing load (name or ID)	Steriliser maintenance and repairs	Comments (including name or ID)
2/11/13								Cleaned, water changed	M Gale, practice nurse
2/11/13	1	H Hodder	3 x suture sets 4 x scissors 1 x excision set	Printout passed 3.5 min @ 134 °C	Pass	Yes	J Smith		
5/11/13	1	K Krane	6 x forceps 2 x scissors	Failed – load rejected		Printer broken			Load repacked and repeated with Class 6 chemical indicator (H Hodder, practice nurse)

### Tracking of instruments and patient tracing

Instrument	Date sterilised	Batch number	Patient ID	Comments
Scissors Suture set	2/11/13	1	Mr I Jones UR 12456	
Forceps	5/11/13	2	Ms P Shane UR 95678	
Excision set	7/11/13	1	Mr E Uren UR 53289	

## Appendix 11. Simple first validation template

### Responsibility

The staff member with designated responsibility for sterilisation to:

1. Review the documented procedures covering all parts of the sterilisation process to ensure reproducibility:
  - workflow issues: dirty through to clean and environmental cleaning
  - precleaning and cleaning of instruments
  - pack contents, packing and sterile barrier system
  - loading of the steriliser
  - mechanical/physical monitoring (chemical indicators and recording of time at temperature) of the sterilisation cycle parameters
  - unloading of the steriliser and checking the packs are dry and intact and checking monitoring results and correct chemical indicator change
  - storage of sterile items
  - maintenance of steriliser as required by the manufacturer (including water changes and cleaning).
2. Perform or supervise the documented procedures.
3. Check that the procedures were successful.
4. Record successful completion of each procedure (*Table A11.1*).

### Procedure

#### Workflow issues: dirty through to clean and environmental cleaning

- Review documentation in practice policy and procedure manual or other documentation.
- Observe or reflect on performance of the tasks from precleaning through to storage, including environmental cleaning relevant to instrument reprocessing.
- Check that workflow from dirty to sterile is not compromised and that environmental cleaning is adequate.
- Record (*Table A11.1*).

#### Precleaning and cleaning of instruments

- Review documentation in practice policy and procedure manual or other documentation.
- Perform or supervise precleaning and cleaning.
- Check using a magnifying loop or glass that the instruments are clean (eg paying special attention to serrations).
- Record (*Table A11.1*).

#### Pack contents, packing and sterile barrier system

- Review documentation in practice policy and procedure manual or other documentation.
- Perform or supervise pack preparation with correct contents, packing and sterile barrier system.

- Check packs:
  - have the correct contents
  - are packed correctly in the correct sterile barrier system and do not exceed those of the documented ‘challenge packs’ (*Table A11.2*)
  - have seals that are intact
  - have a Class 1 chemical indicator on the outside of each pack
  - have been labelled with the date, steriliser number (if applicable), load (batch) number and staff identification of cleaner and packer (if applicable)
  - have instruments loosely open, not tightly closed
  - have hollowware, if packed in laminate pouches, packed with the opening against the paper, not the laminate plastic side
  - have not had ballpoint pens used on critical pack surfaces.
- Record (*Table A11.1*).

### Loading of the steriliser

- Review documentation in practice policy and procedure manual.
- Perform or supervise loading of the steriliser.
- Check that:
  - the total contents of the steriliser do not exceed those of the documented ‘challenge load’ (*Table A11.3*)
  - packs loaded with hollow items are on their sides
  - the paper side of any laminated pack is adjacent to the laminate side of another
  - individual instrument packs are separated on racks
  - trays of unwrapped instruments are not overloaded
  - there is a Class 1 chemical indicator in the tray with unwrapped instruments.
- Record (*Table A11.1*).

### Mechanical/physical monitoring of sterilisation cycle parameters

- Review the documentation in the practice policy and procedure manual for each steriliser used, including:
  - manufacturer’s instructions
  - heat distribution studies (*Table A11.4*)
  - description of the challenge pack and load (*Tables A11.2, 3*)
  - diagram of chamber loading (*Figure A11.1*)
  - penetration times (*Tables A11.3, 5*).
- The service technician should:
  - perform a ‘heat distribution study’ to check for cold spots in the chamber and record (*Table A11.4*).
  - establish the penetration time for the ‘challenge pack’ within the ‘challenge load’ and record (this combination reflects the greatest challenge to the sterilisation process of any load)
  - set the processing time on the steriliser for all loads (ie holding time plus penetration time) and document (*Table A11.5*)
  - check the drying time and reset if required (a trial and error process checking after different lengths of

drying time for load dryness) (*Tables A11.3, 5*)

- perform additional function checks for validation of the sterilisation cycle (ie during the processing and drying time)
- perform physical qualification (checking) of the temperature within the challenge pack within a challenge load with a thermocouple throughout the total processing time (ie 'time at temperature' testing) at least once. This check should continue to check the drying time. The penetration time can also be checked while this is being performed
- check the temperature of the incubator.
- The staff member with designated responsibility for sterilisation should:
  - perform microbiological qualification (checking) of the effectiveness of the sterilisation cycle in processing the challenge pack/load by the use of appropriate indicators in three successive cycles (*Table A11.6*).

### The indicators

- Biological or enzymatic indicators:
  - have a spore count equivalent to  $10^5$
  - are from the same batch.
- Indicators need to be suitable for the type of steriliser and temperature selected (enzymatic indicators on the Australian market are not suitable for gravity displacement bench top sterilisers operating at 134°C and cannot be used for either additional monitoring or validation).
- A minimum of two indicators are required for each load to be validated plus one control indicator.

Note: there are arguments for and against running the physical 'time at temperature' check concurrently with the first microbiological test cycle. It can improve efficiency of the process or may get in the way of the technician, slowing things down. The technician's steriliser leads may alter the pack if not properly sealed where they enter the pack, letting steam in more easily and impinging on both the microbiological and physical check. In addition, if the 'time at temperature' testing determines the need for a longer sterilisation time, the indicators will be wasted. In the case of onsite technical assistance not being available, it would not be possible to run a concurrent time at temperature test and first microbiological test cycle.

### Labelling indicators

Label indicators before starting according to:

- the cycle number (1 for the first, 2 for the second or 3 for the third)
- the position it is to be placed in the steriliser (eg M for middle of challenge pack or C for cold spot if determined or placed anywhere on tray if none), for example:
  - Cycle 1 label one indicator 1/M (1st cycle in the middle of the challenge pack) and the other 1/C (1st cycle on the tray nearest the cold spot)
  - Cycle 2 label one indicator 2/M (2nd cycle in the middle of the challenge pack) and the other 2/C (2nd cycle on the tray nearest the cold spot)
  - Cycle 3 label one indicator 3/M (3rd cycle in the middle of the challenge pack) and the other 3/C (3rd cycle on the tray nearest the cold spot)
- the control (7th) indicator can be labelled Z; this is left outside the steriliser and never sterilised. This indicator, which is treated with the others, will be used to substantiate that the batch of indicators was active.

## Repackaging between cycles

The packs will be reused pack(s) from the previous cycle; the contents of the pack(s) must return to room temperature before repackaging and the next cycle run. To save time, the instruments from the pack(s) will be cooled quickly after unpacking and removing the indicator by placing the instruments in cool water. The instruments will be then dried and repacked with the next indicator and the next cycle run.

## Indicator processing

All indicators are to be incubated according to the manufacturer's instructions and results recorded in *Table A11.6*.

## Interpretation of the results of the indicators

- All the 'M' and 'C' indicators (16) should show no growth or its equivalent; if not, it indicates a process failure and must be investigated. Record the results (*Table A11.6*).
- The single unsterilised control 'Z' indicator should show growth. If not, the batch of indicators or the incubator is faulty (the service technician needs to check it with the thermocouple as part of annual servicing).
- A pass result is 100%. Any failures must be fully investigated as to cause and corrective action documented and the entire procedure repeated.

## Check the steriliser settings and results of steriliser monitoring

- Ensure:
  - time and temperature were correctly set.
  - routine monitoring of each cycle's time at temperature (either by printout, download of data logger, manual recording of time at temperature, or by the use of a Class 4, 5 or 6 chemical indicator) occurred at the correct frequency, was reviewed for adequacy, was signed off and is recorded in a log
  - the physical check of temperature ('time at temperature' testing) inside the challenge pack/load showed that the centre of the pack reached the correct sterilising temperature and that was maintained for the required time. Similarly, that the temperature during drying was also maintained for the correct time
  - the microbiological check with appropriate indicators inside the challenge pack/load showed that the centre of the pack and outside the pack inside the chamber was effective in sterilising these indicators on each of the three cycles (this will take 2 days to verify, as the indicators used require incubation).
- Record (*Table A11.1*).

## Unloading of the steriliser

- Review documentation in the practice policy and procedure manual, or other documentation.
- Perform or supervise unloading.
- Check packs have cooled within the steriliser or on a 'cake rack' and are dry, undamaged, seals are intact and the Class 1 chemical indicator on the outside of each pack or in the tray with unwrapped items has changed colour.
- Record (*Table A11.1*).

## Storage of sterile items

- Review documentation.
- Perform the task of storage.
- Check that stored items are kept dry, dust free and undisturbed, and packs have been processed, marked with the date and load number and stored in a manner to allow stock rotation. Check cleaning of the storage area does not compromise sterility.
- Record (*Table A11.1*).

## Maintenance of the steriliser

- Review documentation in practice policy and procedure manual, manufacturer's instructions and maintenance log.
- Perform or supervise routine maintenance procedures as documented.
- Check that maintenance tasks have been performed and are in accordance with the manufacturer's requirements.
- Record (*Table A11.1*).

**Table A11.1. Validation certificate**

Clinic name:		Steriliser ID:	
Process	Process documented in policy and procedure manual	Process performance, effectiveness and reliability checked (ie validated)	Sign and date
Cleaning of the environment and workflow issues (dirty to clean)			
Precleaning and cleaning of instruments			
Content, packing and sterile barrier system of challenge pack			
Loading of challenge load			
Monitoring of cycle parameters			
Unloading of the steriliser (steriliser log)			
Storage of sterile items			
Maintenance of steriliser (maintenance log)			
Name of service company:			
Steriliser technician:			
Date:			
Name of staff member with responsibility for practice sterilisation:			
Signature:			
Date:			

Table A11.2. Challenge pack (examples)

Excision set
<ul style="list-style-type: none"> <li>Kidney dish containing: <ul style="list-style-type: none"> <li>1 galley pot</li> <li>6 gauze squares (2 in galley pot, 4 in kidney dish)</li> <li>1 needle holder</li> <li>1 standard scissors</li> <li>1 forceps (toothed)</li> <li>1 no. 3 scalpel blade handle</li> <li>1 Class 1 chemical indicator strip</li> <li>pack in a self sealing laminate pouch with the indicator in the kidney dish</li> <li>all instruments to be loosely opened or closed lightly on first ratchet</li> </ul> </li> </ul>
Plastics set
<ul style="list-style-type: none"> <li>Kidney dish containing: <ul style="list-style-type: none"> <li>1 galley pot</li> <li>6 gauze squares (2 in galley pot, 4 in kidney dish)</li> <li>1 fine needle holder</li> <li>1 standard scissors</li> <li>1 fine sharp scissors</li> <li>1 fine curved artery</li> <li>1 forceps (toothed)</li> <li>1 forceps (plain)</li> <li>1 no. 3 scalpel blade handle</li> <li>1 Class 1 chemical indicator strip</li> </ul> </li> <li>Pack in a self sealing laminate pouch with the indicator strip from the seal placed in the kidney dish</li> <li>All instruments to be loosely opened or closed lightly on first ratchet</li> </ul>

Table A11.3. Penetration and drying time (example)

Challenge pack description	Challenge pack/load loading	Penetration time Steriliser 1 (minutes)	Drying time Steriliser 1 (minutes)
Laminate pouches containing 3–4 instruments and no gauze	5–10 packs in the chamber loaded on their sides in one or two racks placed on a tray, laminate surface of one facing paper side of the other	0	5

Table A11.4. Heat distribution (example)

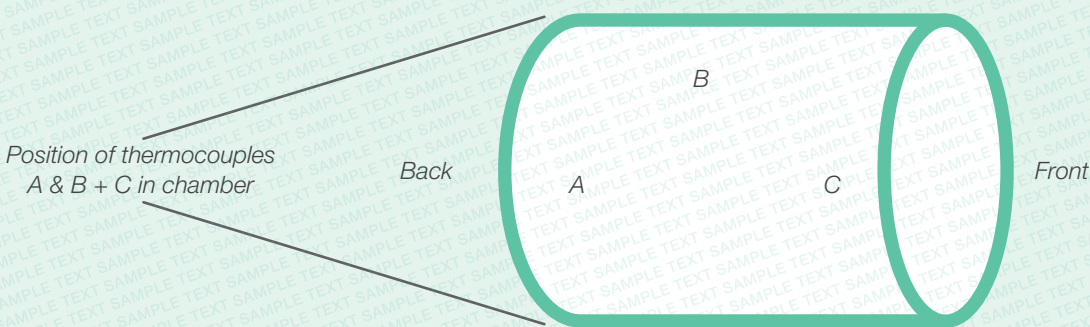
Location of thermocouples	A	B	C	Steriliser temperature gauge reading
Temperature	134.2°C	134.3°C	134°C	134°C
A heat distribution study was performed on an empty chamber. This needs to be established for the challenge load and checked by the designated staff member				
<p>Position of thermocouples</p>  <p>Position of thermocouples A &amp; B + C in chamber</p> <p>Back</p> <p>Front</p>				
Notes: 1. Attach thermocouple record from the service technician. 2. This example shows no significant cold spot.				

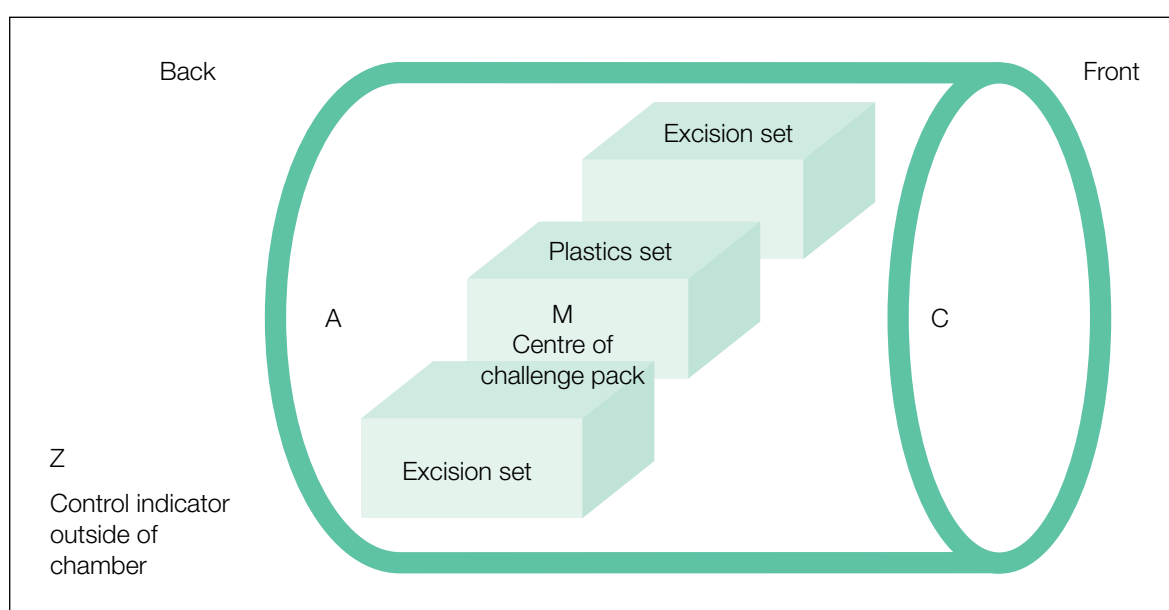
Table A11.5. Processing time (example)

Load description	Sterilising temperature	Pressure in kpa (median)	Penetration time (P) (minutes)	Holding time including safety factor (H) (minutes)	Total processing time (T) (minutes) P + H = T	Drying time (minutes)	Pre-set setting selection (eg 'vasectomy' or 'suture')
2 excision sets and 1 plastics	Set 134°C	203	2	3	5	12	Suture

Table A11.6. Results of physical and microbiological checking (example)

Challenge load	Check type	Cycle 1	Cycle 2	Cycle 3
2 excision sets and 1 plastics set	Microbiological check: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological check: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical check: Time at temperature	Pass*	Not applicable	Not applicable
* Attach thermocouple records from service technician supporting this check				

Figure A11.1. Chamber loading details and position of biological indicators



## *Appendix 12. Complex validation template where validation has been performed previously*

### Responsibility

The staff member with designated responsibility for sterilisation to:

1. Review the documented procedures covering all parts of the sterilisation process to ensure reproducibility:
  - workflow issues: dirty through to clean and environmental cleaning
  - precleaning and cleaning of instruments
  - pack contents, packing and sterile barrier system
  - loading of the steriliser
  - mechanical/physical monitoring (chemical indicators and recording of time at temperature) of the sterilisation cycle parameters
  - unloading of the steriliser and checking the packs are dry and intact and checking monitoring results and correct chemical indicator change
  - storage of sterile items
  - maintenance of steriliser as required by the manufacturer (including water changes and cleaning).
2. Perform or supervise the documented procedures.
3. Check that the procedures were successful.
4. Record successful completion of each procedure (*Table A12.1*).

### Procedure

#### Workflow issues: dirty through to clean and environmental cleaning

- Review documentation in practice policy and procedure manual or other documentation.
- Observe or reflect on performance of the tasks from precleaning through to storage, including environmental cleaning relevant to instrument reprocessing.
- Check that workflow from dirty to sterile is not compromised and that environmental cleaning is adequate.
- Record (*Table A12.1*).

#### Precleaning and cleaning of instruments

- Review documentation in practice policy and procedure manual or other documentation.
- Perform or supervise precleaning and cleaning.
- Check using a magnifying loop or glass that the instruments are clean (eg paying special attention to serrations).
- Record (*Table A12.1*).

## Pack contents, packing and sterile barrier system

- Review documentation in practice policy and procedure manual or other documentation.
- Perform or supervise pack preparation with correct contents, packing and sterile barrier system.
- Check packs:
  - have the correct contents
  - are packed correctly in the correct sterile barrier system
  - do not exceed those of the documented ‘challenge packs’ (*Table A12.2*)
  - have seals that are intact
  - have a Class 1 chemical indicator on the outside of each pack
  - have been labelled with the date, steriliser number (if applicable), load (batch) number and staff identification of cleaner and packer (if applicable)
  - have instruments loosely open, not tightly closed
  - have hollowware, if packed in laminate pouches, packed with the opening against the paper, not the laminate plastic side
  - have not had ballpoint pens used on critical pack surfaces.
- Record (*Table A12.1*).

## Loading of the steriliser

- Review documentation in practice policy and procedure manual.
- Perform or supervise loading of the steriliser.
- Check that:
  - the total contents of the steriliser do not exceed those of the documented ‘challenge load’ (*Tables A12.3, 4*)
  - packs loaded with hollow items are on their sides
  - the paper side of any laminated pack is adjacent to the laminate side of another
  - individual instrument packs are separated on racks
  - trays of unwrapped instruments are not overloaded
  - there is a Class 1 chemical indicator in the tray with unwrapped instruments.
- Record (*Table A12.1*).

## Mechanical/physical monitoring of sterilisation cycle parameters

- Review the documentation in the practice policy and procedure manual for each steriliser used, including:
  - manufacturer’s instructions
  - heat distribution studies (*Table A12.5*)
  - description of the challenge pack and load (*Tables A12.3, 4*)
  - diagram of chamber loading (*Figure A12.1*)
  - penetration times (*Table A12.4, 6*).

- The service technician should:
  - perform a ‘heat distribution study’ to check for cold spots in the chamber and record (*Table A12.5*).
  - establish the penetration time for the ‘challenge pack’ within the ‘challenge load’ and record (this combination reflects the greatest challenge to the sterilisation process of any load)
  - set the processing time on the steriliser for all loads (ie holding time plus penetration time) and document (*Table A12.4, 6*)
  - check the drying time and reset if required (a trial and error process checking after different lengths of drying time for load dryness) (*Table A12.4, 6*)
  - perform additional function checks for validation of the sterilisation cycle (ie during the processing and drying time)
  - perform physical qualification (checking) of the temperature within the challenge pack within a challenge load with a thermocouple throughout the total processing time (ie ‘time at temperature’ testing) at least once. This check should continue to check the drying time. The penetration time can also be checked while this is being performed
  - check the temperature of the incubator.
- The staff member with designated responsibility for sterilisation should:
  - perform microbiological qualification (checking) of the effectiveness of the sterilisation cycle in processing the challenge pack/load by the use of appropriate indicators in three successive cycles (*Table A12.7*).

## The indicators

- Biological or enzymatic indicators:
  - have a spore count equivalent to  $10^5$
  - are from the same batch.
- A minimum of two indicators are required for each load to be validated plus one control indicator.
- Indicators need to be suitable for the type of steriliser and temperature selected (enzymatic indicators on the Australian market are not suitable for gravity displacement bench top sterilisers operating at 134°C and cannot be used for either additional monitoring or validation).

Note: there are arguments for and against running the physical ‘time at temperature’ check concurrently with the first microbiological test cycle. It can improve efficiency of the process or may get in the way of the technician, slowing things down. The technician’s steriliser leads may alter the pack if not properly sealed where they enter the pack, letting steam in more easily and impinging on both the microbiological and physical check. In addition, if the ‘time at temperature’ testing determines the need for a longer sterilisation time, the indicators will be wasted. In the case of onsite technical assistance not being available, it would not be possible to run a concurrent time at temperature test and first microbiological test cycle.

## Labelling indicators

- Label indicators before starting according to the:
  - steriliser (if more than one steriliser)
  - cycle number (eg 1 for the first, 2 for the second or 3 for the third)
  - challenge load (eg V for vasectomy set and E for excision/plastics set) and the position it is to be placed in the steriliser (eg M for middle of challenge pack or C for cold spot if determined or placed anywhere on tray if none).

- Examples of this are:
  - Steriliser 1
    - Cycle 1 label 1 indicator 1/1/V/M (steriliser 1, 1st cycle, vasectomy pack in the middle of the challenge pack) and the other 1/1/V/C (steriliser 1, 1st cycle, vasectomy pack, on the tray nearest the cold spot)
    - Cycle 2 label 1 indicator 1/2/V/M (steriliser 1, 2nd cycle, vasectomy pack in the middle of the challenge pack) and the other 1/2/V/C (steriliser 1, 2nd cycle, vasectomy pack, on the tray nearest the cold spot)
    - Cycle 3 label 1 indicator 1/3/V/M (steriliser 1, 3rd cycle, vasectomy pack in the middle of the challenge pack) and the other 1/3/V/C (steriliser 1, 3rd cycle, vasectomy pack, on the tray nearest the cold spot)
  - Steriliser 2
    - Cycle 1 label one indicator 2/1/V/M (steriliser 2, 1st cycle, vasectomy pack in the middle of the challenge pack) and the other 2/1/V/C (steriliser 2, 1st cycle, vasectomy pack, on the tray nearest the cold spot)
    - Cycle 2 label 1 indicator 2/2/V/M (steriliser 2, 2nd cycle, vasectomy pack in the middle of the challenge pack) and the other 2/2/V/C (steriliser 2, 2nd cycle, vasectomy pack, on the tray nearest the cold spot)
    - Cycle label 1 indicator 2/3/V/M (steriliser 2, 3rd cycle, vasectomy pack in the middle of the challenge pack) and the other 2/3/V/C (steriliser 2, 3rd cycle, vasectomy pack, on the tray nearest the cold spot).
- The control indicator can be labelled Z; this is left outside the steriliser and never sterilised. This indicator, which is treated with the others, will be used to substantiate that the batch of indicators was active.
- The procedure is then repeated for the excision/plastic sets for both sterilisers, the V being replaced by an 'E'.

### Repackaging between cycles

The packs will be reused pack(s) from the previous cycle; the contents of the pack(s) must return to room temperature before repackaging and the next cycle run. To save time, the instruments from the pack(s) will be cooled quickly after unpacking and removing the indicator by placing the instruments in cool water. The instruments will be then dried and repacked with the next indicator and the next cycle run.

### Interpretation of the results of the indicators

- All the 'M' and 'C' indicators should show no growth or its equivalent; otherwise, it indicates a process failure and must be investigated. Record results (*Table A12.7*).
- The single unsterilised control 'Z' indicator should show growth. If not, the batch of indicators or the incubator is faulty (the service technician needs to check it with the thermocouple as part of annual servicing).
- A pass result is 100%. Any failures must be fully investigated as to cause and corrective action documented and the entire procedure repeated.

### Check the steriliser settings and results of steriliser monitoring

- Ensure:
  - time and temperature were correctly set.
  - routine monitoring of each cycle's time at temperature (either by printout, download of data logger, manual recording of time at temperature, or by the use of a Class 4, 5 or 6 chemical indicator) occurred at the correct frequency, was reviewed for adequacy, was signed off and is recorded in a log.

- the physical check of temperature ('time at temperature' testing) inside the challenge pack/load showed that the centre of the pack reached the correct sterilising temperature and that was maintained for the required time. Similarly, that the temperature during drying was also maintained for the correct time.
  - the microbiological check with appropriate indicators inside the challenge pack/load showed that the centre of the pack and outside the pack inside the chamber was effective in sterilising these indicators on each of the three cycles (this will take 2 days to verify, as the indicators used require incubation).
  - all points are checked for each total processing time used for different pack/load types (the sterilisation temperature is not changed for different pack/load types). The use of multiple processing times and multiple sterilisers increases complexity and care must be taken to avoid errors when different cycles are selected.
- Record (*Table A12.1*).

## Unloading of the steriliser

- Review documentation in the practice policy and procedure manual or other documentation.
- Perform or supervise unloading.
- Check packs have cooled within the steriliser or on a 'cake rack' and are dry, undamaged, seals are intact, and the Class 1 chemical indicator on the outside of each pack or in the tray with unwrapped items has changed colour.
- Record (*Table A12.1*).

## Storage of sterile items

- Review documentation.
- Perform the task of storage.
- Check that stored items are kept dry, dust free and undisturbed, and packs have been processed, marked with the date and load number and stored in a manner to allow stock rotation. Check cleaning of the storage area does not compromise sterility.
- Record (*Table A12.1*).

## Maintenance of the steriliser

- Review documentation in the practice policy and procedure manual, manufacturer's instructions and maintenance log.
- Perform or supervise routine maintenance procedures as documented.
- Check that maintenance tasks have been performed and are in accordance with the manufacturer's requirements.
- Record (*Table A12.1*).

Table A12.1. Validation certificate

Clinic name:		Steriliser 1 ID:	
		Steriliser 2 ID:	
Process	Process documented in policy and procedure manual	Process performance, effectiveness and reliability checked (ie validated)	Sign and date
Cleaning of the environment and workflow issues (dirty to clean)			
Precleaning and cleaning of instruments			
Content, packing and sterile barrier system of challenge pack			
Loading of challenge load			
Monitoring of cycle parameters			
Unloading of the steriliser (steriliser log)			
Storage of sterile items			
Maintenance of steriliser (maintenance log)			
Name of service company:			
Steriliser technician:			
Date:			
Name of staff member with responsibility for practice sterilisation:			
Signature:			
Date:			

Table A12.2. Challenge packs (examples)

<b>Vasectomy set</b>
<ul style="list-style-type: none"> <li>• Large kidney dish containing: <ul style="list-style-type: none"> <li>– 1 large needle holder</li> <li>– 1 no. 3 scalpel handle</li> <li>– 1 Allis forceps</li> <li>– 2 curved artery forceps</li> <li>– 2 straight artery forceps</li> <li>– 1 suture scissors</li> <li>– 1 swab holder</li> <li>– 1 ring forceps</li> <li>– 1 sharp artery forceps</li> <li>– 1 diathermy needle tip</li> <li>– 1 small self seal pouch</li> <li>– 1 30cm length of 50 mm wide laminate/paper roll (to act as a sleeve for the diathermy handle and tip)</li> </ul> </li> <li>• On top of which place: <ul style="list-style-type: none"> <li>– half sheet of blue wrap (eg Kinguard) with 5 cm radius circle cut in centre to provide a 'sterile field' then: <ul style="list-style-type: none"> <li>- 1 small galley pot filled with a third of a pack of gauze squares (33 pieces)</li> <li>- 1 large bowl containing 1 sheet low-lint paper towel</li> </ul> </li> </ul> </li> <li>• On each side of the kidney dish place a Huck towel (total 2)</li> <li>• Wrap in a sheet of blue wrap (eg Kinguard), stick Class 1 chemical indicator tape strips several times across the seam</li> <li>• All instruments to be loosely opened or closed lightly on first ratchet</li> </ul>
<b>Excision set</b>
<ul style="list-style-type: none"> <li>• Kidney dish containing: <ul style="list-style-type: none"> <li>– 1 galley pot</li> <li>– 6 gauze squares (2 in galley pot, 4 in kidney dish)</li> <li>– 1 needle holder</li> <li>– 1 standard scissors</li> <li>– 1 forceps (toothed)</li> <li>– 1 no. 3 scalpel blade handle</li> <li>– 1 Class 1 chemical indicator strip</li> </ul> </li> <li>• Pack in a self sealing laminate pouch with the indicator in the kidney dish</li> <li>• All instruments to be loosely opened or closed lightly on first ratchet</li> </ul>
<b>Plastics set</b>
<ul style="list-style-type: none"> <li>• Kidney dish containing: <ul style="list-style-type: none"> <li>– 1 galley pot</li> <li>– 6 gauze squares (2 in galley pot, 4 in kidney dish)</li> <li>– 1 fine needle holder</li> <li>– 1 standard scissors</li> <li>– 1 fine sharp scissors</li> <li>– 1 fine curved artery</li> <li>– 1 forceps (toothed)</li> <li>– 1 forceps (plain)</li> <li>– 1 no. 3 scalpel blade handle</li> <li>– 1 Class 1 chemical indicator strip</li> </ul> </li> <li>• Pack in a self sealing laminate pouch with the indicator strip from the seal placed in the kidney dish</li> <li>• All instruments to be loosely opened or closed lightly on first ratchet</li> </ul>
<b>Pack of 100 unsterile gauze squares</b>

Table A12.3. Challenge loads: contents and loading details (examples)

Challenge load	Loading details
Single vasectomy set	One single set in the chamber loaded on its side on a tray
Two excision sets and one plastics set	Three sets in the chamber, the centre one being the plastics set, loaded on their sides on a tray, laminate surface of one facing paper side of the other
Eight gauze packs	Loaded with labels to the front, separated on a tray

Table A12.4. Penetration and drying time (examples)

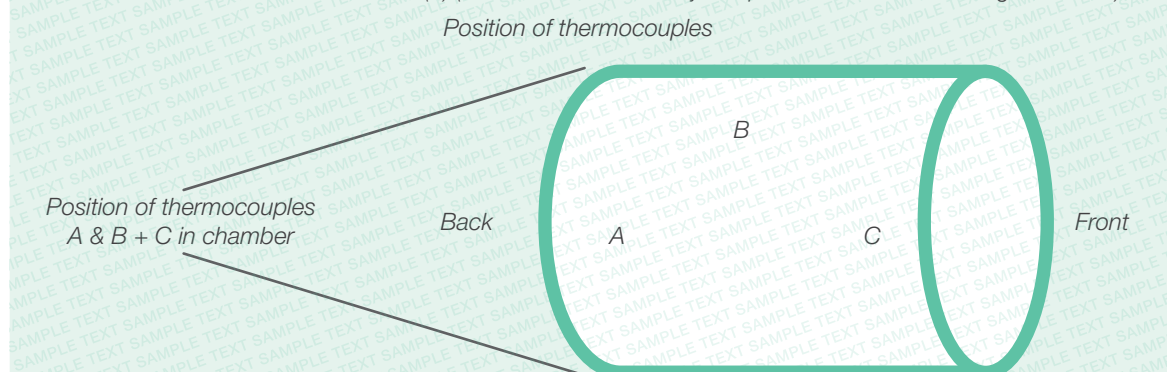
Challenge pack description	Challenge pack/load loading	Penetration time Steriliser 1 (minutes)	Penetration time Steriliser 2 (minutes)	Drying time Steriliser 1 (minutes)	Drying time Steriliser 2 (minutes)
Vasectomy set	One single pack in the chamber loaded on its side on a tray	9	6	20	20
2 excision sets and 1 plastics set	Three packs in the chamber, the centre one being the plastics set, loaded on their sides on a tray, laminate surface of one facing paper side of the other	2	0	12	12
8 unsterile gauze packs	Loaded with labels to the front, separated on a tray	1	1	12	12
Vasectomy set	5–10 packs in the chamber loaded on their sides in one or two racks placed on a tray, laminate surface of one facing paper side of the other	0	0	5	5

Table A12.5. Heat distribution (example)

Location of thermocouples	A	B	C	Steriliser temperature gauge reading
Steriliser 1 temperature	134.2°C	134.3°C	134.1°C	134°C
Steriliser 2 temperature	134.4°C	134.5°C	134.2°C	134°C

A heat distribution study performed on an empty chamber has been previously obtained (this can be from the manufacturer or performed by the steriliser technician) and is recorded in the table above.

The reading on the steriliser temperature gauge should reflect the temperature at the coldest location in the steriliser drain at the rear of the steriliser chamber (A) (service technician to adjust if practicable when checking calibration).



Notes: 1. Attach thermocouple record from the service technician, 2. This example shows no significant cold spot

Table A12.6. Challenge load setting (examples)

Load description	Sterilising temperature	Pressure in kpa (median)	P Penetration time (minutes)	H Holding time including safety factor (minutes)	T Total processing time (minutes) P + H = T	Drying time (minutes)	Pre-set setting selection (eg 'vasectomy' or 'suture')
<b>Steriliser 1</b>							
Single vasectomy kit	134°C	203	6	3	9	20	Vasectomy
2 excision sets and 1 plastics set	134°C	203	0	3	0	12	Suture
<b>Steriliser 2</b>							
Single vasectomy kit	134°C	203	5.5	3	8.5	20	Vasectomy
2 excision sets and 1 plastics set	134°C	203	0	3	0	12	Suture

#### Table notes

Attach thermocouple record from the service technician supporting these checks.

To reduce errors, practices should consider only having two different 'total processing' and 'drying time' settings to cover all the practice's sterilisation (and any outside practice's outsourced packs). These should be clearly marked on the steriliser's pre-select buttons, 'vasectomy' or 'suture' as per the above examples. Practice staff must ensure that the correct cycle is selected for each load type processed.

The IUCD set, circumcision set and loads of gauze packs are considered to pose less challenge than that provided by the vasectomy set load. For these, practices should select 'vasectomy' for all loads containing packs wrapped in blue Kimguard and loads of gauze packs.

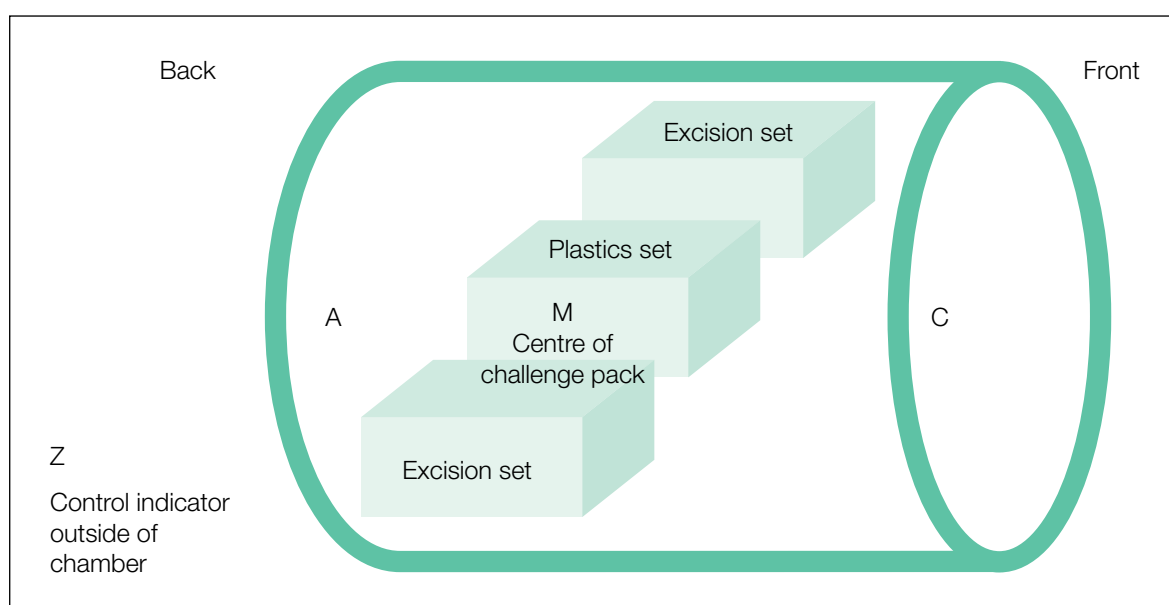
Three excision sets, 10 packs of 3–4 instruments and loose unwrapped instruments are all considered to pose less challenge than that provided by the two excision and one plastic set load. For these, practices should select 'suture' for all loads containing laminate packs or loose instruments only.

Table A12.7. Results of physical and microbiological checking (examples)

Challenge load	Check type	Cycle 1	Cycle 2	Cycle 3
<b>Steriliser 1</b>				
Vasectomy set ('vasectomy' setting)	Microbiological check: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological check: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical check: Time at temperature*	Pass	Not applicable	Not applicable
2 excision sets and 1 plastics set ('suture' setting)	Microbiological check: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological check: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical check: Time at temperature*	Pass	Not applicable	Not applicable
<b>Steriliser 2</b>				
Vasectomy set ('vasectomy' setting)	Microbiological check: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological check: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical check: Time at temperature*	Pass	Not applicable	Not applicable
2 excision sets and 1 plastics set ('suture' setting)	Microbiological check: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological check: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical check: Time at temperature*	Pass	Not applicable	Not applicable
Control indicator		Z growth	Not applicable	Not applicable

\* Attach thermocouple records from service technician supporting this check

Figure A12.1. Chamber loading details and position of biological indicators



## Appendix 13. Infection prevention and control and risk management

### Assessing the risk of (cross-) infection in a structured way

Because it can be important to return to first principles in evaluating and managing the risk of (cross-) infection, a structured approach can be helpful.

The Australian New Zealand Standard on risk management (AS/NZS 4360:2004) provided a useful framework for many Australian contexts. This has been superseded by ISO 31000:2009 *Risk management – Principles and guidelines*, which builds on the advice provided.

### Broad steps for risk management

These are:

1. Communicate and consult
2. Establish the context
3. Identify risks
4. Analyse risks
5. Evaluate risks
6. Treat risks and identify potential safeguards
7. Monitor and review
8. Record key information.

#### Step 1. Communicate and consult

Ongoing communication to those in the practice who may 'need to know' is important as circumstances change (eg a local measles outbreak may occur).

Communication with those likely to be affected is central as it is important for the people involved to understand the basis on which decisions are made and the purpose of particular actions.

Good communication across the practice also helps identify risks, as people will have different perceptions of the risk based on the role they play. Different people will also have a range of ideas about how to reduce and manage risks.

#### Case study 1. A measles outbreak

State health authorities have notified the practice of an outbreak of measles. In this context it is important to communicate this information to all doctors, other health professionals and practice staff, and to discuss, formulate and implement the practice's procedures to presentations that may be measles.

The practice may hold a brief staff meeting where doctors, other health professionals and practice staff are informed of the outbreak and educated about the presenting signs and symptoms of measles.

They are also educated about appropriate infection prevention and control measures to use if a patient with suspected measles presents (eg segregation and airborne precautions).

To ensure that staff absent from the meeting are also informed and to reinforce the message, an email or memo may be sent to all staff outlining the actions to be taken in the event of a person presenting with possible symptoms of measles.

Staff may consider placing a poster at reception that describes the symptoms and shows pictures of a typical measles rash.

## Step 2. Establish the context

The nature and size of the risks of (cross-) infection are affected by the context in which the practice operates.

The external environment plays a role (eg access to an infectious diseases unit, or poor infrastructure in the local community that makes the maintenance of good hygiene difficult for people attending the practice). Local and national disease outbreaks (eg avian flu) also affect the way that a practice will need to address infection prevention and control.

Other factors that can influence the context of the risk include the:

- equipment (eg sterilising equipment within the practice in contrast to single-use instruments)
- people (eg the presence of staff trained in infection prevention and control or the presence of new, less skilled staff)
- processes (eg undertaking advanced procedures within the practice)
- culture of the practice (eg one that encourages rather than discourages identification of risks and then implements appropriate risk management processes).

All of these factors, individually and together, affect the nature and likelihood of the risk of (cross-) infection.

In this discussion, the focus has been on clinical risk, but financial risks – which lead to cost cutting or skimping on equipment and surveillance – may also be important factors in increasing the risk of transmission of infection. For example, risk would be increased in a practice that continues to use a steriliser without a drying cycle to sterilise bagged instruments instead of choosing a safer option such as replacing the steriliser. Overall, this step involves establishing the parameters within which the risk management process needs to occur.

## Step 3. Identify risks

The basic questions in this step of the process are:

- What can happen?
- When and where?
- How and why?

Step 3 involves developing a comprehensive list of the sources or risks, and the events that might prevent, delay or increase the achievement of effective management of the risk of (cross-) infection.

In considering 'What can happen?', reflect on the range of activities undertaken in the practice and any risks that accompany them. It may be useful to reflect on the vectors of transmission and consider the risk.

In terms of 'When and where?', walk around the practice and consider where risks may arise (eg in the waiting area, treatment area). Also reflect on the risks that arise from home or other visits or when there are particular types of patients at the practice (eg small children or people who are immunosuppressed). This could be done as part of the practice's work health and safety hazard identification and risk-control processes.

In terms of 'How and why?', consider previous 'near misses', where (cross-) infection almost occurred, but something or someone prevented it, or any episodes of cross-infection.

Some sources of risk are common (eg poor respiratory etiquette) and others less common (eg failure to use sterile equipment in a high-risk procedure). Some risks might be more particular to the context of the practice (eg poor water quality).

### Case study 2. An inexperienced staff member

A new staff member commenced at the practice. Experienced staff provided training for the new staff member and then allowed the staff member to perform functions such as cleaning and bagging of instruments and putting away cooled instruments that had been previously sterilised.

One day, a more experienced staff member noticed that the new staff member was about to place cleaned and bagged instruments not yet sterilised in the sterile stock cupboard, and prevented the 'near miss' developing into an incident.

Risk analysis revealed that:

- the new staff member did not yet have all the skills required to assume full responsibility for the sterilisation process
- there were no other incidences of nonsterile stock put back into circulation before the documented incident.

Training and competency assessment and supervision of new staff was reviewed. The new staff member was subsequently given more training and supervision.

## Step 4. Analyse risks

In analysing risks, the purpose is to increase understanding of what risks need to be managed and what appropriate and cost-effective ways of managing the risks are available. Generally, there are two dimensions to consider:

- magnitude of impact (what degree of impact would occur)
- likelihood (how likely is the event, and its associated consequences).

It may be useful to do an initial screening of the risks to identify those that require greater attention. In this case, a simple scoring system can help (*Table A13.1* and *Box A13.1*).

**Table A13.1. Risk analysis scoring system**

Magnitude of impact	3	Severe impact, difficult to control
	2	Some impact, able to control
	1	Limited impact, unlikely to need control
Likelihood	3	Very likely to occur
	2	Likely to occur
	1	Unlikely to occur

Each risk is scored by rating it on both dimensions (magnitude of impact and likelihood), and then multiplying the two together (*Box A13.1*)

### Box A13.1 Risk analysis scoring (examples)

#### Example 1

A health professional may assess that the practice has inadequate airborne safety measures to control the transmission of infection from a patient with suspected measles to other susceptible patients in the waiting area. This would be reflected by the following risk assessment:

- Magnitude of impact: 3
- Likelihood: 3
- Risk:  $3 \times 3 = 9$

Another health professional may assess that the likelihood of spread of measles is unlikely to occur because they are confident of herd immunity. This would be reflected by the following risk assessment:

- Magnitude of impact: 3
- Likelihood: 1
- Risk:  $3 \times 1 = 3$

This variation in the perception of risk is important. It may lead to overly cautious behaviour or to inappropriate risks being taken. In these situations, it would be essential for the issue to be discussed and an agreed position taken

#### Example 2

The iatrogenic spread of influenza in a particular setting may be assessed as follows:

- Magnitude of impact: 2
- Likelihood: 3
- Risk:  $2 \times 3 = 6$

#### Example 3

The iatrogenic spread of pandemic influenza in a particular setting may be assessed as follows:

- Magnitude of impact: 3
- Likelihood: 3
- Risk:  $3 \times 3 = 9$

#### Example 4

A patient acquiring HBV or HIV infection because of incorrectly sterilised instruments in a particular setting may be assessed as follows:

- Magnitude of impact: 3
- Likelihood: 1
- Risk:  $3 \times 1 = 3$

It is useful for doctors, other health professionals and practice staff to consider and discuss the nature, magnitude and likelihood of risks of cross-infection in their particular setting. As illustrated in *Box A13.1*, there are situations where health professionals may have different opinions about the risk and therefore their approach to the risk. Where possible, it is important for discussions to occur before an event so that a consistent approach can be decided upon before an incident occurs (eg before seeing a patient with avian influenza for the first time).

Consider the basis for differences in risk rating (eg where one doctor feels an event is much more likely to occur than other doctors do). The differences in perception are likely to give rise to different approaches within the practice. Variation itself may increase risk.

## Step 5. Evaluate risks

Evaluating the risk is about combining information about the organisation context with the level of risk. This involves considering which risks need to be actively managed, why and how; and which risks will be 'tolerated' because the practice believes it is minimal.

Doctors, other health professionals and practice staff are understandably concerned about prioritising improvements. Prioritising is the ability to identify, critically appraise and grasp the critical elements of what is happening in the practice.

One way of prioritising is to use an 'ease impact analysis'. First, look at causes (or problems) that might be easy to fix: a 'quick win'. Consider putting aside for a moment those that are hard to fix, except if the risk is high or potentially catastrophic.

Second, look at improvements that will make a substantial impact. This approach can be shown in a simple matrix where each potential solution is slotted into one of four quadrants (*Box A13.2*); refer also to the worked example (*Box A13.3*).

## Step 6. Treat risks and identify potential safeguards

Most practices have existing policies, procedures and equipment that can assist in providing safeguards against error. Despite this, a reassessment of the situation (eg after a 'near miss') can identify vulnerabilities in these systems and processes.

Having taken account of all the relevant factors, it is important to act on identified priority risks of (cross-) infection.

Start with the potential solutions/safeguards that are easy to do and have a high impact (eg repositioning sharps containers at point of use, locating alcohol-based hand-hygiene products in all patient care areas to improve hand-hygiene compliance and reduce the risk of cross-infection).

Then, give attention to those that are hard to do, but have a high impact.

### Box A13.2. Risk evaluation matrix

EASY to do Has LITTLE IMPACT	EASY to do Has a HIGH IMPACT
HARD to do Has LITTLE IMPACT	HARD to do Has a HIGH IMPACT

### Box A13.3. Worked example of a practice's risk evaluation matrix

EASY to do Spray surfaces with a household disinfectant spray Has LITTLE IMPACT No more effective than the use of detergent and water solution, spray or wipes	EASY to do Provide hand-hygiene products in every clinical treatment area and consulting rooms Has a HIGH IMPACT Shown to improve hand-hygiene compliance and reduce the risk of cross-infection
HARD to do Changing linen between every patient Has LITTLE IMPACT Linen is not a high-risk cause of cross-infection	HARD to do Educate potentially infectious patients to report their state before attending the practice (eg measles) Has a HIGH IMPACT Can reduce incidence of iatrogenic infection

## Step 7. Monitor and review

It is important to maintain a focus on what is going on around individuals. This assists with finding vulnerabilities in the system.

Have systems in place to monitor and review. Examples include regular infection prevention and control audits, recording and reviewing the results of the sterilisation cycle, or including infection prevention and control as a discussion point in a clinical meeting after changes to policy.

An example of performance indicators to assess staff adherence to hand-hygiene protocols is:

- survey (direct observation) to monitor adherence to hand-hygiene protocols
- monitor the volume of hand-hygiene products used over a period of time as an indirect indicator of hand hygiene.

In rare cases, epidemiological trends in laboratory results may assist staff to ascertain whether there is a breakdown in infection prevention and control techniques. In most settings the occurrence of iatrogenic infection is low. In such a case, single 'signal' incident reporting and investigation of the event is feasible.

It is also important to monitor environmental issues (eg the outbreak of a communicable disease) that may affect your patients.

It is important that breaches in infection prevention and control procedures are reported to the person who has the responsibility to investigate and that appropriate measures are instituted to minimise the risk of recurrence. Acts of omission can also be considered to be a breach (ie when something didn't occur as it should have).

## Step 8. Record key information

Recording of information needs to be purposeful. It is important to ask, 'What use will our practice make of this information? Is it the 'right' information for that purpose?'

Recording can provide a baseline on which to assess the effectiveness of your systems. This record may be in the form of an incident log. Recording and publishing case studies of near misses and actual incidents and the practice response may be useful to colleagues. However, the records, even if they do not identify an individual, may be uncovered in legal proceedings (including tribunals such as the Coroner's Court).

The record could include suggested changes, the timeline for review of the changes and the results of any review of the changes, to 'fine tune' the activities at the practice. The RACGP's *Using near misses to improve the quality of care for your patients* includes a more detailed example.

If any part of a discussion is to be published (eg journal article), it should be as a 'fictitious case' and not contain any means of identifying people involved. Care must be taken to ensure that not only names and dates are changed, but also details of the actual incident disguised if it is possible for others to still identify the people involved.

## *Appendix 14. Community-acquired methicillin resistant Staphylococcus aureus*

CAMRSA has been reported in eastern Australian states since mid-1990. Other, related strains have since emerged. It is an increasingly common cause of infections.

There is patchy distribution geographically, with increased incidence in South Pacific Islanders. Currently it is less common in Victoria/Tasmania than other states.

There are various strains in circulation:

- southwest Pacific (Samoa, Tonga, New Zealand)
- Western Australia (several strains)
- Queensland.

CAMRSA is a non-multiresistant form of MRSA that:

- is susceptible to erythromycin, trimethoprim-sulphamethoxazole, clindamycin, tetracycline, ciprofloxacin, gentamicin, vancomycin, rifampicin and fusidic acid
- is highly pathogenic (these strains usually carry the genes for a virulent toxin 'Panton-Valentine leukocidin' or PVL, which destroys leukocytes and causes tissue necrosis)
- is easily communicable (ie to other family members)
- predominantly causes skin and soft tissue infections (eg boils, carbuncles, which are often recurrent)
- may cause cellulitis, osteomyelitis, endocarditis, bacteraemia, necrotising pneumonia and death.

### Management of patients presenting with skin and soft tissue infections

- Use standard precautions.
- Use transmission-based precautions for contact spread.
- Take swabs and/or blood for culture before treatment.
- Drain abscesses (schedule at the end of session, not before invasive procedures on uninfected patients if possible).

#### Low risk of CAMRSA

- Use flucloxacillin, dicloxacillin or cephalexin (in patients without history of penicillin allergy)
  - in a staphylococcal infection the population of organisms can be heterogeneous with sensitive and resistant strains present. There may be an initial response to flucloxacillin/dicloxacillin as sensitive variants will be killed leaving the resistant organism to become predominant. Consider changing to erythromycin/clindamycin, or cotrimoxazole or tetracycline if the clinical response is slow while awaiting sensitivities.

#### Suspected or high risk of CAMRSA

- Start on erythromycin-clindamycin or cotrimoxazole or tetracycline. Ciprofloxacin is not recommended.

## High risk of CAMRSA in the more seriously ill

- Consider admission to hospital.
- Consider the use of vancomycin or the addition of gentamicin to flucloxacillin/dicloxacillin.
- Dispose of items of personal protective equipment (gloves and aprons or gowns).
- Perform environmental cleaning after examination or treatment with consideration of the use of disinfectants.

Note: the epidemiology does not support Australian antibiotic prescribing as an initial cause for the emergence of this infection. However, the ongoing control and potential to retard further emergence of more resistant virulent strains will be assisted by conservative antibiotic use and the application of basic infection prevention and control principles.

## Glossary

### A

**Acts of omission** Processes not performed which could lead to harm

**Antimicrobial** Substances or processes that inhibit the growth or tend to destroy or inhibit the pathogenic action of microorganisms including bacteria, viruses and fungi

**Asepsis** The absence of infectious agents that may produce disease

**Autoclave** A colloquial term for small steam steriliser

### B

**Bioburden/biofilm** A layer of material on the surface of an instrument or device which contains biological material and in which microorganisms may be embedded

**Biological indicator** A carrier on which a defined number of test microorganisms have been deposited, contained within its primary pack and ready for use, that provides a defined resistance to the specified sterilisation process (colloquially known as a 'spore test')

### C

**Chemical indicator** A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

**Cleaning** The process of removing all visible dust, soils and other material from a surface. Manual cleaning is usually performed by using detergents and a physical action such as rubbing or brushing. Meticulous cleaning of instruments and other reusable equipment is required before disinfection or sterilisation

**Contamination** The introduction of microorganisms or foreign matter (or both) to sterile or nonsterile materials or living tissue

### D

**Decontamination** The removal of microorganisms and foreign matter from materials or living tissue

**Disinfection** Any process that destroys or removes disease-causing organisms such as viruses, bacteria or protozoa. It may not destroy spores. Disinfection is not the same as sterilisation

### E

**Enzymatic indicators** Use enzymes from microorganisms in tablet or strip form to imitate biological indicators

**Epidemiological** A branch of medical science that deals with the incidence, distribution and control of disease in a population

**Equilibration time** See *Penetration time*

## H

**Health professional** Someone who provides clinical care

**Herd immunity** Immunity of a group or community. The resistance of a group to invasion and spread of an infectious agent based on the resistance to infection of a high proportion of individual members of the group

**High-efficiency filtration** Filtration with a particle removal efficiency of 90–95%

**Holding time** Minimum time at a given temperature that has been established to destroy all microorganisms

**Hollow devices** If a device is open at one end, it is hollow if the ratio of cavity length to diameter is greater than 1. If a device is open at both ends, it is hollow if the ratio of cavity length to diameter is greater than 2

**Hollow load A** Hollowware devices with a narrow lumen where the ratio of length to diameter of the cavity is greater than or equal to 5, such as hormone implant devices (trocar and cannula), dental handpieces and thin tubing. These items are particularly difficult to clean and sterilise and require the use of Class B cycles to adequately process them. The EN 13060 definition states that a hollow load A is a single open-ended space where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than or equal to 750 ( $1 \leq L/D \leq 750$ ) and where the length of the cavity is not greater than 1500 mm ( $L \leq 1500$  mm) or a double-ended open space where the ratio of length to diameter of the cavity is greater than or equal to 2 and less than or equal to 1500 mm ( $2 \leq L/D \leq 1500$  mm) and where the length of the cavity is not greater than 3000 mm ( $L \leq 3000$  mm) and which is not a hollow load B

**Hollow load B** Hollowware devices with a narrow lumen item where the ratio of length (or depth) to diameter of the cavity is greater than or equal to 1 and less than or equal to 5 (eg punch biopsy tips, jugs). These items are more difficult to clean and sterilise than usual instruments and require the use of a Class S or B cycle. The EN 13060 definition states that a hollow load B is a single-ended space where the ratio of length to diameter of the cavity is greater than or equal to 5 ( $1 \leq L/D \leq 5$ ) and where the diameter is greater than or equal to 5 mm ( $D \geq 5$ ) or a double-ended open space where the ratio of length to diameter of the cavity is greater than or equal to 2 and less than or equal to 10 ( $2 \leq L/D \leq 10$ ) and where the diameter is greater than or equal to 5 mm ( $D \geq 5$ )

**Hollowware** An item where the ratio of depth to diameter (or width) of the cavity is less than one (eg bowls, kidney dishes)

## I

**Iatrogenic** Resulting from the professional activities of health professionals. In the infection prevention and control context, this refers to infections acquired by the patient during the course of treatment

**Immunity** The state of being protected from infection

**Immunocompromised** A person whose immune system is not functioning well (eg those undergoing chemotherapy, or on antirejection medication or high doses of steroids)

**Instrument detergent** A detergent developed for cleaning instruments and equipment

## M

**May** Where the word *may* is used in this document, this indicates that the practice can consider options other than those offered. *May* indicates a suggestion

**Must** Where the word *must* is used in this document, there is strong documentary evidence that harm to patients or staff may result if a direction is not followed. *Must* indicates a requirement

## N

**Need(s) to** Where the term *needs to* is used in this document, there is a risk of harm to patients or staff if a direction is not followed. *Need(s) to* indicates a requirement

## P

**P2/N95 mask** A high-efficiency filtration mask capable of filtering extremely small particles. Used with airborne precautions

**Particles** A state of matter in which solid or liquid substances exist in the form of aggregated molecules or particles. Airborne particulate matter is typically in the size range of 0.01–100 µm diameter

**Pathogen** Any disease-causing microorganism

**Pathogenic** Having the capability to cause disease

**Penetration time (equilibration time)** The time taken to heat the centre of a pack to the sterilising temperature from when the steriliser chamber has reached the sterilising temperature

**Personal protective equipment** Equipment used as an infection prevention and control measure. Includes the use of gloves, waterproof gown, goggles/face shield, mask and appropriate footwear

**Process challenge device** A device containing a chemical indicator used as a test of steriliser function

**Prion** A microorganism resistant to most cleaning, disinfection and sterilisation techniques. Prions are responsible for vCJD

## R

**Respiratory etiquette** Public health measures used to reduce the spread of respiratory infections by encouraging covering the mouth when coughing or sneezing, using tissues to blow the nose, disposing of tissues into waste, and washing hands after touching the nose

## S

**Safety data sheets** A document prepared by the manufacturer of a hazardous substance which describes its properties, uses, health hazard information, and precautions for use, safe handling information and first aid information. A safety data sheet can be obtained by contacting the distributor/manufacturer

**Safety factor** Extra time included in the holding time to ensure sterilisation is achieved. It is a precautionary measure and forms 25% of the holding time

**Should** Where the word *should* is used in this document, this indicates what is thought to be best practice by experts in the primary care field. *Should* indicates a recommendation

**Social distancing** The practice of separating patients from each other for the purpose of reducing the risk of contact, droplet and airborne spread of disease

**Soil** Any matter that contaminates objects and may protect microorganisms from disinfection or sterilisation (eg blood and other body fluids)

**Standard precautions** Assuming that all blood and body fluids are potentially infectious, health professionals use a range of methods and practices to prevent infection of themselves and others

**Sterile** The state of being sterile is an absolute one and denotes the absence of protozoa, spores, mycobacteria, fungi, Gram-positive and Gram-negative bacteria, chlamydia, *Rickettsia*, mycoplasma and viruses

**Sterilisation** A validated process used to render a product free from all forms of viable microorganisms. The nature of microbial death is described by an exponential function, and although the probability can be reduced to a very low number, it can never be reduced to zero

**Sterilisation time** The total time of the sterilisation stage after the sterilising chamber has reached the sterilising temperature (penetration time plus holding time)

## T

**Time at temperature testing** Testing performed to check that the correct temperature is maintained within the challenge pack for the entire sterilisation cycle. It is performed during validation and can be extended to check penetration and drying times

**Transmission-based precautions** In certain circumstances standard precautions may not be sufficient to prevent infection in the health professional or others. Transmission-based precautions include droplet precautions, airborne precautions and contact precautions and involves the use of personal protective equipment, isolation and other measures

## V

**Validation** A documented procedure for obtaining, recording and interpreting the results of testing of sterilisers required to establish that a process consistently yields sterile products

## Resources

### Dealing with infectious and communicable diseases, including pandemics and bioterrorism

#### Australia

##### Emergencies and pandemics

- Australia's health emergency preparedness and response resources and fact sheets, Australian Government Department of Health, available at [www.health.gov.au](http://www.health.gov.au); specific information on MERS is also available from this website
- Australian health management plan for pandemic influenza, Australian Government Department of Health 2009, available at [www.health.gov.au](http://www.health.gov.au)
- The RACGP Pandemic flu kit, available at [www.racgp.org.au](http://www.racgp.org.au)

##### Communicable and infectious diseases

- *Australian immunisation handbook*, Australian Government Department of Health 2013, available at <http://immunise.health.gov.au>
- *The blue book: guidelines for the control of infectious diseases*, Communicable Disease Prevention and Control Unit Victorian Department of Health, available at [www.health.vic.gov.au](http://www.health.vic.gov.au)
- Communicable Diseases Network Australia, available at [www.health.gov.au](http://www.health.gov.au)
- National notifiable diseases surveillance system, Australian Government Department of Health, available at [www.health.gov.au](http://www.health.gov.au)
- Additional resources on communicable diseases and the activities of the Office of Health Protection, Australian Government Department of Health 2013, available at [www.health.gov.au](http://www.health.gov.au)

##### Infection control in healthcare

- *Australian guidelines for the prevention and control of infection in healthcare*, National Health and Medical Research Council, 2010, available at [www.nhmrc.gov.au](http://www.nhmrc.gov.au)
- Information on safety data sheets, Safe Work Australia, available at [www.safeworkaustralia.gov.au](http://www.safeworkaustralia.gov.au)
- Travel health information, Australian Government Department of Health, available at [www.health.gov.au](http://www.health.gov.au)

#### United States of America

- US Centers for Disease Control and Prevention, available at [www.cdc.gov](http://www.cdc.gov)

## Standards

### Australian and New Zealand

These are available at [www.standards.org.au](http://www.standards.org.au)

- AS/NZS 1715:2009 *Selection, use and maintenance of respiratory equipment*
- AS/NZS 1716:2012 *Respiratory protective devices*
- AS/NZS 3816:1998 *Management of clinical and related waste*
- AS/NZS 4187:2003 *Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment and maintenance of the associated environment in health care facilities*
- AS/NZS 4360:2004 *Risk management* and AS/NZS ISO 31000:2009 *Risk management – Principles and guidelines*
- AS/NZS 4815:2006 *Office based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*

### European standards

- These are also available at [www.standards.org.au](http://www.standards.org.au)
- EN 13060:2004 *Small steam sterilizers*
- EN 1500:2013 *Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements*

## Other organisations

- World Health Organisation, available at [www.who.int](http://www.who.int)
- Australian Commission on Safety and Quality in Health Care, available at [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)
- National Health and Medical Research Council, available at [www.nhmrc.gov.au](http://www.nhmrc.gov.au)





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