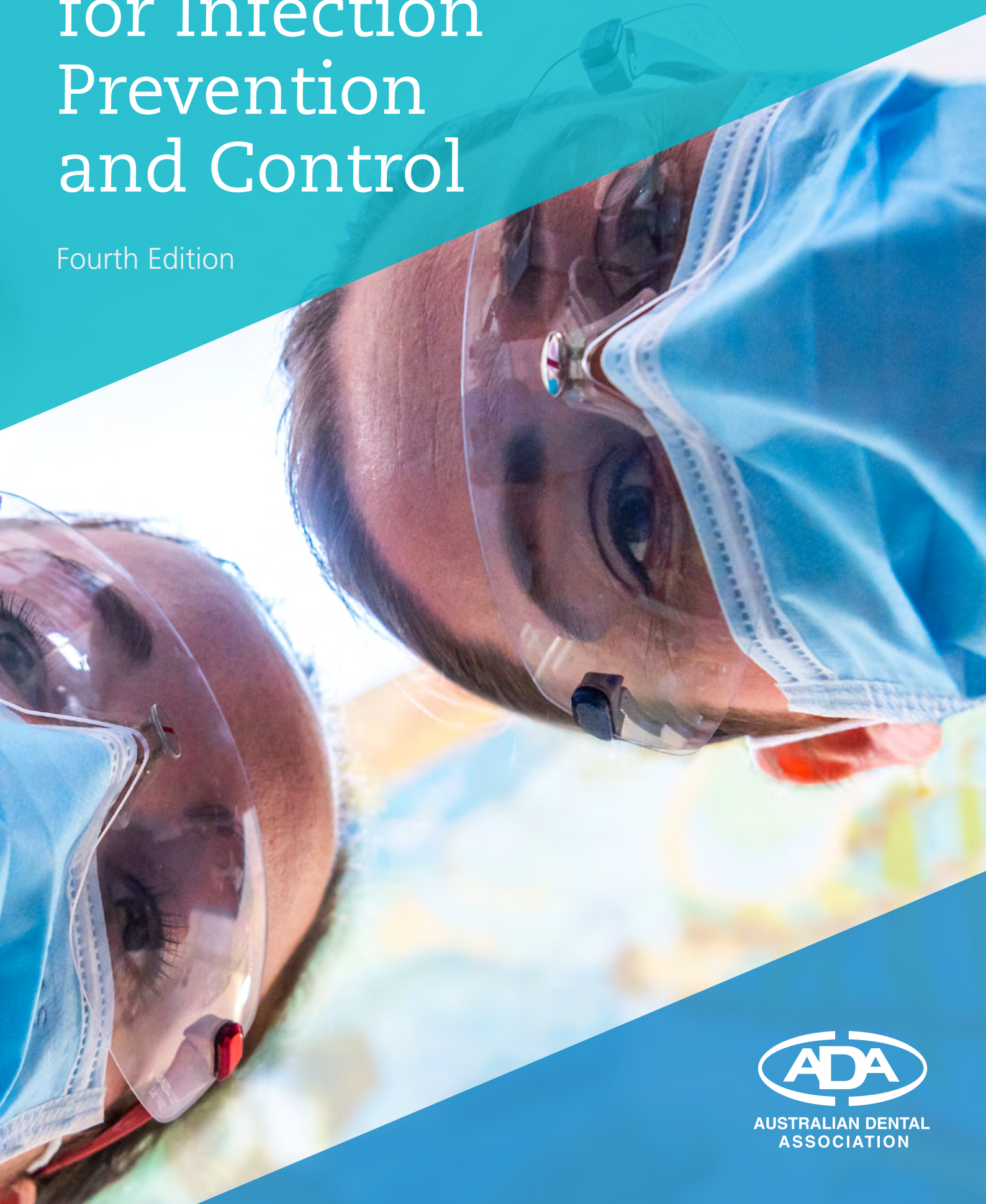


# Guidelines for Infection Prevention and Control

Fourth Edition



*Guidelines for Infection Prevention and Control*

Fourth Edition

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**Disclaimer:** The routine work practices outlined in these Guidelines are designed to reduce the number of infectious agents in the dental practice environment, prevent or reduce the likelihood of transmission of these infectious agents from one person or item/ location to another, and make items and areas as free as possible from infectious agents.

Professional judgement is essential in determining the necessary application of these Guidelines to the particular circumstances of each individual dental practice.

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# Foreword

This fourth edition of the Australian Dental Association (ADA) Guidelines for Infection Prevention and Control incorporates a number of changes that have arisen since the publication of the third edition in 2015. Primarily this includes updates of the Australian National Guidelines for the Management of Health Care Workers Known to be Infected with Blood-Borne Viruses from the Communicable Diseases Network of Australia (CDNA) published in 2018 and the Australian Guidelines for the Prevention and Control of Infection in Healthcare from the National Health and Medical Research Council (NHMRC) published in 2019, as well as amendments to Australian standards related to infection prevention and control. The fourth edition contains some reference to infection prevention and control learnings as a result of the COVID-19 pandemic. As further evidence emerges, it is anticipated that supplementary information will be made available.

This ongoing process of revision follows a commitment by the ADA to follow contemporary Australian Guidelines and to align with current international best practice in evidence-based infection prevention and control. These Infection Prevention and Control Guidelines will continue to be updated periodically to ensure they remain contemporary and evidence-based.

These Guidelines are the result of more than 30 years of dedicated work by the members of the ADA's Infection Control Committee and input from key stakeholders. The ADA Infection Control Committee is comprised of registered dentists, dental specialists and non-dentists who are experts in infection prevention and control in clinical dental practice, and who work in the public sector, private sector and tertiary education settings. They represent the dental profession on national committees developing infection prevention and control standards including the NHMRC, the Communicable Disease Network of Australia, subcommittees supporting the National COVID-19 Clinical Evidence Taskforce, the National Clinical Taskforce, and Standards Australia.

In 2020, documents developed by the Committee were reviewed by the Chair of the Federal Infection Control Expert Group (ICEG) prior to being endorsed by the Australian Health Protection Principal Committee (AHPPC). They were subsequently referenced by the Australian Commission on Safety and Quality in Healthcare and the Dental Board of Australia in providing guidance to the dental profession.

The ADA's Guidelines for Infection Prevention and Control has been recognised as a key source of information for the NHMRC Guidelines and at the time of finalisation (May 2021) is identified by the Dental Board of Australia (DBA) as a mandatory resource for dental practitioners. It was also used as the major reference source for the New Zealand Dental Council's 2016 Infection Prevention and Control Practice Standard.

It is important that every registered dental practitioner and all members of the dental team familiarise themselves with each

new element of infection prevention and control practice included in this document and incorporate these changes into daily work practices. These changes will also need to be reflected in each practice's infection prevention and control manual.

The production of this document has required considerable effort over a long period of time. In developing the 4th Edition, the ADA actively sought input from a broad range of stakeholders including the Dental Board of Australia, the NSW Dental Council as well as peak dental professional bodies, namely, the Dental Hygienists Association of Australia, the Australian Dental and Oral Health Therapists Association, the Australian Dental Prosthetists Association and the Dental Assisting Professional Association.

Special thanks and acknowledgment are due to the current and former members of the ADA's Infection Control Committee (ICC) and in particular Professor Laurie Walsh AO, the 2021 ICC chair, who has been instrumental in the revision of this document.

Other members of the Committee include:

Associate Professor Sharon Liberali (ICC Chair 2020)

Dr Brendan White (Vice Chair)

Dr Kate Amos

Dr Martin Lavery

Dr Heidi Munchenberg

Dr Martin Webb

Dr Greg Whiteley.

In addition, we acknowledge the significant contribution from the ADA Federal office, ADA Branches and other dental professional bodies who have contributed time, technical advice and expertise in preparing this document.



Dr R Mark Hutton

Federal President

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# Introduction

When applying for or renewing their registration, all dental practitioners undertake to comply with all relevant state and commonwealth legislation related to their practice. Most notably, they confirm that they will comply with the Dental Board of Australia (DBA) registration standards, codes, and Guidelines, and this includes the Board's current Guidelines on Infection Control.

In Australia, a combination of Guidelines, standards and manuals underpin requirements for infection prevention and control practices. In most instances, these documents are formed for broader health or hospital settings rather than dentistry in particular. The ADA's *Guidelines for Infection Prevention and Control* serves to synthesise current requirements into a resource that can be readily applied by dental practitioners and their teams in the dental setting specifically. The ADA's *Guidelines for Infection Prevention and Control* is published freely by the ADA for all dental practitioners, as is appropriate for a document referenced directly by the DBA Infection Control Guidelines, in the interest of public safety standards.

The ADA *Guidelines for Infection Prevention and Control* is a key resource to guide practitioners in applying complex documentation in a practical way that acknowledges the specific challenges of the dental environment. It reflects a shared interest of regulators and the ADA to ensure public safety is at the forefront of our profession through clarity, accessibility and consensus in our professional practices.

The ADA *Guidelines for Infection Prevention and Control* describe the infection prevention and control procedures that dental practitioners and their clinical support staff are expected to follow in a dental practice. The document outlines the primary responsibilities of practitioners and the rationale for those obligations, the routine work practices designed to reduce the number of infectious agents in the dental practice environment, ways to prevent or reduce the likelihood of transmission of these infectious agents from one person or item/location to another, and methods to make items and areas as free as possible from infectious agents. Professional judgement is essential in determining the application of these Guidelines to the situation of the individual dental practice environment. Greater details on key technical aspects are provided in the ADA's *Practical Guide to Infection Control*, which provides supporting scientific references that underpin the guidelines.

Where no evidence base is available for issues specific to dental practice, these Guidelines draw upon current international best practice and expert knowledge and advice in infection prevention and control. These Guidelines will be reviewed and updated in light of changes in the evidence and knowledge base.

Responsibility for infection prevention and control compliance rests with each registered dental practitioner and cannot be delegated. Failure to comply with the Board's Guidelines may lead to a practitioner's conduct being investigated by the DBA or by a public health regulator in the jurisdiction in which they practice. As regulators are frequently tasked with determining if conduct falls substantially below an appropriate standard, such consensus documents have an important role to play as a clear reflection of professional expectations. Therefore, each dental practitioner must ensure that they fulfil their obligations to practise in a safe and hygienic manner in accordance with the guidelines. This includes a responsibility to ensure that support staff have dedicated infection prevention control procedures in place in alignment with the ADA's *Infection Prevention and Control Guidelines*, and ongoing training to ensure consistent implementation.

# Supporting and reference documents

In these Guidelines, where key details reside in external documents, those references are listed in the footer of each page in which they are cited, and can be directly accessed for further information.

The ADA's *Infection Prevention and Control Guidelines* are informed by the following key reference documents:

- [Dental Board of Australia Guidelines on Infection Control \(2010\)](#).
- [Australian Guidelines for the Prevention and Control of Infection in Healthcare \(NHMRC 2019\)](#).
- [AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment and AS/NZS 4187:2014 \(Amendment 2, 2019\) Reprocessing of reusable medical devices in health service organisations](#).
- [The National Hand Hygiene Initiative](#).
- [National Guidelines for the Management of Healthcare Workers Living with Blood Borne Viruses Who Perform Exposure Prone Procedures \(CDNA 2018\)](#).

The NHMRC Guidelines describe the principles of infection prevention and control that apply across all healthcare settings, including dental practice. They also provide specific advice on situations where additional risks exist such that transmission-based precautions are warranted.

The two standards from Standards Australia that are relevant to instrument reprocessing in dental practice are the Australian and New Zealand Standards AS/NZS 4815:2006 *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* and AS/NZS 4187:2014 *Cleaning, disinfecting, and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*.

According to the DBA's Guidelines on Infection Control, dental practitioners work under AS/NZS 4815:2006, unless they work within an organisation that operates under AS/NZS 4187:2014. General practice dental clinics should follow AS/NZS 4815:2006, as it is relevant to office-based dental practice.

AS/NZS 4187:2014 (as amended in 2018 and 2019) covers health service organisations (HSO) such as hospitals and day procedure centres. It discusses the reprocessing requirements of complex patient procedures. The current version of AS/NZS 4187:2014 makes extensive reference to international standards that apply to aspects of instrument reprocessing and global guidelines, such as those from the International Organization for Standardization (ISO).

At the time of writing (May 2021), both AS/NZS 4815:2006 and AS/NZS 4187:2014 are current. It is anticipated that in 2022, a new Australian and New Zealand standard will be published that covers both office-based practice and large health care facilities. This new standard will have a new number. Until the new standard is published, dental practitioners should continue to follow the Standards appropriate to their type of practice.

## Key compliance points for applying the guidelines to your clinical practice setting

- Identify which of the two current Australian instrument reprocessing standards (AS/NZS 4187 or AS/NZS 4815) you will follow.
- Maintain access to copies of the key reference documents listed above.
- Update your dental practice infection prevention and control protocols to ensure that they align with the content in this edition of the ADA Guidelines for Infection Control.
- Apply professional judgement when determining how it applies to your individual dental practice environment.

# Glossary & Definitions

**ACSQHC:** The Australian Commission on Safety and Quality in Health Care. ACSQHC leads and coordinates key improvements in safety and quality in health care across Australia.

**AGP:** Aerosol generating procedure.

**AS or AS/NZS:** refers to the Australian and/or Australian and New Zealand standards, as produced by Standards Australia. These are referred to as either AS or AS/NZS followed by the relevant standard number and the year of publication.

**Alcohol-based Hand Rub (ABHR):** an alcohol-based gel or solution that is intended to be used on the hands without the use of water in a hand rubbing procedure.

**Antibacterial Hand Wash:** a detergent-based formulation intended to be used with water in a handwashing procedure.

**Australian Register of Therapeutic Goods (ARTG):** this is the register of all therapeutic goods which is maintained in real time by the TGA. It is accessible via the TGA web portal.

**Autoclave:** a device used to achieve steam sterilisation.

**Bare Below the Elbow:** all hand, wrist, or nail jewellery (e.g., rings with stones or non-smooth surfaces, bangles and bracelets), watches, and wearable devices such as 'Fitbits', must be removed by clinical staff prior to putting on gloves, as their presence impairs correct handwashing, compromises the fit and integrity of gloves, and promotes the growth of skin microorganisms.

**Batch Control Identification (BCI):** also referred to as tracking, is the ability to link a patient procedure involving critical items back to the records for a specific steriliser cycle. This is done for a set, package, or cassette of instruments, by transferring batch information from the label into the patient's record for that appointment. This includes the date of processing, cycle or load number, and if more than one steam steriliser is in use, its identification number.

**Blood-borne Viruses (BBVs):** include hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). These viruses are transmitted primarily by blood-to-blood contact.

**Bowie-Dick Test:** a challenge test that assesses air removal and steam penetration for porous loads.

**CDNA:** Communicable Diseases Network Australia provides national public health co-ordination and leadership and supports best practice for the prevention and control of communicable diseases.

**Clinical Support Staff Members:** are those staff, other than registered dental practitioners, who assist in the provision of dental services – including but not limited to, dental assistants, dental laboratory assistants, sterilising/reprocessing assistants, and dental technicians. It is recognised that some individuals may have both clinical and administrative roles.

**Contaminated Zone:** is that area of work in which direct contamination by patient fluids (blood and body fluids, including saliva) may occur by transfer, splashing, or splatter of material. It includes the operating field in the dental operatory, as well as the instrument cleaning area within the reprocessing room.

**Dental Board:** refers to the Dental Board of Australia (DBA).

**Dental Practitioner:** is an inclusive term that refers to those registered by the DBA to provide clinical dental care to patients, and comprises general dentists, dental specialists, dental prosthetists, dental therapists, dental hygienists, and oral health therapists.

**Dental Staff:** is an inclusive term for all those employed in a dental practice setting – namely, dental practitioners, clinical support staff, and clerical or administrative staff.

**Disinfectant: means a substance:**

- a. that is recommended by its manufacturer for application to an inanimate object to kill microorganisms; and
- b. that is not represented by the manufacturer to be suitable for internal use.

**Disinfection:** is the destruction of pathogenic and other kinds of microorganisms by physical or chemical means.

**Exposure Incident:** is any incident where a contaminated object or substance breaches the integrity of the skin or mucous membranes or comes into contact with the eyes.

**Exposure Prone Procedures (EPPs):** are procedures where there is a risk of injury to dental staff resulting in exposure of the patient's open tissues to the blood of the staff member. EPPs are defined in the 2018 edition of the CDNA *Australian National Guidelines for the Management of Health Care Workers Known to be Infected with Blood-Borne Viruses* as procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the Health Care Worker's (HCW) gloved hands from sharp instruments, needle tips, and/or sharp tissues, including spicules of bone or teeth. In such circumstances, it is possible that exposure of the patient's open tissues to the HCW's blood may go unnoticed or would not be noticed immediately. Such procedures include maxillofacial surgery and oral surgical procedures, including the extraction of teeth (but excluding extraction of highly mobile or exfoliating teeth), periodontal surgical procedures, endodontic surgical procedures, and implant surgical procedures. Other procedures undertaken in dentistry would not normally be regarded as EPPs because the hands and fingertips of the HCW are usually visible and outside the body most of the time and the possibility of injury to the worker's gloved hands from sharp instruments and/or tissues is unlikely. If injury occurs, it is likely to be noticed and acted upon quickly to avoid the HCW's blood contaminating the patient's open tissues.

**Fit check:** a test performed each time a dental practitioner puts on a P2 respirator to make sure it is properly applied.

**Fit test:** identification of which size and style of P2 respirator is suitable for an individual, usually by a trained operator.

**Hand Wash:** hand hygiene that uses water.

**Hand Rub:** hand hygiene that does not use water.

**HCW:** health care worker.



**Helix Test:** used to test air removal and steam penetration in hollow loads.

**Infection Prevention and Control:** the creation of safe healthcare environments through the implementation of evidence based practices that minimise the risk of transmission of infectious agents (NHMRC, 2019).

**NHMRC:** the National Health and Medical Research Council is an expert body supporting the translation of health and medical research into better health outcomes and promotion of the highest standards of ethics and integrity in health and medical research.

**Penetrating Injury:** is any injury from a sharp object such as an injection needle, scalpel blade, dental bur, or denture clasp contaminated with a patient's blood or saliva.

**PPE:** Personal Protective Equipment.

**Steam Steriliser:** device used widely for sterilising instruments in office-based dental practices; otherwise known as an Autoclave.

**Standard Aseptic Technique:** the infection prevention and control strategies applied to all non-surgical procedures in dentistry where transmission-based precautions are not required. This includes the use of gloves, items of personal protective equipment, and rigorous hand hygiene practices.

**Sterilant:** a process which achieves a sterility assurance level of  $10^{-6}$  [1 in 1 million].

**Surgical Aseptic Technique:** applied to all surgical procedures and consists of additional precautions including the use of sterile gloves, surgical hand hygiene, sterile drapes, and irrigation solutions and instruments that are sterile at the point of use (with batch control identification).

**TGA:** Therapeutic Goods Administration.

**Transmission-based Precautions:** additional infection prevention and control measures which add to the standard precautions. These are tailored to the mode of transfer [contact/droplet/airborne] specific to the infectious agent concerned.

# Section A. Infection prevention and control

## 1. What is infection prevention and control?

The purpose of infection prevention and control in dental practice is to prevent/minimise the transmission of disease-producing agents such as bacteria, viruses, and fungi from one patient to another, from dental practitioners and dental staff to patients, and from patients to dental practitioners and/or other dental staff. In addition, infection prevention and control also involves measures that limit the spread of infectious agents.

Successful infection prevention and control involves:

- understanding the basic principles of infection prevention and control;
- creating systems that allow infection prevention and control procedures to be implemented effectively and to make compliance with them easy (this includes having clear procedural documentation and comprehensive and ongoing training of dental staff, together with a process of regular monitoring of the application of these systems and procedures);
- keeping up to date regarding new or re-emerging infectious diseases, particularly newly evolving strains of human influenza viruses and multiple antibiotic-resistant organisms, and how to take precautions against them; and
- identifying settings and situations that require modified infection prevention and control procedures (e.g., when performing dental care when mobility is restricted, in a patient's home, or at a residential aged care facility).

The DBA stipulates that dental practitioners *'must practise in a way that maintains and enhances public health and safety by ensuring that the risk of the spread of infectious diseases is prevented or minimised. Dental practitioners must ensure that the premises in which they practise are kept in a clean and hygienic state to prevent or minimise the spread of infectious diseases and that, in attending a patient, they take such steps as are practicable to prevent or minimise the spread of infectious diseases'*.

In dental practice, microorganisms may be inhaled, implanted, ingested, injected, or splashed onto the skin or mucosa. They can spread by direct contact from one person to another, or through indirect contact via instruments and equipment, such as when a dental staff member's hands or clothing become contaminated, when patient care devices are shared between patients, when infectious patients have had contact with other patients, or when environmental surfaces are not regularly decontaminated.

In the dental practice setting, microorganisms can also spread by airborne transmission – when dental staff or others inhale small particles containing infectious agents. A number of infectious agents, including human viral influenza, can be transmitted through airborne particles generated by a person who is coughing, sneezing, or talking. Transmission via large droplets (splash and splatter) requires close contact, as large droplets

do not remain suspended in the air indefinitely but settle onto surfaces because of the influence of gravity.

Droplet transmission can occur when hands become contaminated with respiratory droplets and transferred to susceptible mucosal surfaces such as the eyes, or when infectious respiratory droplets are expelled by coughing, sneezing, or talking and come into contact with another person's mucosa (eyes, nose, or mouth), either directly or via contaminated hands.

There is good evidence that viral influenza and certain other respiratory infections can spread via droplets. This has implications in terms of how far away to position clean items, such as open boxes of gloves, from the patient's mouth. A separation distance of 1.829 m (6 feet) has been recommended for medical staff who are examining patients with suspected influenza.<sup>1</sup>

This distance of 1.829 m also serves as a useful evidence-based measure of how far particles from a cough or sneeze may travel forward, in a straight line, when expelled from the mouth. It is prudent that supplies of clean items (including open glove boxes) should be no closer than this distance from the patient's mouth if they are situated directly in front of the dental chair. A forward separation distance of 1.829 m will prevent these items from being contaminated with droplets expelled from the patient's mouth, should the patient cough or sneeze.

Whether or not the spread of microorganisms results in clinical infection depends in part on the virulence (power to infect) of a particular microorganism and on the susceptibility of the host. As explained in the 2018 CDNA Guidelines, hepatitis B virus (HBV) is highly infectious and the chance that this disease will be transmitted by a contaminated penetrating injury to a non-immune dental staff member is on average approximately 30%, but may range from as low as 1% to as high as 62%, depending on the infective status of the source patient. In comparison, the chance of transmission of the hepatitis C virus (HCV) by similar means is approximately 3% on average (but may range up to 7%), and for HIV/AIDS, the risk of transmission from an infected patient to a HCW is on average 0.3% (1 in 300).

Patients and dental staff have varying susceptibilities to infection depending on their age, state of health, underlying illnesses, and immune status (which may be impaired by medication, disease, cancer therapy, and other factors such as malnutrition and hormone deficiency).

Infection prevention and control focuses on limiting or controlling factors that influence the transmission of infection or contribute to the spread of microorganisms. The spread of microorganisms can be reduced by:

- limiting surface contamination by microorganisms;
- adhering to good personal hygiene practices, particularly effective hand hygiene and cough etiquette;
- using PPE correctly;

- using disposable products where appropriate (e.g., paper towels); and
- following risk minimisation techniques such as the use of high-volume evacuation, dental dam and pre-procedural mouth rinsing.

### **Standard Precautions (see Section B for further details)**

Standard precautions are the basic processes of infection prevention and control used to minimise the risk of transmission of infection. They include:

- undertaking regular hand hygiene [5 moments: before touching a patient, before a procedure, after a procedure, after touching a patient, after touching a patient's surroundings (including their belongings)], before gloving [donning] and after glove removal [doffing], and at other 'moments' or opportunities when transmission of infection may occur;
- using personal protective barriers such as gloves, masks, eye protection, and gowns;
- wearing appropriate protective equipment during clinical procedures and when cleaning and reprocessing instruments;
- correctly handling contaminated waste;
- appropriately handling sharps;
- appropriately reprocessing reusable instruments;
- effectively undertaking environmental cleaning;
- following respiratory hygiene and cough etiquette;
- using the correct aseptic non-touch technique where indicated;
- appropriately handling used linen and clinical gowns; and
- using, where appropriate, single-use environmental barriers such as plastic coverings on surfaces and items that may become contaminated and are difficult to clean. This includes when the use of a barrier has been stipulated by the manufacturer of the piece of equipment.

These standard precautions minimise the risk of transmission of infection from person to person and are required for the treatment of all dental patients regardless of whether a particular patient is infected with or is a carrier of an infectious disease. They apply to all situations whenever dental practitioners or their clinical support staff touch the mucous membranes or non-intact skin of a dental patient.

Standard precautions are also essential when cleaning the dental surgery environment, when handling items contaminated with saliva (e.g., radiographic films or sensors, dentures, orthodontic appliances, wax rims, and other prosthetic work that have been

in a patient's mouth), when handling blood (including dried blood), saliva, and other body fluids (excluding sweat), whether containing visible blood or not, and when cleaning and processing instruments.

In some circumstances, patients have a specific, highly infectious condition that necessitates the use of transmission-based precautions in addition to standard precautions, in order to address the increased risk of transmission.

### **Transmission-based precautions**

Transmission-based (risk-based) precautions are applied when patients are suspected or confirmed to be infected with agents transmitted by contact, droplet, or airborne routes. The agents of most concern to dental practice are respiratory viruses.

The range of measures used in transmission-based precautions depends on the route(s) of transmission of the infectious agent. The application of transmission-based precautions is particularly important in containing multi-resistant organisms (MROs) in hospital environments and in the management of outbreaks of norovirus gastroenteritis in institutions such as hospitals and nursing homes.

Details of the transmission-based precautions that are required for specific infectious diseases are given in the 2019 version of the Australian Guidelines for the Prevention and Control of Infection in Healthcare from the National Health and Medical Research Council (NHMRC). In brief, transmission-based precautions are used when there is a risk of direct or indirect contact transmission of infectious agents (e.g., viral influenza, MRSA, *Clostridium difficile*, or highly contagious skin infections or infestations) that are not effectively contained by standard precautions.

Droplet precautions are intended to prevent transmission of infectious agents through respiratory or mucous membrane contact with respiratory secretions. These microorganisms do not travel over long distances in droplet form due to their size (larger than 5 microns).

Airborne precautions, which include the use of P2 (N95) surgical respirators, are designed to reduce the likelihood of transmission of microorganisms that remain infectious over time and distance which remain suspended in the air for longer periods of time due to their small size (less than 5 microns). These agents may be inhaled by susceptible individuals who have not had face-to-face contact with (or been in the same room as) the infectious individual. Infectious agents for which airborne precautions are indicated include measles, chickenpox (varicella), and *Mycobacterium tuberculosis*, as well as novel respiratory pathogens such as H5N1 influenza, avian influenza, and certain coronavirus infections.

1. Bischoff WE, Swett K, Leng I, Peters RF. Exposure to influenza virus aerosols during routine patient care. *J Infect Dis*, 2013;207:1037-1046.

There is strong evidence to support and recommend the use of negatively pressurised rooms for patients who are at risk of transmitting infectious organisms via the airborne route. This means that patient care under airborne precautions is often not possible in a private small office practice setting (unless special modifications have been made to the airconditioning plant and approved by an appropriately trained engineer). For effective airborne precautions, a P2 (N95) surgical respirator is required, which forms an airtight seal with the face. In order to be effective, these respirators must be fit tested at regular intervals, and then fit checked at the time of each use. HCWs with facial hair must be aware that this prevents the formation of an airtight seal between the respirator and the facial skin.

At present, there is a lack of evidence from clinical trials regarding the additional benefits of P2 (N95) respirators over conventional surgical masks for reducing the risk of transmission of viral influenza. A surgical mask that is sealed tightly to the face has been shown to block entry of 95% of total influenza virus particles, while a tightly sealed N95 surgical respirator can block over 99% of virus particles. In contrast, a loosely fitted surgical mask blocks 56%, and a poorly fitted respirator only 66% of infectious virus particles.<sup>2</sup> In other words, a poorly fitted P2 (N95) surgical respirator does not perform as well as a tightly sealed surgical mask. This is why fit testing and fit checking is essential for surgical respirators.

The majority of procedures undertaken in dentistry generate aerosols (AGPs). Some items of equipment are more likely to generate intense aerosols, such as ultrasonic scalers and high-speed air turbine handpieces. Therefore, it is important to recognise that patients with viral influenza, active tuberculosis, measles, or chickenpox pose a considerable risk to dental staff and to other patients if they undergo dental treatment. For patients for whom airborne precautions are indicated, a formal risk assessment should be undertaken to determine the need for dental treatment. Non-urgent treatment should be delayed or postponed.

Patients with viral influenza should not have elective dental treatment while they are infectious (two weeks for a patient aged 13 years and above, three weeks after symptoms develop for patients aged 12 or less).

If patients with viral influenza require urgent care, transmission-based precautions must be followed. The additional measures needed include:

1. the patient is seen as the last patient of the day;
2. ensuring that staff providing treatment have been immunised against the current circulating influenza strains;
3. use of a pre-procedural mouth rinse;
4. use of a dental dam for restorative procedures;
5. minimising the use of aerosol-generating techniques;
6. applying two complete cycles of cleaning for environmental surfaces; and
7. If the patient is seen during the day, allowing 30 minutes of fallow-time before the room is used for further procedures on the same day.

There will be few situations encountered where the dental emergency is such that analgesics and other conservative measures will not allow a temporary delay in dental treatment until the patient is no longer infectious.

## 2. Legislative frameworks

Registered dental practitioners are legally required to comply with the DBA's [policies and guidelines](#). The responsibilities around infection prevention and control are stipulated in the [Dental Board of Australia's Guidelines on Infection Control](#).

As mentioned previously, these responsibilities cannot be delegated to dental assistants, practice managers, or practice owners. Rather, each registered dental practitioner must ensure that they fulfil their obligations to practise in a safe and hygienic manner.

### Key compliance points for reducing the spread of infection

- Locate open boxes of gloves and masks away from where contamination is likely to occur.
- Minimise the number of items of equipment and the amount of consumable supplies that are kept on benchtops in the operatory.
- Minimise the number of items of equipment in the operatory that are located beside the patient's head or directly in front of the dental chair (facing toward the patient's feet) because these are likely locations for contamination to occur.
- Apply risk-based precautions for patients with viral influenza.
- Consult the NHMRC *Australian Guidelines for the Prevention and Control of Infection in Healthcare* for specific advice on other situations where additional risks are likely and where transmission-based precautions are required.

2. Noti JD, Lindsley WG, Blachere FM, Cao G, Kashon ML, Thewlis RE, et al. Detection of infectious influenza virus in cough aerosols generated in a simulate patient examination room. *Clin Infect Dis*. 2012;54:1569-1577.

It is essential for staff members to understand that the infection prevention and control policies of a dental practice reflect these legislative requirements, as well as other obligations of law, including work health and safety legislation, which stipulates the need to follow legal directions, including written safety instructions or directives from the employer (a term which includes compliance with written infection prevention and control protocols).

### 3. Duty of care

Dental practitioners have a common law legal duty of care to their patients and must ensure that effective infection prevention and control measures are in place and are complied with in the practice. Consequently, all dental practitioners and clinical support staff have a responsibility to follow the specific infection prevention and control policies that apply in their place of work.

All staff members have duties of care to themselves and to others (in this case, other workers and patients of the practice) whose health and safety would be compromised by the staff member not following correct procedures. Compliance of staff members with workplace protocols should be a key element of assessment of their performance.

As mentioned previously, the DBA stipulates that dental practitioners must take 'such steps as are practicable to prevent or minimise the spread of infectious diseases'.<sup>3</sup>

Dental practitioners must:

- ensure the premises in which they practise are kept in a clean and hygienic state to prevent or minimise the spread of infectious diseases;
  - develop and implement work practices to ensure compliance with infection prevention and control standards;
  - document their infection prevention and control protocols in an infection prevention and control manual that is based on the requirements set out in these Guidelines, in the NHMRC 2019 Guidelines, and in the relevant Australian standard for instrument reprocessing;
  - ensure that all dental staff have read the infection prevention and control manual and have been trained in the infection prevention and control protocols used in the practice;
  - provide their dental staff with access to key resources such as these ADA Guidelines, the current edition of the NHMRC Guidelines, and the most recent edition of the relevant standard for instrument reprocessing (e.g., AS/NZS 4815:2006 or AS/NZS 4187:2014 (as amended));
  - have in place a system of reporting, monitoring, and rectifying breaches of infection prevention and control protocols (which would involve addressing this topic in staff meetings and recording the outcomes from such discussions);
- ensure an immunisation program for dental staff is in place and is in accordance with the current edition of the Australian Immunisation Handbook;
  - maintain an immunisation status record for each member of the dental staff (see Section E for a list of recommended immunisations);
  - maintain a record of workplace incidents and accidents (including sharps injuries) as required by national WHS legislation;
  - maintain an allergy record for each member of the dental staff;
  - implement specific training and education on the correct use of PPE;
  - implement a hand hygiene program consistent with the current version of the National Hand Hygiene Initiative, which promotes the use of ABHRs in situations where hands are not visibly contaminated;
  - implement systems for the safe handling and disposal of sharps;
  - implement systems to prevent and manage occupational exposure to blood-borne viruses (BBVs);
  - implement systems for environmental cleaning;
  - implement systems for processing of reusable instruments and devices as per the relevant standard;
  - be aware of their immune status. Dental practitioners have a professional and ethical responsibility to know their status for BBVs. The DBA stipulates that all dental practitioners must be aware of their infectious status for HBV, HCV, and HIV. Information on the appropriate frequency of testing is based on the nature of the work being done. The 2018 CDNA Guidelines stipulate that all HCWs who perform exposure prone procedures (EPPs) should be tested at least once every three years;
  - not perform EPPs if viraemic for HBV, HCV, or HIV. There are specific pathways documented in the 2018 CDNA Guidelines for managing practitioners who are positive for HBV, HCV, or HIV. Such individuals must seek expert medical advice; and
  - follow through after potential exposures to BBVs, including reporting the incident if it was an occupational exposure, undergoing testing, and if necessary, seeking specialist medical management. Note that it is not necessary for practitioners to stop performing EPPs after an exposure incident, unless baseline testing reveals that they are already infected with a BBV.

3. See the Dental Board of Australia Guidelines on Infection Control, July 2010 ([www.dentalboard.gov.au/Codes-Guidelines/Policies-Codes-Guidelines.aspx](http://www.dentalboard.gov.au/Codes-Guidelines/Policies-Codes-Guidelines.aspx)).



Under work health and safety (WHS) legislation in all Australian jurisdictions, practice owners have an obligation to provide and maintain a safe working environment for employees and for members of the public. This means that practice owners must provide their employed dental practitioners and dental staff with the required materials and equipment to allow these employees to fulfil their legal obligations for implementing effective infection prevention and control in their workplace.

It is a breach of anti-discrimination laws for dental practitioners to refuse to treat or impose extra conditions on a patient who is infected with or a carrier of a BBV.<sup>4</sup>

#### Key compliance points for documentation

- Your practice has a comprehensive infection prevention and control manual that is updated on a regular basis, which staff have read and are following. In March 2019, the ADA released an Infection Control Manual template that can be customised to an individual dental practice.
- Your staff have access to these ADA Guidelines, the 2019 edition of the NHMRC Guidelines, and one of the two standards for instrument reprocessing (AS/NZS 4815 or AS/NZS 4187).
- Your practice has a vaccination status record and an allergy record for each staff member, and both are updated annually.
- There is a record of workplace injuries.

#### 4. Treating patients with BBV infections

Patients with hepatitis B, C, or HIV are treated using standard precautions, and the same cleaning and sterilisation techniques are used for these patients as for other patients. It is important for dental practitioners and their staff to feel assured that their infection prevention and control procedures are adequate for all patients – whether patients carry BBV infections or not. Patients should not want to hide their infectious status because of the way the staff act in their presence.

#### 5. Infected dental practitioners

When applying for or renewing their registration, all dental practitioners must declare that they are aware of their infection status for BBVs and will comply with the 2018 CDNA *Australian National Guidelines for the Management of Health Care Workers Living with Blood-borne Viruses and Healthcare Workers who Perform Exposure Prone Procedures at Risk of Exposure to Blood-borne Viruses (CDNA Guidelines)*. This requirement applies irrespective of what local 'workplace' guidelines are in place. It also applies to students studying dentistry, dental prosthetics, oral health therapy, and dental hygiene.

If a dental practitioner or student knows or suspects that they have been infected with a BBV, they must consult an appropriately experienced medical practitioner or infectious disease specialist to seek appropriate and ongoing medical care, in line with the CDNA Guidelines. They must follow the advice of their treating medical practitioner and any additional stipulations of jurisdictional public health authorities. It is not appropriate for a practitioner to rely on their own assessment of the risk that they pose to patients.

Diagnosis with a BBV no longer limits the clinical practice of HCWs who perform EPPs. If infected HCWs under treatment with antiviral medications subsequently meet the criteria for viral suppression or elimination as set out within the CDNA Guidelines, it is possible to return to clinical work undertaking EPPs.

According to the CDNA Guidelines, with regard to hepatitis B virus infection, HCWs who are HBV deoxyribonucleic acid (DNA) positive are permitted to perform EPPs if they have a viral load below 200 International Units (IU)/mL and meet the other criteria set out in detail within the CDNA Guidelines. Effective antiviral therapy for HBV infection can reduce clinical progression of liver disease.

With regard to hepatitis C virus infection, HCWs must not perform EPPs while they are HCV ribonucleic acid (RNA) positive but may be permitted to return to EPPs after successful treatment or following spontaneous clearance of HCV RNA. There are a number of direct-acting antiviral hepatitis C medications that are associated with very high cure rates.

HCWs who are HIV positive are permitted to perform EPPs if they have a viral load below 200 copies/mL and meet the criteria set out in detail within the CDNA Guidelines. Early identification of HIV (before the onset of symptoms) will allow the early start of combination antiretroviral therapy (cART) which can reduce the risk of clinical progression, viral transmission, and the morbidity and mortality associated with the condition.

<sup>4</sup> Anti-discrimination, privacy, industrial relations and equal opportunity laws apply. Relevant state, territory and commonwealth legislation is listed in the References and Additional Reading.

EPPs in dentistry increase the risk of BBV transmission from either an infected HCW or an infected patient. While performing EPPs, it is possible that injury to the infected HCW could result in the worker's blood contaminating the patient's open tissue, but there is a very low risk of transmission of a BBV from an infected HCW to a patient in Australian health care settings.

*Table 1: Risk of BBV transmission per exposure episode from untreated infected HCW to patient and untreated infected patient to HCW (in the absence of additional risk management).*

Blood Borne Virus	Risk of infected HCW to patient transmission	Risk of infected patient to HCW transmission
Hepatitis B virus	0.2% - 13.19%	1% - 62%*
Hepatitis C virus	0.04% - 4.35%	0% - 7%
Human immunodeficiency virus	0.0000024% - 0.0000024%	0.3%

\*There is a wide variability in infectiousness of people with hepatitis B reported in the literature and this depends on their hepatitis B e-antigen status.

Source: 2018 CDNA Guidelines.

The magnitude of the risks is summarised in Table 1 below, which is taken from the 2018 CDNA Guidelines. In general, HCWs are at greater risk of acquiring infections than are dental patients.

The risk of transmission from an infected clinician to a patient is dependent on a range of factors including the infectivity of the source clinician (e.g., viral load and effect of viral treatments), the clinical treatment type, and the operator skill and experience.

Effective antiviral drug treatment protocols reduce the infectivity of individuals. Once zero viral load has been achieved, there are ongoing requirements, with regular testing for BBVs for the duration of the practitioner's career, to ensure that virus levels remain undetectable.

While the protection of the public's health is paramount, employers of dental practitioners should also consider, and comply with, relevant anti-discrimination, privacy, industrial relations, and equal employment opportunity legislation. Employers must ensure the status and rights of infected staff members as employees are safeguarded.

#### Key compliance points for BBV disease status

- Staff in your practice are aware of the new CDNA Guidelines.
- Dental practitioners who perform exposure prone procedures undergo testing for antibodies to Hepatitis B, Hepatitis C, and HIV at least once every three years.
- When a contaminated sharps injury occurs to a staff member, it is followed up correctly with baseline tests of the injured staff member.

# Section B. Standard precautions for infection prevention and control

The following standard precautions form the basis of infection prevention and control and must be carried out routinely for all patients.

## 1. Hand hygiene

Hand hygiene is a general term applying to processes that aim to reduce the number of microorganisms on the hands by using either a TGA-approved hand wash or hand rub. The purpose of hand hygiene is to prevent transmission of microorganisms from the hands of dental staff to other staff and patients, or from one patient to another patient, either directly or by touching contaminated surfaces or objects. Microorganisms that are present on the patient's skin can be picked up by direct contact (e.g., by handshaking). They are also shed into the area immediately surrounding the patient, depending on factors such as how long the patient is sitting there. These microorganisms can spread if hand hygiene is not performed at all or is inadequate.

Hand hygiene involves either:

1. the application of a TGA-approved hand wash or hand rub, e.g., ABHR, foam, or solution to the surface of the hands; or
2. the use of a liquid soap solution and water, followed by patting dry with single-use linen or disposable paper towels.

The HHA protocol involves use of an ABHR for all clinical situations where hands are visibly clean. The normal routine in a dental practice when no oral surgery is being undertaken should be for dental staff to use ABHR between patient appointments and during interruptions within the one appointment. For regular hand hygiene, ABHR is applied onto dry hands and rubbed on for 15–20 seconds, after which time the hands will be dry.

For non-surgical dentistry, the advantages of ABHR are that it is efficient (taking approximately 15–20 seconds), does not require a sink with running water, detergent, and paper towels, and is much less irritating and drying to the skin than using soap and water (provided an appropriate moisturiser is also used during the day). Unlike detergents, ABHRs do not remove skin lipids and they do not require paper towel for drying.

### When to perform hand hygiene

'Moments' or opportunities for hand hygiene are points when there is a perceived or actual risk of pathogen transmission from one surface to another via the staff member's hands.

The 5 Moments for Hand Hygiene are:

Moment 1: Before touching a patient.

Moment 2: Before a procedure.

Moment 3: After a procedure or body fluid exposure risk.

Moment 4: After touching a patient.

Moment 5: After touching a patient's belongings.

Note that two moments or opportunities may coincide (i.e., overlap fully).

From 1 November 2019, the Australian Commission on Safety and Quality in Health Care (ACQSHC) commenced coordinating all aspects of the National Hand Hygiene Initiative (NHHI) for Australian health service organisations. For more information on the free online educational modules, resources and the HHCApp, click [here](#).

Hand hygiene must be undertaken before and after contact with every patient, and before gloves are put on. It must also be undertaken after removal of gloves, as an essential step before the dental practitioner uses their bare hands to write or type up patient notes. ABHR is used again immediately before gloving for the next patient, and if there is any contact made between the bare hands and contaminated items or contaminated environmental surfaces.

If handshaking occurs, either at the start or end of an appointment, it may increase the risk of transmission of skin-borne pathogens.<sup>5</sup> This risk can be mitigated by undertaking additional hand hygiene after shaking hands. Practitioners should not shake a patient's hand when greeting them without having first completed hand hygiene.

### How to apply ABHR for regular hand hygiene

When using a hand gel dispenser, apply enough gel for at least 20 seconds of rubbing (which is about the same time as singing the 'Happy Birthday' song twice). Follow the instructions for use in regard to the quantity of gel to be used (usually 1–2 squirts). Ensure that there is sufficient gel to remain on the hands for at least 20 seconds (if there is no gel left on the hands after rubbing for only 10 seconds, add additional gel).

Only apply gel to dry hands, as water remaining on the hands after handwashing dilutes the product, thus decreasing its effectiveness.

Further information on hand decontamination with ABHR, and posters on 'How to Hand Rub' can be downloaded [here](#).

5. [http://apps.who.int/iris/bitstream/10665/78060/1/9789241503372\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/78060/1/9789241503372_eng.pdf) and [http://whqlibdoc.who.int/publications/2009/9789241597906\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf).

### How to select an appropriate ABHR product

When selecting an ABHR product, ensure that the product meets the EN1500 testing standard for bactericidal effect and that the product has been approved by the TGA for use as a hand hygiene product for a healthcare setting. A range of ABHR products are registered with the TGA and are listed on the Australian Register of Therapeutic Goods (ARTG). This listing will normally be indicated on the product label, and cost should never dictate the use of a non-compliant product. Approved products include gels, liquids (solutions), and foams.

For staff whose selection and use of an ABHR product may be influenced by religious factors, it is important to know that using hand gel does not result in any significant alcohol absorption through the skin, and thus, using hand gel in the clinic does not breach a prohibition around alcohol (ethanol) consumption. The issue can be avoided by choosing an isopropanol-only hand gel product that has no ethanol at all.

Choose an ABHR product that suits the skin type of the staff. When the correct product is chosen, the emollient agent(s) in the gel will prevent the skin from becoming dry or irritated and should not leave a sticky residue on the hands. A poorly chosen ABHR product that has poor acceptance is unlikely to be used. Staff with an existing skin irritation or skin disease may experience a stinging sensation when first using ABHR. Usually, this subsides over several weeks with the ongoing use of an emollient-containing ABHR. However, medical advice should be sought if symptoms persist.

There are specific high potency ABHRs designed for surgical hand decontamination, which may be used as a substitute for antimicrobial soaps in a surgical scrub. Such products are specifically labelled as being for surgical hand preparation. They are formulated in a different way to those marketed for regular hand hygiene. They have higher concentrations of ethanol and/or isopropanol and are tested using a more stringent performance test. Such products require a prolonged rubbing time (typically 90 seconds) to achieve surgical hand hygiene. When using such products, be aware that the extended rubbing time requires use of a clock to ensure that the exposure time is sufficiently long to achieve surgical hand decontamination. These products require a multi-step process or multiple applications to achieve the required level of skin preparation. Following the product instructions is critical for their proper use and storage. Note that high potency ABHRs designed for surgical hand decontamination are flammable at room temperature and these must be stored away from sources of ignition (such as gas burner flames, electrosurgery or diathermy).

### Location of hand gel dispensers

Keep hand gel dispensers away from children to prevent accidental ingestion of gel.

Avoid having hand gel dispensers located at handwashing sinks – as this might cause confusion for staff who think that they should do both handwashing and ABHR application (in fact, only one is needed). Washing hands with soap and water immediately before or after using an ABHR is not only unnecessary but may lead to occupational irritant dermatitis. For this reason, there is no need to position ABHR dispensers near the handwashing sink. It is both desirable and convenient to position ABHR dispensers close to the clinical working area, provided their location is not prone to splashing from patient fluids.

Keep bulk supplies of hand gel well away from any sources of high temperature or ignition, such as open flames. All ABHR products are flammable, with flashpoints ranging from 21 °C to 24 °C, depending on the type and concentration of alcohol present. The maximum total quantity of all flammable liquids allowed for 'minor storage' is no more than 10 litres per 50 square metres of floor space (as per AS 1940:2004 *The Storage and Handling of Flammable and Combustible Liquids*, Section 2, Table 2.1).

Bottles of ABHR should not be 'topped up' because the outside of the dispenser may become contaminated. Never tip or pour hand gel from one bottle to another, as this may cause contamination of the second bottle and its contents. Empty bottles of hand gel are to be discarded and not reused.

### Use of moisturiser

ABHR can be used as often as is required. However, a compatible water-based moisturiser should be applied, as required, up to four times per day.

### When is handwashing needed, rather than ABHR?

Hands must always be washed under the following situations:

1. at the start of a working session;
2. at the end of a session, when leaving for a meal or other break, or at the end of the day;
3. after toilet breaks; and
4. whenever they are visibly dirty, contaminated with proteinaceous material, or visibly soiled with blood or other body fluids.

Washing hands with liquid soap and water is preferred in each of these situations due to the mechanical removal effect.

Further information on hand washing, and posters on 'How to Handwash' can be downloaded [here](#).

Handwashing should be undertaken in dedicated sinks located in the clean zone. These sinks should preferably be fitted with non-touch taps (e.g., operated by elbow controls or by sensors); otherwise, handwashing should be carried out using a non-touch technique. If conventional (hand-operated) taps are used, they should be operated with the use of a paper towel, rather than with bare hands. Handwashing must not be undertaken using the sink in the contaminated zone that is used for cleaning or rinsing instruments.

Handwashing, rather than ABHR, is required when dental practitioners work outside the normal clinical environment, e.g., in a nursing home or at a patient's home, since ABHR products do not reliably inactivate norovirus, rotavirus, hepatitis A, and certain other enteric viruses which spread readily from contact with contaminated surfaces.

Do not put hand gel dispensers in the toilet area. Alcohols have limited activity against non-enveloped (non-lipophilic) viruses such as those linked to highly contagious gastrointestinal infections including rotavirus, norovirus, and hepatitis A. Toilets need proper handwashing facilities, and a suitable means for drying the hands, such as paper towel. Some practices use hot air dryers as an alternative. These tend to spread microorganisms from the skin into the environment much more than paper towels, with the worst being jet air dryers.



### Hand care

Hands must be well cared for because intact skin is a first-line defence mechanism against infection. Damaged skin can lead to infection in the host and can harbour higher numbers of microorganisms than intact skin, increasing the risk of transmission to others. Damaged skin in dental practitioners and clinical support staff is an important issue because of the high frequency of dry, itchy skin among these staff from irritant contact dermatitis. It is caused most often by frequent and repeated use of handwashing products (especially liquid soap),

and poor quality paper towel that abrades the skin. Other factors that may contribute to dermatitis include the fragrances and preservatives found in domestic hand care products (which can cause contact allergies), donning gloves while hands are still wet, use of hot water for handwashing, and failing to use appropriate moisturisers.

Lacerated, chafed, or cracked skin can allow entry of microorganisms. Any cuts or open wounds need to be covered with a flexible, fluid-proof/waterproof dressing.

### Appropriate preparation of the hands and wrists – 'bare below the elbows'

A dental practice needs a clear policy within their infection prevention and control manual regarding the 'bare below the elbows' principle. In line with the National Hand Hygiene Initiative, all hand, wrist, or nail jewellery (e.g., all rings (including rings with smooth surfaces and rings with stones), bangles and bracelets), watches, and wearable devices such as 'Fitbits', must be removed by clinical staff prior to putting on gloves, as their presence impairs correct handwashing, compromises the fit and integrity of gloves, and promotes the growth of skin microorganisms. Areas of skin beneath rings on the fingers become much more heavily colonised with microorganisms than adjacent areas, and wearing rings increases the carriage rate of Gram-negative bacteria on the hands of clinical staff. This is why rings should be removed.

Each dental practice needs a clear policy statement within its infection prevention and control manual regarding the need for clinical staff to keep their nails both short and natural. Wearing nail polish, artificial fingernails, or fingernail extenders is not permitted, as these cause larger amounts of microorganisms to be retained on the hands, particularly around the nail beds, despite handwashing. Keeping nails short also prevents them from puncturing gloves and makes hand hygiene easier to perform.

The 'bare below the elbows' approach also includes avoiding wearing cloth coats or linen gowns with long sleeves during a non-surgical working day. Long sleeves on clothing that is worn over a clinical session will become contaminated with microorganisms from the working environment, and from patients, and may impede proper handwashing. When a long-sleeved gown or coat is used (for example, during surgical procedures such as implants), this should be removed after the procedure and prior to seeing the next patient.

#### Key compliance points for 'bare below the elbows'

- Check that gowns, coats and undershirts worn by clinical staff have short sleeves.
- Ensure that fingers, hands, and wrists are free of items that retain micro-organisms or hinder hand hygiene.
- Ensure that nails are kept short and natural, without coatings.



## 2. Personal protective equipment (PPE)

Wearing personal protective clothing and equipment where splashes and aerosols are likely to be generated is an important way to reduce the risk of transmission of infectious agents. Dental practitioners and clinical support staff must be provided with all appropriate necessary protective clothing and equipment for the procedure being undertaken, and need to be educated on the correct use of these items.

Barrier protection of the body, including gloves, mask, eyewear, and an outer layer of protective clothing (such as a clinical gown or other dedicated outer clothing), must be removed before leaving the work area (e.g., dental surgery, instrument processing or laboratory areas) for a meal break. Likewise, contaminated gloves are to be removed when leaving the contaminated zone (for example, when moving from the treatment room to reception areas).

### Gloves

Wearing gloves does not replace the need for hand hygiene, because hands may still become contaminated as a result of manufacturing defects in new gloves that were not obvious to the user, or because of damage (such as tears and pinpricks) that occurs to gloves during use.

For dental clinicians, disposable gloves provide an essential layer of protection to separate their own skin from contact with patient fluids (including saliva and blood) and from the over 700 species of bacteria normally present in the mouth. This has direct benefits, including the elimination of nailbed infections caused by bacteria, viruses, and fungi (i.e., whitlow).

Dental practitioners and clinical support staff must wear gloves for all clinical procedures and whenever there is a risk of exposure to blood, saliva, or other body secretions, as well as when the hands will come in contact with mucous membranes. The infection prevention and control manual used in the dental practice should list the protocols for glove-wearing and for hand hygiene before gloving and after de-gloving.

The infection prevention and control manual should also specify the types of gloves that are available for use within the practice, both for routine non-surgical work and (where appropriate) for surgery.

Gloves are now available in a range of materials, including latex, nitrile, neoprene, and polyisoprene, with hypo-allergenic versions having reduced levels of polymerising agents on the gloves because of extensive washing. Because of the frequency of allergic reactions to polymerising agents (also known as cross-linking agents), such hypo-allergenic versions should be considered when staff experience skin reactions that are not due to incorrect hand care (such as failing to apply moisturisers every day).

Disposable or single-use gloves used in patient care must not be washed before use. These gloves must not be reused; a new pair of gloves must be used for each patient. Gloves must be changed

as soon as they are cut, torn, or punctured. Gloves must be removed, and hand hygiene undertaken, before accessing items in drawers or touching areas in the clean zone.

Gloves must be removed as soon as clinical treatment is complete, and then hand hygiene must be undertaken immediately to prevent the transfer of microorganisms to other patients or environmental surfaces. Gloves that are contaminated with bacteria arising from biofilms have been shown to re-contaminate surfaces for up to 19 subsequent touches.<sup>6</sup>

### Glove selection

To protect the skin of the wearer, the glove must cover the hand and wrist region. As dental clinical staff work in short-sleeved clothing when undertaking non-surgical dentistry in the 'bare below the elbows' approach, gloves must have a sufficient 'cuff length' to cover and protect the skin of the wrist from splashes of material.

Defects present in new gloves potentially expose the skin of the HCW to patient fluids, environmental contaminants, and microorganisms from the patient. Defects can develop as the glove material is stretched during use, for example, in the thumb and forefinger regions as a result of grasping items with force, and in the fingertip regions from exposure to sharp items. A higher-quality glove will be more durable and will develop fewer defects over the time it is worn.

Many dental procedures involve the use of sharp instruments and items; thus, the glove material must resist tears and punctures. Glove materials vary in their physical properties such as their tear strength. To achieve suitable resistance to tearing, the glove material must be strong and must also have sufficient thickness to handle the stresses of donning gloves, and the shear forces imparted when items are grasped with force. Nitrile gloves are less likely to develop small tears and leaks during use compared to latex gloves, despite not being thicker.

Gloves also reduce exposure to the many hazardous substances used in everyday clinical dental practice, including strong acids, strong alkalis, organic monomers of various types, and solvents such as acetone and ethanol, which are found in the bonding agents used in adhesive dental procedures. Use of high-quality gloves contributes to the long-term health of the hands by limiting contact with other chemicals used in dentistry that can cause irritation or allergy, such as methacrylate resins and aldehydes. Glove materials vary in their resistance to chemical agents. Compared to natural rubber latex, gloves made from nitrile have greater resistance to detergents, acids, and common organic solvents (such as ethanol). Latex gloves may impair the setting reaction of certain elastomeric impression materials because they contain zinc diethyldithiocarbamate as a preservative and vulcanising accelerator. This chemical can completely inhibit polymerisation of elastomers. Thus, the type of glove chosen must be appropriate for the procedure being undertaken.

6. Tahir et al, *Infect Control Hosp Epidemiol*, 2019;40:60-64:doi:10.1017/ice.2018.285.

Non-sterile examination gloves are to be worn for non-surgical (semi-critical) general dental procedures. Non-sterile gloves supplied for use in a dental practice are required to conform to AS/NZS 4011:2014 *Single-use examination gloves*, and sterile gloves to AS/NZS 4179:2014 *Single-use sterile rubber surgical gloves*. Sterile gloves must be worn when a sterile field is necessary for procedures such as dentoalveolar surgery, periodontal surgery or endodontic surgery, endodontic procedures on vital pulp tissue (such as pulpotomy or regenerative endodontics), or implant placement. For surgical dental procedures, the surgical gloves need to cover the cuffs of the surgical gown sufficiently well to form an effective seal.

In addition to meeting these two sets of standards for single-use gloves, clinical staff may also consider other factors such as the acceptable quality level (AQL) (defect rate) and whether the gloves are powder-free, hypo-allergenic, or have low levels of latex proteins.

Glove AQL is determined by examining gloves for various nonconformities or imperfections, including physical dimensions (width, length, and thickness), watertightness, tensile strength and elongation, and air and water tests to indicate any tears, holes, or pinpoint defects. The lower the AQL, the better.

A glove that is labelled as being 'powder-free' will have trace amounts of residual former-release powder (2 mg or less per glove) and no intentionally added donning powder. Powder-free gloves are recommended because they reduce occupational allergy to latex in HCWs via both respiratory and contact routes.

Polymerising agents are used in latex, nitrile, neoprene, and polyisoprene gloves, and are a common cause of delayed hypersensitivity reactions to disposable gloves. Staff who have suspected or confirmed allergic reactions to polymerising agents in gloves should use hypo-allergenic gloves that have low levels of chemical residues.

Gloves must be worn when cleaning instruments and environmental surfaces. The type of glove worn must be appropriate to the task. For example, disposable latex or nitrile gloves are appropriate for cleaning the dental operator during changeover between patient appointments.

Heavy-duty utility, puncture-resistant gloves must be used during manual cleaning of instruments in the sink, rather than disposable latex gloves. Utility gloves should be used for loading instrument washers with contaminated items. These utility gloves can be reused but must be washed in detergent at the end of the day, stored dry, and replaced if torn, cracked, peeling, or showing signs of deterioration. Alternatively, single-use utility gloves may be used by the one staff member in the instrument reprocessing area, for a single day, and then discarded. Appropriate utility gloves must be used when loading the chamber of a steam steriliser. Heat-resistant gloves should be worn for unloading items after completion of the sterilisation cycle to prevent burns to the hands and forearms from hot items. These heat-resistant gloves must remain as clean items.

If a dental practitioner, clinical support staff member, or patient has a proven or suspected allergy to latex, alternative glove materials must be used, such as neoprene or nitrile gloves. A latex-free protocol must also be followed, including use of a non-latex dental dam and non-latex materials such as prophylaxis cups. Note that patients with multiple food allergies (e.g., banana, chestnut, avocado, kiwi fruit, tomato) have an elevated possibility of latex allergy. It is prudent to use a latex-free approach when treating such patients. Further information can be found in the Latex Allergy chapter of the ADA's *Practical Guide to Infection Control*.

### Accessibility and Storage of Gloves

Keeping glove boxes accessible is important since many dental procedures require planned changes of gloves during the procedure for the chairside assistant or the clinical operator. This is in addition to unplanned interruptions, such as the need to replace gloves that show visible tears or other defects during use.

Opened and unopened boxes of gloves must be stored away from where they could be exposed to splashes of fluid from patient care. Open glove boxes need to be kept away from the direction where most splash occurs, i.e., heading from the patient's mouth towards their feet. If the glove box is located on a wall or a benchtop that is *to the side* of the patient's head, a suitable separation distance of at least 1 metre sideways from the patient's mouth should be implemented to prevent splashes of material reaching the box.

### Key compliance points for gloves

- Ensure that gloves are worn as part of standard precautions during treatment and when cleaning.
- Check that the types of gloves being used by dental team members are suitable for the purpose for which they are being used.
- Check that the placement of glove boxes in the clinic area prevents contamination prior to use.
- Ensure staff in the practice understand the need for hand hygiene before and after wearing gloves.



## Masks

Masks are an essential item of PPE; wearing a mask forms part of standard precautions. Masks protect the mucous membranes of the nose and mouth, and they protect the skin of the face and neck from splashes of material. Masks must be worn wherever there is the possibility of splashing, splattering, or spraying of blood, saliva, or body substances, or where there is a probability of inhalation of aerosols with the potential for transmission of airborne pathogens. It is recommended that masks be worn at all times when treating patients, as this also prevents contamination of the working area with the operator's respiratory or nasal secretions/organisms.

Dental practitioners and clinical support staff must wear suitable well-adapted, close-fitting, fluid-resistant masks. A surgical mask that has been properly adapted to the face can block entry of up to 95% of microorganisms, but this filtration capability falls away quickly when the mask is not fitted tightly against the face.

The filtration ability of a mask begins to decline significantly after approximately 20 minutes because of moisture on the inner and outer surfaces of the mask. After this time, the performance reduces progressively. It is necessary to change masks during long procedures (such as surgical procedures), if the mask has become completely wet through, from within or from the outside. As well, at the end of a long procedure (e.g., greater than 60 minutes in duration), a mask has become significantly less effective and should be replaced with a new mask.

To provide effective filtration, it is critical that a mask is fitted closely to the user's face, by adapting the nose bridge piece and the sides to reduce leakage of air. The design of the mask influences how well it can be adapted to the face of the wearer. An earloop mask tends to gape at the sides, which allows greater leakage of air compared to a surgical mask that has two separate ties. Earloop masks cover less of the face and neck than masks with two ties.

Dental procedures can generate large quantities of aerosols (AGPs), 5 microns or less in size, and a number of diseases may be transmitted via the airborne route. In the dental surgery environment, the most common causes of airborne aerosols are the ultrasonic scaler, the high-speed air rotor handpiece, and the triplex syringe. The aerosols produced from the patient's fluids may be contaminated with bacteria, fungi and viruses from the oral cavity. Aerosols from powered dental equipment also contain microorganisms that have originated from dental unit waterlines.

Masks supplied for use in routine dental practice are required to conform to AS/NZS 4381:2015 *Single-use face masks for use in health care*. This standard describes both procedural masks (level 1 splash protection) and surgical masks (with level 2 or level 3 splash protection). A disposable *procedural* mask with level 1 splash protection would *only* be appropriate for those clinical situations where no exposure to fluids or splashing is expected (e.g. dental prosthetics, review appointments in removable prosthodontics, minor orthodontic adjustments where the triplex syringe is not used). Any procedure using a powered dental handpiece, irrigation or a triplex syringe requires the use of a mask with at least level 2 splash protection.

Disposable *surgical* masks used in routine dentistry must have 98% or greater bacterial filtration efficiency and be splash resistant (equivalent to American Society for Testing and Materials (ASTM) Level 2 splash protection) so that they are resistant to the penetration of fluid. The level of protection should be clearly labelled on the mask box or on the mask itself. Where more than minimal blood droplet exposure is expected, e.g., complex oral surgery procedures such as multiple implant placement, a risk assessment should be undertaken to determine whether the mask type should be upgraded to Level 3 splash protection to cope with greater potential exposure to blood and other body fluids.

Most masks have reduced filtration performance for particles ranging from 0.1–0.3 microns in size, which is the diameter range for human influenza virus (0.08–0.12 microns). Thus, it is recommended that, when assessing the performance data of a disposable surgical mask, there should be a particle filtration efficiency (PFE) value from 0.1–0.3 microns and a bacterial filtration efficiency (BFE) value from 1–3 microns.

The following are some basic protocols to be observed in relation to masks as items of PPE.

Mask Musts	Mask Must Nots
Be put on before performing hand hygiene and donning gloves prior to a procedure.	Be touched by the hands while being worn, other than to remove it completely using the strings / loops.
Be fitted and worn according to the instructions for use – this means using both tie strings where the mask has two ties and adapting the mask to the bridge of the nose.	Be lowered to expose the nose.
Cover both the nose and mouth, and where possible, fold the mask out to fully cover the chin and upper neck.	Be worn for extended periods of time (e.g. more than 2 hours, since after 2 hours, a mask is completely ineffective).
Be removed by touching the strings and loops only.	Be worn around the neck. Be removed while touching the front of the mask.

As previously described, for procedures undertaken on patients who have a current active respiratory infection, it is important to consider the additional risks to clinical staff from aerosols that are generated during patient treatment. While measures such as pre-procedural rinsing and high-velocity evacuation can greatly reduce the load of microorganisms found in these aerosols, it is still a requirement that staff wear a suitable mask which conforms to AS/NZS 4381:2015 and that the mask is fitted properly so that it adapts closely to the face.

#### Key compliance points for masks

- Check that appropriate masks for the procedures taking place are available for use and that dental team members are trained on appropriate mask donning and doffing.
- Ensure that masks are closely adapted to the face and neck when worn.
- Ensure that masks are removed once treatment is complete, and not left dangling around the neck.



#### Eye protection

Many clinical procedures generate particles that travel towards the face of the clinical operator or their chairside assistant. For this reason, dental practitioners and clinical support staff must wear protective eyewear to protect the mucous membranes of the eyes during procedures where there is the potential for penetrating injury or exposure to aerosols, splattering, or spraying with blood, saliva, or body substances.

Eyewear protects the eyes from a broad range of hazards, including projectiles, and should be worn for most clinical procedures. Protection from projectiles is particularly important during scaling, when using rotary instruments (particularly when removing existing restorations), when cutting wires, and when cleaning instruments and equipment.

Eyewear must be optically clear, anti-fog, distortion-free, and close-fitting. It is essential that eyewear be shielded at the sides. Prescription lenses worn for vision correction are not a substitute for protective eyewear because corrective spectacles in regular frames do not have side protection. Most designs do not cover the orbit fully, and thus, they will not protect the wearer from splashes of material or projectiles.

Reusable or disposable eyewear supplied for use in dental practice is required to conform to AS/NZS 1337:2012 *Personal eye protection*. Part 6 of that standard describes minimum requirements for eye protectors fitted with prescription lenses intended to provide low or medium impact eye protection from flying particles and fragments in occupational situations.



Prescription lenses worn for vision correction can become a sound form of protective eyewear when the lenses are inserted in frames designed to provide a suitable level of protection to the orbital region. A variety of corrective lenses (including bi- and tri-focals or transition lenses) can be put into frames approved as protective safety glasses.

Clinicians need to be aware that eyewear becomes contaminated during the course of clinical treatment and therefore, needs to be decontaminated between patients.

Clinicians using protective eyewear with either retractable loupes or with a light attachment which has an integrated curing shield, need to avoid cross-contamination by ensuring that the eyewear is decontaminated between patients. This includes cleaning the lenses as well as any parts of the eyewear that may be touched by gloved hands while working. Examples of such parts include orange curing filters on lights mounted onto eyewear, and handles for changing the position of flip-down loupes.

An alternative to protective eyewear is a face shield. Corrective glasses or magnifying loupes may be worn beneath a face shield. A face shield may be an independent transparent visor supported in front of the face to shield the face and front of the neck, or it may be attached to a mask as a single unit. Because a face shield does not protect the wearer from inhaled microorganisms, it must always be worn in conjunction with a surgical mask.

Patients must be provided with protective eyewear to minimise the risk of possible injury from materials or chemicals used during treatment. Tinted lenses may be used to protect patients from the glare of the operating light. Spectacles worn by patients for vision do not typically provide sufficient protection. If patients refuse to wear protective eyewear, the risks should be explained, and refusal noted in their dental records.

Eyewear for patients may be either disposable or designed for reuse after cleaning with detergent and water. Reusable protective eyewear for patients touches their intact skin, which is a non-critical site. In cases where the patient has sustained significant facial trauma and it is likely that blood contamination of the patient's protective eyewear will occur, it is advisable to use disposable eyewear in order to remove the need for complex decontamination procedures.

#### Key compliance points for eyewear

- Both staff and patients use protective eyewear that protects the orbit fully and has side protection.
- Regular corrective spectacles worn by staff are not used as a substitute for protective eyewear.
- Eyewear worn by clinical staff is decontaminated between patients.
- Reusable eyewear for patients is treated as a non-critical item and is cleaned with detergent.

#### Protective clothing

The most suitable type of protective clothing and equipment varies according to the nature of the procedure and is a matter of professional judgement. A key concept is that of layering, so that street clothes worn underneath do not become contaminated with material from patient treatment, and then transfer that contamination beyond the dental clinic environment, and back to the home of the staff member on their person. Items of protective clothing worn during non-surgical dental procedures must be changed as soon as possible when they become visibly soiled or after repeated exposure to contaminated aerosols (i.e., at the end of the session or the end of the working day).

Protective coats or gowns that have been worn in the clinical area must be removed before taking a meal break or leaving the practice premises. When scrubs are worn as the everyday practice uniform throughout the clinic, it is necessary to wear a suitable layer of protective clothing *on top* of these. This would normally be a suitable disposable or reusable gown (e.g. short-sleeved for routine dentistry, or long-sleeved and sterile for surgical dental procedures). Alternatively, scrubs may be worn over a uniform or street clothes, and removed prior to moving to clean zones (such as after a clinical session, prior to a meal break).





Protective clothing (e.g., disposable gown or washable gown or coat), should be worn while treating patients whenever splatter or aerosols are likely to be generated. This includes procedures using powered instruments such as ultrasonic scalers or dental handpieces, or those that involve use of the triple syringe.

Disposable gowns with long sleeves should be changed after every patient. Long sleeves become contaminated with microorganisms from the working environment and from patients, and can impede proper handwashing.

Disposable sterile surgical gowns are suitable for use for oral surgery as a single-patient-use item. These gowns typically have long sleeves that extend to the area of the wrist that will be covered by the cuff of sterile gloves. At the end of the procedure, they should be placed into the general waste, or if visibly contaminated with blood, disposed of according to local waste management regulations.

Cloth gowns and coats worn by dental practitioners and clinical support staff must be clean and in good condition. Reusable cloth gowns and coats need to be laundered or reprocessed according to AS/NZS4146:2000 *Laundry Practice*.

#### Footwear

Dental practitioners and clinical support staff should wear enclosed footwear that will protect them from injury or contact with sharp objects (e.g., accidentally dropped sharps or spilt chemicals). Footwear should be non-slip and easy to clean in the event of spills and splashes.

#### Key compliance points for protective clothing and footwear

- A layering approach is used so that street clothes worn underneath do not become contaminated with material from patient treatment.
- Gowns worn for non-surgical dental treatment have short sleeves.
- Shoes are closed in so they protect the foot from dropped objects.

### 3. Surgical procedures and surgical aseptic technique

The principles of the surgical aseptic technique must be applied to all surgical procedures undertaken in the dental practice setting. Sterile gloves must be used for vital pulp therapy, incisions into mucosal soft tissues, surgical penetration of bone, or elevation of a mucoperiosteal flap. Sterile gloves are required for the surgical removal of teeth (including fully unerupted teeth, residual root tips, and enucleation of radicular cysts); for minor oral surgery procedures including biopsies, pericision, or frenectomies; and for periodontal surgery, surgical endodontics, and dental implant placement. As noted above, sterile gloves supplied for use in dental practice are required to conform to AS/NZS 4179:2014 *Single-use sterile rubber surgical gloves*.

In addition to sterile gloves, the requirements for oral surgical procedures also include surgical hand hygiene, sterile drapes, sterile irrigation solutions (such as saline), and instruments that are sterile at the point of use (with batch control identification). Long hair must be tied back and covered (e.g., with a disposable cap or hair net) and beards must also be covered.

For surgical hand hygiene, the appropriate and preferred method is the application of a hand gel that is formulated specifically for surgical hand hygiene and uses an extended rubbing time (such as 90 seconds, as discussed earlier). Use of antimicrobial handwashing solutions for surgical scrubbing is no longer recommended due to concerns of antimicrobial resistance or occupational allergy.

Supplies for use during oral surgery, such as sterile cotton pellets and gauze, can be packaged and sterilised in the dental practice using a cycle for porous loads; however, it may be more efficient and practical for a dental practice to purchase drapes, gowns, gauze, and other sterile supplies, rather than to prepare these in-house. Refer to the section on porous loads for more information.

#### Key compliance points for surgical procedures

- Staff perform surgical hand preparation and wear sterile gloves.
- Staff wear an appropriate gown, and hair is controlled.
- There is a defined working field, with sterile drapes.
- Any irrigation solutions used are sterile.
- All instruments that enter tissue are sterile at the point of use, and have been wrapped, with the use of batch control identification.
- All staff involved in surgical procedures should be trained regularly in surgical asepsis and their competency assessed and performance reviewed.

## 4. Management of sharps

Frequently, the practice of dentistry involves the use of sharp items and instruments. Occasionally, when undertaking high-risk EPPs, conditions of limited access and poor visibility will increase the risk of a penetrating injury to dental staff, potentially exposing the patient to the blood of the dental staff member.

Inappropriate handling of sharps, both during and after treatment, is the major cause of penetrating injuries involving potential exposure of staff to blood-borne diseases. Consequently, it is essential that all sharp instruments are handled and used with care, and appropriate techniques are employed to minimise the risk of penetrating injuries to dental staff.

Sharp instruments such as scalpels and scalers must never be passed by hand between dental staff members. They must be placed in a cassette or puncture-resistant tray or bowl after each use. Instruments and sharp items must be carried from the surgery to the reprocessing area in a lidded puncture-resistant container.

Needles must not be re-sheathed unless using an approved recapping device or single-handed technique. Practitioners should consider using devices that are designed to eliminate the risks of sharps injuries associated with common tasks, e.g., devices for removing and disposing of scalpel blades and the use of safety syringes, as appropriate to the nature of the work being undertaken.

Contaminated needles must never be bent or broken by hand or removed from disposable syringes. Dental practitioners are responsible for their used needles and must develop an appropriate management system to render them safe to ensure that support staff members are not injured during patient changeover.

Further information on the safe handling of sharps and appropriate risk reduction methods can be found in the ADA's *Practical Guide to Infection Control*.

The dental practice must have an easily accessible, clear set of written instructions on the appropriate action to take in the event of an exposure incident such as a sharps injury. These instructions must be understood and followed by all dental staff.

For further information on exposure incident follow-up, see Appendix: *Blood and Body Fluid Exposure Protocol*.

### Disposal of sharps

The clinician who has been using a disposable sharp item is responsible for its immediate safe management or disposal after use. This disposal is always best done at the point of use (i.e., into a sharps bin located in the operatory or treatment room).

Used disposable needle syringe combinations, empty or partially used glass cartridges of local anaesthetic solution, used burs, needles, scalpel blades, orthodontic bands, endodontic hand files, and all other single-use sharp items must be discarded in an approved, clearly labelled, puncture and leak-proof sharps container. Any sharp item labelled as single-use must be discarded

during or at the end of the patient appointment, into a sharps container. Appropriate sharps containers are those conforming to AS 4031:1992 *Non-reusable containers for the collection of sharp medical items used in health care areas* or AS/NZS 4261:1994 *Reusable containers for the collection of sharp items used in human and animal medical applications*, as applicable.



A separate sharps container should be located in each operatory, close to the operator, to facilitate the timely disposal of sharp items. When choosing the size of a sharps container, take into consideration the size of items that will be placed into it, so that items remain below the fill line of the sharps container. Do not locate sharps bins above sinks or waste bins, as this may lead to errors. It will also complicate the retrieval of sharp items that are misplaced.

Position sharps containers so that they are readily accessible and so that the opening of the container can be seen into. Sharps containers should be wall-mounted at a height of 1100–1300 mm from the floor to enable access from a sitting position, or a minimum of 1300 mm if access is required from the standing position, so as to allow staff to be able to see into the opening of the container. If not mounted into a dedicated bracket, determine another suitable method of achieving a stable, upright position for the sharps container.

Each practice must undertake a risk assessment to identify issues associated with the location of each sharps container. Sharps containers must be placed in a safe position within the treatment room to avoid accidental tipping over and must be out of the reach of small children. If considering mounting sharps containers into joinery (e.g., just under an opening or chute in a benchtop), undertake a risk assessment to ensure that (a) it is still possible to safely deposit sharp items, (b) the fill level of the container can be checked, and (c) it will be possible to safely close the container lid before removing the container.

Disposable sharps, if not placed by the operator into a sharps container located at the chairside, may alternatively be placed after use in a safely contained puncture-proof dish, to minimise risk of injury during transport to another area of the practice. In this situation, the operating clinician has a responsibility to minimise the risk of sharps injury when they have finished using the disposable item. Likewise, when safe disposal is carried out by another member of staff, the responsibility for safe disposal remains with the operating clinician.

Sharps containers must be sealed when they have been filled to the line marked on the container (or in the absence of a fill line, when three-quarters full). The containers should then be collected by licensed waste contractors for disposal, according to local waste management regulations.

Any reusable sharp items, such as multi-use burs or ultrasonic scaler tips, are to be placed into an appropriate stand or container. Burs should be removed from handpieces, and tips removed from ultrasonic scalers, as the first step in the changeover process between patients. Burs should be removed from handpieces before disconnecting the handpiece from the dental unit. Dental assistants should be trained to check that sharps such as burs and orthodontic wires have been removed by the operator before commencing the changeover procedure.

#### Key compliance points for sharps handling and disposal

- Correct sharps handling procedures are in place.
- Sharp items are removed from the working area early in the changeover sequence.
- Approved sharps containers are used for disposal, and these are located at appropriate locations.

## 5. Management of clinical waste

Waste in the dental practice should be separated according to its category, in line with jurisdictional contaminated or clinical waste regulations. This should be done at the point of generation, i.e., at the chairside. All aspects of the management of medical and related waste (also referred to as contaminated waste) must conform to the relevant local state or territory regulations. The Environmental Protection Agency (EPA) regulations should be consulted for accepted waste management protocols, as these vary between jurisdictions.

Domestic waste goes into the normal waste stream. Medical and related waste (also referred to as contaminated waste or clinical waste) must be placed into appropriately colour-coded and labelled waste bags that conform to AS/NZS 3816:1998 *Management of clinical and related wastes*. These bags will be leak-proof, thick yellow bags labelled with the biohazard symbol. These bags are then placed into secure storage containers until

the waste is collected by licensed waste contractors for final disposal. Small bags can be used to collect waste chairside, provided that these are then placed into medical waste bags. Sharps containers are also to be placed into the medical waste stream.

Standard precautions (gloves, mask, and protective eyewear) must be used when handling medical waste bags and containers. Medical waste bags and containers must not be overfilled and must not be compacted by hand. Medical waste and hazardous chemical waste (which includes some chemicals and waste amalgam) must never be disposed of at local refuse tips that use compaction of open landfill.

Extracted teeth, once cleaned of visible blood, debris, adherent soft tissues, and saliva, may be placed in the general waste or given to the patient sealed in a suitable container or in a sealed steriliser pouch.

#### Key compliance points for waste

- Waste is segregated at the point of generation.
- Clinical staff are aware of the jurisdictional definitions of what constitutes clinical waste, and this is included in the practice infection prevention and control manual.
- Approved bags are used for clinical waste.
- Clinical waste containers outside the practice are kept secure.

In some states and territories, it is illegal to incinerate teeth that have been restored with amalgam because of issues with mercury vapour emissions; therefore, these teeth must not be placed in medical waste or into sharps containers. As different rules apply in each jurisdiction, practices should check their local arrangements.

## 6. Environment

A range of environmental controls can be used to reduce the risk of transmission of infectious agents in the dental practice. These should be considered when designing or refurbishing a dental practice.

#### Design of premises

The design of the premises and the layout of the dental surgery and treatment areas are important factors in implementing successful infection prevention and control. Work areas should be well lit and ventilated, with sufficient uncluttered and easily cleaned bench space to accommodate necessary equipment.

Examples of template designs and specifications can be found in Part D (Infection Prevention and Control) of the [Australian Health Facility Guidelines](#) (AusHFG).

The dental operatory and instrument reprocessing rooms must have clearly defined clean and contaminated zones. The contaminated zone is the area which becomes contaminated

by splashes of fluid and droplets originating from the patient's mouth (typically in a direction forward of the patient's mouth). Aerosols generated from patient care may remain in the air until the particles settle onto surfaces or are removed by filters in the air conditioning system.

The clean zones of the dental practice include office areas, staff room (used for meals, meetings, etc.), waiting and reception areas, as well as those areas used for storage of supplies and sterilised instruments and equipment.

The contaminated zone is the area that may become contaminated with material from patients, both during clinical treatment and during instrument cleaning. After gloving, staff may move from the clean zone to the contaminated zone but never in the reverse direction.

Contact with the clean zone after moving from a contaminated zone will cause potential contamination of the clean zone. In this instance, the violated clean zone should then be considered part of the contaminated zone and must be treated the same as any other contaminated zone.

Likewise, in the dental operatory, workflow for instruments and materials must be from the clean zone to the contaminated zone. Care must be taken to avoid contaminated instruments or equipment re-entering clean areas. Dental assistants should put on new gloves for cleaning work surfaces during the changeover between patients, rather than using contaminated gloves from assisting with the previous patient.

Appropriate detailing of joints in joinery will avoid areas that are difficult to clean. Gaps between surfaces should be avoided or properly sealed. Key areas of concern are gaps between benches and walls, between cupboards and floors or walls, and between skirting and floors.

Floor coverings in the dental operatory must be non-slip and impervious with sealed joints. Welded vinyl flooring is widely used as it is long-wearing and easily cleaned. Coved joints between the flooring and the walls are preferred for ease of cleaning. Carpet is acceptable in the waiting room and office areas, but must not be used in clinical, laboratory, and instrument reprocessing areas as it is not impervious.

Attention should be paid to the location and design of any computer keyboards in the dental operatory, to avoid these becoming contaminated. They should be located away from areas of direct splash and should only be used with clean (ungloved) hands.

Patient notes written by hand or electronically must follow a protocol which prevents environmental contamination of the hard copy notes or computer keyboard. Traditional computer keyboards are not waterproof and are likely to be damaged by repeated application of detergent. Alternatively, if keyboards are operated by contaminated (gloved) hands, they must be specially designed so they can be wiped over with detergent-impregnated wipes between patient appointments.

Meal rooms and other common room areas for dental staff must be separate from patient treatment areas, instrument reprocessing areas, and the dental laboratory. They must conform to the relevant requirements of work health and safety regulations. Crockery and cutlery used by staff must not be washed in the handwashing sinks, or in sinks used for washing or rinsing instruments. Food must not be stored in a refrigerator with dental materials, sealed clinical specimens, or medical products such as drugs or blood products, because of the risks of cross-contamination.

#### Key compliance points for environment

- Ensure that the practice has clearly defined clean and contaminated zones and that clean areas are physically segregated from contaminated areas.
- Verify that working areas are kept free of clutter and are easy to clean.
- Implement procedures to handle retrieval of items and supplies from clean areas, so that these do not become contaminated.

#### Cleaning the environment

State and territory public health regulations require that premises be kept clean and hygienic. Cleaning schedules should be developed and should specify the frequency of cleaning for various parts of the dental practice. This schedule should include window sills, door handles, and telephone handsets, as well as parts of dental equipment that do not come into contact with patients but are in the zone where contamination may occur (e.g., the arms of an intra-oral x-ray unit and the support arm of a dental operating light).

Floors and walls pose minimal risk of disease transmission in a dental practice; nevertheless, these surfaces must be maintained in a clean and hygienic condition and kept free of dust. Walls, blinds, and window curtains in patient care areas must be cleaned when they are visibly dusty or soiled.

Inanimate objects such as door handles, toys, or tablet devices in the waiting room act as fomites and can spread infections through indirect contact. For this reason, it is prudent to wipe down these high-touch hard surfaces daily using detergent-impregnated wipes designed for use on clinical hard surfaces, to reduce the levels of transient microorganisms.

Environmental surfaces such as benchtops in the dental operatory that are outside the contaminated zone must be cleaned at least daily using a product containing detergent. In times of greater risk, such as pandemics, use a two-step approach with both detergent and disinfectant (two separate wiping steps). Alternatively, perform two cycles of wiping down using a product that has combined a detergent with a disinfectant.

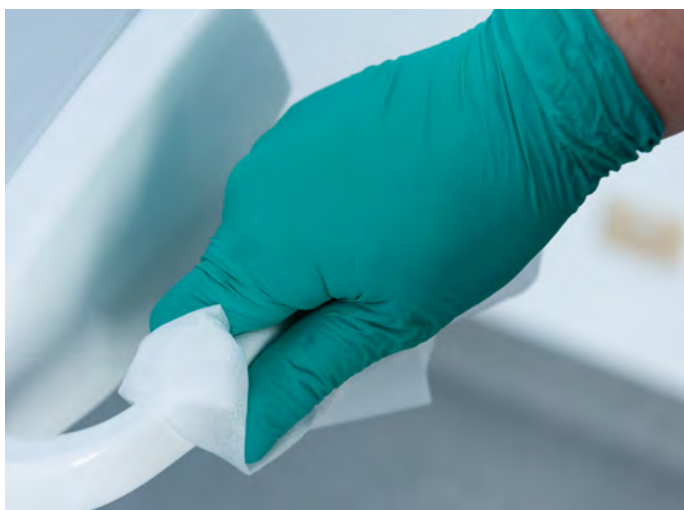


Cleaning methods must avoid the generation of aerosols. Damp dusting, dust-retaining mops, and vacuum cleaners with air filtration of the exhaust are recommended. Brooms must not be used in clinical areas as these disperse dust and bacteria into the air. Mops and cloths must be cleaned after use and allowed to dry before reuse. Alternatively, single-use, disposable mop heads or cloths may be used.

### Treatment areas

Routine cleaning of the contaminated zone within the dental operatory is necessary to maintain a safe environment because deposits of dust, soil, and microbes on environmental surfaces can transmit infection.

Surfaces of dental units must be impervious as they may become contaminated with potentially infective material. Work surfaces and benchtops in treatment areas must be non-porous, impervious to water, smooth without crevices, and have sealed joints to facilitate cleaning and prevent the accumulation of contaminated matter.



Working surfaces in the contaminated zone must be cleaned after every patient by wiping the surface with a product based on a pH neutral or mildly alkaline detergent, which may be combined with or followed by a disinfectant, according to a risk assessment or public health advice. Such environmental cleaning products should be approved by the TGA and included on the ARTG as Class 1 Medical Devices. Standard precautions (including wearing new gloves and other items of PPE) must be implemented when cleaning these surfaces. The detergent may be mixed with water and the resulting solution dispensed onto paper towel. Alternatively, the practice may use pre-moistened wipes. Neutral or mildly alkaline pH detergents are best for environmental cleaning because they are less likely than acidic or strongly alkaline detergents to damage metals such as stainless steel or to cause skin irritation. Neutral detergents also leave little residue on surfaces.

If preparing detergent solutions in-house, prepare fresh solutions daily and dilute these according to the instructions for use. Discard any unused solution at the end of the day, then rinse the containers and leave them to dry overnight prior to refilling for subsequent use.

Written protocols for cleaning the practice must state the methods used and the frequency of cleaning for the various parts of the operatory. Spittoons should be cleaned after each patient by wiping with neutral detergent using disposable paper towels.

Special products may be needed for cleaning soft surfaces such as the upholstery of the dental chair and stools used by the clinical operator and dental assistant. The formulation of products designed for use with upholstery may contain additional components such as conditioners, and lack others such as alcohols, to prevent degradation of the upholstery over time. It is important to follow the dental chair instructions for use regarding the appropriate surface management protocol and products to be used.

For further guidance on appropriate frequency of cleaning for different items, refer to Table B5.1 Recommended Routine Cleaning Frequencies for Clinical, Patient and Resident Areas in Acute Settings in the 2019 NHMRC Guidelines.

### Key compliance points for environmental cleaning

- Check that the practice has a cleaning schedule that covers all areas of the practice.
- Verify that cleaning methods do not damage surfaces, nor do they generate dust or aerosols.
- Ensure the practice uses appropriate products for handling both hard and soft (upholstery) surfaces in the dental operatory.



# Section C. Infection prevention and control strategies within the contaminated zone

It is essential that contaminated zone boundaries are clearly defined, since this has implications for surface management (wiping down) and for the location of equipment, to prevent contamination from splashing. The goal during dental treatment is to contain contamination within this zone, by both determining what is touched and where the spread of droplets, splash, and splatter will occur.

Reducing the extent of contamination of the dental operatory can be achieved in part by the use of dental dams, pre-procedural antiseptic mouth rinses, proper placement of high-volume evacuation, and correct patient positioning. Dental dams minimise spread of the patient's blood or saliva into the operatory when using powered instruments. When a dental dam is not applied during restorative dentistry, high-volume aspiration becomes essential.

All surfaces and items within the contaminated zone must be deemed contaminated by the treatment in progress. The items in the zone must be disposed of, decontaminated, or cleaned and sterilised before commencing treatment of the next patient. Clinical contact surfaces in the contaminated zone that are not covered with a barrier must be cleaned after each patient.

Note: Instruments placed into the contaminated zone for a treatment session, but not used during the session, must be regarded as contaminated. For this reason, all bulk supplies such as opened boxes of gloves, cotton rolls, or gauze must be stored outside the contaminated zone and protected from contamination from splashes of patient fluids.

For difficult to clean equipment, consider the use of a protective barrier. The instructions for use must be followed in terms of how items are managed, both from a regulatory perspective and to ensure they are not damaged by incorrect processing. If the instructions for use stipulate that a barrier must be applied, then these directions must be followed. Likewise, if the instructions for use state that the item is to undergo sterilisation using steam, this must be done – rather than covering it with a barrier or wiping it over with a detergent-based product.

Depending on age and complexity of design, items where barrier protection may be required include:

- operating light handles and hand-operated switches, x-ray heads, tubing for suction, triplex syringe controls, handpiece couplings and tubing, and instrument cradles or hangers;
- polymerising lights, intra-oral cameras, fibre optic illuminators, intra-oral scanners; and
- bracket tables and handles.

Consideration should be given to how to ensure consistent and reliable management of surfaces across different operatories by multiple staff members. There must be a well-documented method for cleaning, and this should specify where barriers are needed on certain items.

## 1. Clean and contaminated zones

Within the dental surgery, clean and contaminated zones must be clearly demarcated. Clean areas include surfaces and drawers where clean, disinfected, or sterilised instruments are stored and never come into contact with contaminated instruments or equipment. All dental staff must understand the purpose of and requirements within each zone, and must adhere to the outlined protocols. A system of zoning simplifies the decontamination process at the end of a patient appointment.

Dental practitioners and clinical support staff should not bring their personal effects (including telephones, water bottles, changes of clothing, or handbags) into clinical (patient treatment) areas and leave them in locations (such as on benchtops) where cross-contamination is likely to occur.

It is recommended, where possible, that common consumable materials such as cotton rolls, dental floss, gingival retraction cord, and restorative materials are pre-dispensed from bulk supplies. The bulk supplies are then kept in closed drawers or cupboards, or in containers, so that contamination from splashes or aerosols does not occur.

If additional instruments and materials have to be retrieved from outside the contaminated zone during an appointment that is underway, it must be by a method that does not contaminate other instruments or materials in the drawers or cupboards.

The recommended technique is to remove gloves, perform hand hygiene with ABHR, retrieve and dispense the additional materials using clean hands, and then perform hand hygiene again and put on fresh gloves. The same 'clean hands' approach can be used when moving from the contaminated zone to a clean zone when the intention is to touch non-clinical items without a barrier, such as the operating controls of an intra-oral x-ray unit. It is no longer acceptable to use over-gloves or to open drawers by elbow touch and then retrieve items with transfer tweezers. This is because such retrieval methods have inherent risks of contaminating clean supplies.

Cartridges of local anaesthetic must be stored appropriately to prevent environmental contamination by aerosols, splatter, and droplets generated by clinical patient care. Cartridges should be kept in their individual bubble packs until use to protect them from contamination. They must never be stored loose, out of their blister packaging, in cardboard containers, as these containers absorb water and cannot be cleaned. Likewise, containers of medicaments, including topical anaesthetic tubes or jars and endodontic medicaments, must be kept free of environmental contamination.

Once used, glass local anaesthetic cartridges or carpules are classified as sharp items and must be disposed of as sharps waste. Polymer cartridges must be emptied of all remaining local anaesthetic solution (into the sink if permitted by local water board regulations), before being disposed of into the regular waste. Polymer carpules can also be placed into the sharps waste, if preferred. Any carpules or cartridges that still contain local anaesthetic solution are considered pharmaceutical waste and must be dealt with as such according to local waste regulations. Typically, pharmaceutical waste requires incineration.

The logical method of decontaminating a dental chair is high to low, clean to dirty. The rationale is that the least contaminated surface is cleaned first, moving towards 'dirtiest' surfaces, thereby reducing the risk of transferring a more heavily contaminated surface load to a less contaminated surface. A dental chair can be divided up into different sections, such as the light handle, the dental chair itself and associated bracket table and attachments, and the associated arms and spittoon. Following this approach, a minimum of two impregnated wipes or paper towels moistened with the cleaning product would be needed for the process to be completed

#### Key compliance points for clean and contaminated zones

- Ensure all staff are aware of the boundaries of the clean and contaminated zones.
- Document the sequence of cleaning of the dental operatory in the practice's infection prevention and control manual.
- Use barriers stipulated by manufacturers for items such as intra-oral cameras and intra-oral scanners.
- Ensure supplies (including medicines and local anaesthetics) are being stored in a way that protects them from environmental contamination.

## 2. Waterlines and water quality

The organisms that grow in waterline biofilms are environmental in origin and are found in lakes, rivers, and other water sources. They flourish in the waterlines of a dental unit because the lines to the handpieces, triplex syringe, and ultrasonic scaler are small in diameter, and hence, have very slow flow rates and large surface area to volume ratios. The cup fill and spittoon lines are larger in diameter and pass more water at higher flow rates, and thus, tend to show lower levels of biofilm than those lines with small diameter tubing.

Waterlines from any device connected to the dental water system that enters the patient's mouth (e.g., handpieces, ultrasonic scalars, air/water syringes) should be flushed for a minimum of two minutes at the start of the day and for at least 30 seconds

between patients, with handpieces in place. Flushing lines at the start of the day can reduce bacterial levels caused by overnight or weekend biofilm accumulation.

Dental unit waterline biofilms are a reservoir of microbial contamination. Biofilms in dental unit waterlines may be a source of known pathogens (e.g., *Pseudomonas aeruginosa*, non-tuberculous mycobacteria, and *Legionella* species). Waterlines must be treated with a suitable chemical agent in accordance with the instructions for use. Likewise, those instructions may dictate the use of specific protocols for sanitising waterlines or testing bacterial levels.

An independent (bottled) water supply can help to reduce the accumulation of biofilm as it makes adding chemical agents to the water easy to undertake. The instructions for use should be followed with respect to appropriate methods to maintain the recommended quality of dental water and for monitoring water quality. This may include purging water from the lines or using sanitising solutions when the chair is not being used for extended periods. Biofilm levels in dental equipment can be minimised by using a range of measures, including ozonation, electrochemical activation, and chemical dosing of water (e.g., with hydrogen peroxide, oxygen compounds, hypochlorites, chloramines, iodine, silver ions, or nanoparticle silver).

All waterlines must be fitted with non-return (anti-retraction) valves to help prevent retrograde contamination of the lines by fluids from the oral cavity.

#### Water quality

Sterile irrigant solution, such as sterile saline as a coolant, is required for surgical procedures such as dentoalveolar surgery, endodontic surgery, and dental implant placement.

In line with the Australian drinking water quality guidelines, water for tooth irrigation during cavity preparation and for ultrasonic scaling should be of no less than potable standard, as specified in the current edition of the [Australian Drinking Water Guidelines](#) (updated August 2018). The number of bacteria in water used as a coolant/irrigant for non-surgical dental procedures should be less than 200 CFU/mL since this is a widely used international limit for safe water for medical applications.<sup>7</sup> Bacterial levels can be tested using commercially available test strips, dip slide testers, or through commercial microbiology laboratories. Typical dip slide or dipstick tests for levels of microorganisms in dental unit waterlines are incubated at room temperature for up to seven days, after which time colony counts are made.

It is good practice to test microbial levels in water from dental unit waterlines on a regular basis, for example, six-monthly or annually, when tested levels are found to be below the target level of 200 CFU/mL. When high counts are found, the waterlines will need to undergo additional sanitising treatments (also called shock treatments) to remove biofilms and bring the bacterial levels

7. CDC (2003) Guidelines for Infection Control in Dental Health-Care Settings, page 29.

back to within an acceptable range. Follow the instructions from the supplier of the dental chair. Ensure that any sanitising agent is compatible with the control blocks of the dental chair, and is flushed completely from the waterlines before using the chair. After sanitising, test water levels more frequently (e.g. every 3 months) to ensure that the biofilm control measures being used are adequate.

Each practice should develop an appropriate routine for hygiene aspects of the water bottle, if present. Water bottles on dental chairs need to be checked visually for the development of biofilm, and cleaned periodically to ensure that the bottle does not become contaminated. Likewise, staff who are handling water bottles or adding in chemical treatment agents must wear gloves so that skin bacteria do not contaminate the water in the bottle.

Further information on dental unit waterlines can be found in the ADA's *Practical Guide to Infection Control*.

#### Key compliance elements for waterlines

- Ensure that the practice has a protocol for testing waterlines and water quality.
- If water samples reveal high loads of bacteria, undertake a sanitising treatment recommended for the chair make and model, then re-test.
- Verify that any chemical treatment of the waterlines is in accordance with the manufacturer's instructions for the dental chair.

### 3. Single-use items

Single 'one patient' use sterile items should be used whenever indicated by the clinical situation. These items include, but are not limited to, local anaesthetic needles, local anaesthetic cartridges, sutures, and scalpel blades. Dental local anaesthetic solution and needles must be sterile at the time of use and are only for single-patient use. Used local anaesthetic cartridges must be discarded after each patient. Similarly, suture materials, suture needles, and scalpel blades must be used for one patient and then disposed of immediately into an approved sharps container.

Single 'one patient' use non-sterile items, including disposable triple syringe tips, disposable low- and high-velocity evacuator tips, prophylaxis cups, micro-brushes, disposable plastic Dappen dishes, and disposable impression trays, must not be reprocessed and reused on another patient, but must be discarded after use. It is not acceptable to attempt to clean and then reuse these items.

Complete sets of dental instruments (including restorative instruments and oral surgery instruments) are now available commercially as single-use items, having been sterilised by the manufacturer. It is not acceptable to attempt to use these items and then reprocess them. They are single use, and therefore must

be disposed of immediately into a sharps container. The same principles apply to single-use burs.

Single-use consumable items that are not classified as sharps, such as single-use impression trays, disposable suction tips, and disposable triplex tips, should be disposed of, as these are not able to be reprocessed.

A number of very small and/or sharp instruments are difficult to clean and should be considered single use. Such instruments must not be reused unless a validated and safe cleaning process is employed. This is why matrix bands, stainless steel endodontic files, reamers, and broaches are to be considered single-use items, because there is currently no cleaning method validated as being effective in removing organic material from these items.

Many dental practices now use disposable triple syringe tips to replace the dual lumen ('pipe inside a pipe') metal tips used with DCI or A-dec type triple syringes. Disposable triple syringe tips are preferred for efficiency reasons (difficulty of cleaning, progressive build-up of inorganic residues within the lumen, and challenges with air removal and steam penetration). Moreover, these dual lumen metal triple syringes need to be sterilised in a pre-vacuum cycle to ensure air removal and steam penetration. Therefore, many practices find using disposable plastic tips for DCI or A-dec triple syringes a better and more convenient approach

#### Key compliance points for single-use items

- Identify the single-use items at your practice and ensure that these are discarded after use.
- Make sure that no attempts are made to reuse single-use items.

### 4. Matrix bands

Matrix bands in contact with the gingiva often become contaminated with blood during use, and if pushed down hard into the tissues, will draw blood. A matrix band is not a surgical blade and it is not necessary to sterilise plain stainless steel matrix bands before use. A wide range of matrix bands are now available, including some combined with wedges for interdental protection; these are not suitable for sterilisation with steam because of their heat-sensitive components (e.g., combination of a steel plate and a plastic wedge). As noted above, matrix bands are single-use items.

Other items used interdentally, such as wooden or plastic wedges, interdental brushes, and dental floss, are not supplied sterile. There is no evidence base around infections arising from these items or from contamination on matrix bands, dental floss, or interdental brushes.

## 5. Burs

According to the Australian standards on instrument reprocessing, items to be reused must be free of corrosion and suitable for use in order to be reprocessed. Stainless steel burs, which become blunt and corrode after several uses, must be discarded into the sharps waste as soon as any visible signs of corrosion appear. Therefore, staff must look for the tell-tale signs of corrosion when these burs are being reprocessed. Typically, this is seen after the third or fourth cycle of use, particularly when a corrosion inhibitor is not used during reprocessing.

Stainless steel burs used in restorative dentistry are also difficult to clean. Without special lighting and magnification, it is not possible to properly clean and inspect burs with small cutting heads. For these reasons, some dental practices now opt to use lower-cost stainless steel burs as single-use items to eliminate the need to clean and inspect them. This ensures that burs, when used, are always sharp. If such burs are to be reused, magnification is essential to check for cleanliness and corrosion.

Most diamond burs are designed for reprocessing. The resin carrier for the diamond does degrade with multiple steriliser cycles. Some brands of diamond burs use chrome cobalt alloy as a matrix for the diamond particles; these are very long-lasting.

Most surgical burs for dentoalveolar surgery are designed for reprocessing and are made of materials such as tungsten carbide that do not degrade when sterilised using steam. Likewise, silicon nitride burs are also designed for reprocessing.

## 6. Implant hardware

It is essential to follow the instructions for use for implant hardware, as the materials used in implant drills, impression copings, and other components vary, with some being intended for reuse and others intended for single use only. Reuse (where permitted by the instructions for use) is only possible when an implant drill is undamaged and has been cleaned properly so that it is free of contamination.

Further information on implant drills can be found in the ADA's *Practical Guide to Infection Control*.





# Section D. Instrument reprocessing

Since contaminated instruments can transmit infections between patients, it is essential that instruments are correctly reprocessed between each patient. The type of instrument and its intended use will determine the method of reprocessing. As a general rule, if an instrument cannot be cleaned, it cannot be safely reprocessed. Protocols for reprocessing instruments are specified in both AS/NZS 4815:2006 *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* and AS/NZS 4187:2014 *Reprocessing of reusable medical devices in health service organisations*.

## 1. Categories of instruments: Infection risk relative to instrument use

Contaminated instruments can transmit infections to patients during clinical procedures. The risk of this happening is related to the site of use. The intended use of the instrument dictates the amount of reprocessing or preparation required for reusable instruments and equipment. The Spaulding classification describes three instrument/risk categories (critical, semi-critical, and non-critical), each of which has specific reprocessing requirements.<sup>8</sup> When purchasing new instruments and equipment, it is important to consider the requirements for reprocessing, and determine whether the practice has the necessary equipment, e.g. some items require the use of a washer disinfectant for cleaning them.

Equipment and instruments used in the treatment of mucosal lesions or diseased soft tissue, and which come in direct contact with mucosa and gingiva or blood, must be single-use disposable or cleaned and re-sterilised after each patient. Examples are the tips used with electrosurgery or cryotherapy devices.

### Critical Items

Where there is entry or penetration into sterile tissue, cavity, or bloodstream (e.g., surgical dental procedures such as the removal of a fully impacted tooth, extraction, and endodontic procedures on vital pulp tissue).

*Examples: dental forceps and elevators, flap retractors and surgical burs, instruments used in the placement of implants, implantable items including mini implants, and surgical dental handpieces.*

1. These instruments must be sterile at the time of use and must be either 'single-use disposable' or capable of being steam sterilised.
2. Critical items must be sterile at the point of use. This means that after use, they are cleaned, rinsed, dried, inspected, then bagged prior to sterilisation and kept stored in bags until use. Instruments stored in bags found to be damaged must be re-sterilised before use. As an alternative in an emergency, critical items may be used immediately after sterilisation.

3. All critical items require batch control identification. Details of the batch numbers of all surgical instruments and other critical items must be recorded in the patient's notes.

### Semi-critical Items

Where there is contact with intact non-sterile mucosa or non-intact skin.

*Examples: mouth mirrors, restorative instruments, dental tweezers and probes, metal impression trays.*

1. Instruments must be sterilised between patients where possible. When not possible, use thermal disinfection or instrument-level disinfection, or cover with a disposable barrier (e.g., curing light tip).
2. Instruments should be 'single-use disposable' or sterilised after use.
3. After processing, semi-critical instruments should be stored so as to prevent contamination prior to use. This can be achieved by having them kept in bags in closed drawers or in dedicated containers such as instrument cassettes.
4. Instruments used in semi-critical procedures do not need batch control identification and are not required to be sterile at the point of use. This means that placing them in bags is optional.
5. In some rare instances, the items cannot withstand sterilisation using steam, and thus, thermal disinfection (using an instrument washer with a thermal disinfection cycle) or instrument-level disinfection (e.g., with ortho-phthalaldehyde (OPA)) may be used as an alternative in accordance with the instructions for use. Professional judgement needs to be exercised.

<sup>8</sup> The Spaulding classification system as described in the 2019 NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare.



## Non-critical Items

Where there is contact with intact skin (lowest risk).

*Examples: prosthetic gauges and measuring devices, face bows, protective eyewear, bib chain, and Willis gauges. Generally, cleaning alone with detergent and water is sufficient, but in some cases, thermal disinfection with heat and water is appropriate. After processing, these items are to be stored in the same way as semi-critical instruments to prevent environmental contamination prior to use.*

### Key compliance items for the Spaulding classification

- Identify which Spaulding classification category each item/device fits into.
- Ensure that all critical items are wrapped or pouched, with batch code identification.
- Check that batch codes are recorded for critical items in the patient notes.

## 2. Instrument reprocessing area and workflow

Reprocessing is a term which includes all steps necessary to make a contaminated reusable device ready for its intended use. These steps may include cleaning, inspection, functional testing, packaging, labelling, disinfection, and sterilisation.

The instrument reprocessing area must be appropriate in layout and size for the volume of instruments being reprocessed. Part of the dental premises must be designated as the reprocessing area for reusable instruments (including cleaning, packaging, and sterilising) and must not be used for any other purpose. Ideally, this should be a dedicated room that is physically separate from the treatment room(s).

If that is not possible because of limited space, instrument reprocessing should occur well clear of the contaminated zone, in an area that is partitioned off, with good workflow processes established, and where there is minimal risk of aerosol contamination of the reprocessing area. Use of physical segregation (such as dividers or partitions) becomes important in such situations, to ensure proper segregation. Such physical segregation is an important consideration in the design of reprocessing areas.

To minimise particulate contamination and bioburden (pathogenic bacteria, fungi, and viruses), the principles of environmental control need to be observed.

The cleaning process must flow in one direction, from contaminated to clean. To achieve this, the reprocessing area must be divided into distinct areas for:

- receiving, cleaning, and decontamination;
- preparation and packaging;
- sterilisation; and
- storage (only if not done elsewhere).

Processed instruments must not be stored in an area where contaminated instruments are held or cleaned or where there is a possibility of contamination from organisms carried in droplets or aerosols.

### Design of the reprocessing area

The following are design features for the reprocessing area that will help to facilitate successful infection prevention and control:

- use of lighting, signs, or features to indicate the direction of instrument flow, and the separation of contaminated and clean areas;



- good lighting to minimise the risk of sharps injury during instrument handling, and magnification to enable proper inspection of cleaned instruments. This may be assisted by the installation of strip lighting over the area where instruments are inspected;
- efficient ventilation;
- non-slip water-impervious flooring that is readily cleanable;
- smooth work surfaces, without crevices, made of non-porous materials such as stainless steel or laminate, to facilitate cleaning. There must be no inaccessible areas where moisture or soil can accumulate;
- work benches of a standard height and storage cupboards located at heights to minimise bending over or stretching overhead;
- sinks must be deep enough to avoid frequent splashing onto the bench, and taps provided with anti-splash devices. Ideally, there should be several sinks – one separate basin for handwashing that is fitted with elbow-operated or sensor-operated taps, and at least one sink for rinsing or manually cleaning contaminated instruments, that has hot and cold water taps (and is preferably fitted with a goose-neck type hose for flushing items after cleaning);
- handwashing must only occur in the dedicated separate basin for handwashing, and not in the sinks used for instrument reprocessing;
- both hot and cold water taps in the instrument reprocessing area should ideally be non-touch (e.g., elbow operated) or electronic in operation; liquid handwash dispensers should be operated by the elbow, knee, or foot;
- sufficient drawers, cupboards, and shelves to keep work benches as clutter-free as possible and to facilitate temporary storage of sterilised packages as well as general items such as labelling guns, logbooks, cleaning agents, and self-sealing bags;
- sufficient bench space for drying and packaging areas to enable efficient work practices; and
- a cooling rack for sterile items awaiting storage; essential to prevent damage to packs and dampness from condensation during cooling.

### 3. Transfer of contaminated instruments and sharps

Instruments should be carried to the reprocessing area in a cassette or in a container that is preferably lidded and puncture-proof, to minimise manual handling of items. Use of a lidded container also reduces the chance of deposits drying onto the surfaces of instruments before they are cleaned and lowers the risk of a penetrating injury if the container is dropped during transport.

A systematic approach to the decontamination of instruments after use will ensure dirty instruments are segregated from clean items. Contaminated instruments should be carried with

gloved hands to the cleaning area and placed on the bench in the 'contaminated zone' of the reprocessing room. For the staff members working in the reprocessing room, suitable utility gloves are to be worn when loading items into ultrasonic cleaners or into instrument washers. Appropriate thick utility gloves are also required for manual lubrication of handpieces, for loading automated handpiece lubricators, and for the manual cleaning of delicate or specialised items. Before putting on utility gloves, hand hygiene must be performed. In the reprocessing room, this involves handwashing.

Once the cleaning process commences, instruments must pass in one direction only, from contaminated to clean.

### 4. Cleaning

The presence of organic material left on instruments/equipment may prevent steam penetration during sterilisation. Therefore, it is essential that instrument surfaces are completely cleaned before being sterilised. Cleaning also dramatically reduces the number of microorganisms remaining on surfaces that need to be killed during sterilisation, which lessens the chance of microorganisms multiplying on instruments before steam sterilisation commences.

#### PPE requirements during instrument cleaning

Clinical support staff who are cleaning and reprocessing instruments must be provided with formal training in the relevant procedures.

When loading ultrasonic cleaners or instrument washers, or performing manual cleaning, in addition to heavy-duty utility (puncture and chemical-resistant) gloves, staff must wear eye protection/face shield to protect them from splashes. A mask must also be worn to protect from splashes to the lower face and from aerosols.

While not always required, a waterproof/fluid-resistant gown/apron is also recommended when undertaking large amounts of manual cleaning, to prevent any splashes of water or cleaning agents reaching the skin. Any such splashes on the skin must be washed quickly with clean water, and the site treated in accordance with the instructions for use.

Wearing a hair net is recommended when packaging instruments, to prevent any shed hair falling onto the work area or into packages. For the same reason, beards should be covered.

During operation of the ultrasonic cleaner, the lid must be kept on to prevent dispersion of aerosols and droplets of fluids.

#### Pre-cleaning at the chairside

Used dental instruments becoming heavily contaminated with blood and saliva during use makes later cleaning more challenging. To reduce this problem, instruments may be pre-cleaned by wiping using a one-handed method at the chairside. This will remove residues of blood, cements, and other materials that may become hard over time. A one-handed method must be used during the wiping action to prevent the risk of sharps injury. This pre-cleaning technique is strongly recommended to improve the safety and effectiveness of instrument reprocessing.

### Procedure for delayed cleaning

Dental instruments and devices contaminated with blood, saliva, cements, and other contaminants that are not able to be cleaned immediately must be covered with a suitable hydrating solution to prevent the substances drying on them. Instruments must be rinsed well before the next step of the cleaning process is commenced.

Note that there is a specific application for approved enzymatic agents in the cleaning of rotary nickel-titanium endodontic files, as part of a validated protocol.

### Rinsing prior to cleaning

Rinsing instruments prior to cleaning aims to reduce adherent deposits of saliva, blood, and other materials. Only warm water (around 35 °C) should be used for this initial rinsing. Hot water will coagulate proteins and thus, entrap microorganisms inside the mass formed, making cleaning more challenging. Use of cold water will precipitate and solidify lipids. Use of warm water prevents such problems.

### Mechanical cleaning

Mechanical cleaning of instruments can be carried out in instrument washers (also known as thermal disinfectors) or using ultrasonic cleaners. Instrument washers are more efficient at pre-sterilisation cleaning than both ultrasonic cleaners and manual cleaning.

Mechanical cleaning is preferred to manual cleaning as it is more efficient and reduces the risk of exposure to blood, and the risk of penetrating skin injuries from sharp or pointed instruments.<sup>9</sup> Mechanical cleaners used in dental practices may be instrument washers (which also provide thermal disinfection), ultrasonic cleaners, or combination units which perform both.

Note that the use of domestic dishwashers to process dental instruments is not permitted. Instrument washers must not be used as a substitute for steam sterilisation.

Automated washing devices specifically designed for use in clinical practice are regulated as Medical Devices by the TGA. An ARTG reference/inclusion number should be available from the supplier as evidence of the regulatory status.

There are both benchtop and floor-mounted instrument washers designed for use in dental practice. These connect into the water supply and drainage systems and must be serviced according to the instructions for use. These systems must comply with AS 2945:2002 *Batch-type washer/disinfectors for health care facilities* or AS 3836:1998 *Rack conveyor washers for health care facilities*. Washer/disinfectors must be well maintained and cleaned regularly to prevent formation of biofilms that could contaminate the instruments being processed. A suitable performance test (soil test) should be used in each load and the results recorded.

Ultrasonic cleaners complying with AS 2773:2019 *Ultrasonic cleaners for health care facilities* – Benchtop may be used for instrument cleaning, especially for small items such as nickel-titanium endodontic files (following a validated protocol) and



dental burs which are designed for reprocessing. Ultrasonic cleaners can be used for cleaning jointed instruments such as scissors and stainless steel syringes, or those with serrated beaks, such as artery and extraction forceps.

Items must be free of visible soil before being placed in an ultrasonic cleaner. In addition:

- lids, tanks, gaskets, and strainers must be cleaned daily;
- water must be de-gassed before use;
- cleaning fluid must be changed a minimum of twice daily (or when it appears visibly cloudy and thus, heavily contaminated);
- an aluminium foil test (or another approved performance test recommended by the manufacturer, such as the pencil test) must be performed daily and the result recorded. This foil test can be done at the end of the day or during the day immediately prior to emptying the solution from the chamber, as this represents a greater challenge to effective operation. This timing also avoids issues from fragments of aluminium foil contaminating items in the chamber;
- lids must be closed during operation (to avoid dispersal of aerosols);
- instruments must be completely submerged in the fluid; and
- no part of the operator's fingers or hands is permitted to be immersed in the fluid during operation of the ultrasonic cleaner.

9. TMiller CH, Tan CM, Beiswanger MA, Gaines DJ, Setcos JC, Palenik CJ. Cleaning dental instruments: measuring the effectiveness of an instrument washer/disinfectant. *Am J Dent* 2000;13 (1):39-4.

The standard is silent on when to perform the foil test, however, the test would be considered more of a challenge when done immediately prior to changing the solution.

The number of foil pieces used in the testing should reflect the volume of the chamber of the ultrasonic cleaner. A large chamber will have several transducers and will require several pieces of foil to check that all transducers are operating correctly.

Do not leave items overnight in solutions in the chamber of an ultrasonic cleaner. At the end of the day, the chamber must be emptied and rinsed thoroughly, then left to dry overnight.

### Manual cleaning

Manual cleaning is discouraged wherever mechanical cleaning can be used, i.e., there must be no hand scrubbing before instruments are placed into an ultrasonic cleaner or into an instrument washer/thermal disinfectant.

The requirements for manual cleaning should be minimal since all routine instruments should be processed through a mechanical cleaning device, namely, an ultrasonic cleaner or instrument washer (not both) for regular solid instruments, and a lubricator for dental handpieces.

If it is necessary to clean a delicate or specialised item, cleaning techniques used should aim to avoid spraying liquids into the air. The instruments should be held low in a dedicated instrument cleaning sink that has been pre-filled with lukewarm water and instrument-grade detergent (not domestic detergent). To remove debris, a long-handled instrument brush or a non-scratch nylon scourer should be used until the item is visibly clean. Abrasive cleaners such as steel wool and abrasive cleaning powders should not be used as they can damage instruments and may leave residue. A wire bur brush, maintained in good condition, may be used for cleaning tungsten carbide and diamond burs. All cleaning brushes used for manual cleaning must be washed, rinsed, and then stored dry.



Lukewarm tap water is to be used for manual cleaning of instruments. As discussed earlier, for the initial rinsing step, hot water should not be used as it coagulates proteins, which then increases the difficulty of cleaning, while cold water solidifies lipids.

Common household domestic detergents must not be used for manual instrument cleaning in dental practice as they are high foaming. This characteristic impairs the visibility of instruments and increases the risk of a penetrating injury during cleaning. They also leave residues after rinsing.

Instrument detergents will have a neutral or mildly alkaline pH, unlike those used in ultrasonic cleaners (moderately alkaline) or in instrument washers (strongly alkaline). The greater the pH of a detergent, the better it works, but it is more likely to cause skin irritation.

Following manual cleaning, instruments must be rinsed thoroughly with warm to hot running water to remove all traces of detergent, and must then be visually inspected.

### Rinsing after ultrasonic cleaning or manual cleaning

Thorough rinsing is essential after ultrasonic cleaning or manual cleaning in order to remove residues of microorganisms and their products. Of particular concern are bacterial endotoxins associated with Gram-negative bacteria. These heat-tolerant molecules are highly inflammatory when introduced into wounds and trigger high fevers in patients. If endotoxins remain on instruments after ultrasonic or manual cleaning, they may cause intense localised inflammatory reactions, including granulomas, when instruments enter the tissue. This is why there are limits on the allowed levels of endotoxins in water used for the final rinsing of instruments in AS/NZS 4187:2014 *Reprocessing of reusable medical devices in health service organisations*. Each facility using AS/NZS 4187:2014 should refer to this standard for guidance on endotoxin levels and testing.

If an instrument washer is used, there is no requirement for further rinsing at the end of the cycle.

### Drying instruments

Instruments that will be sterilised using steam must be dried thoroughly prior to sterilisation as residual moisture on instruments following cleaning may impede the sterilisation process and may stain or damage the instrument or device. Suitable methods include use of a drying cabinet, low lint disposable or lint-free cloth, and a short rinse in very hot water.

The drying cycle of instrument washers eliminates the need for a separate drying step.



## Inspection

Following either mechanical or manual cleaning, instruments should be checked visually under good lighting and magnification to ensure all soil/contaminants have been removed. Damaged or rusted instruments must be repaired or discarded, and those with visible residue soil/contamination must be re-cleaned. If the item is not clean, the sterilisation process will be compromised.



## 5. Packaging prior to steam sterilisation

Decisions around packaging and presentation of routine instruments to be used in semi-critical sites have implications for instrument inventory and the cost of reprocessing. Each practice will need to examine their work mix to optimise the inventory of instruments required to support the practice.

In a specialist orthodontic practice where no oral surgery is undertaken, the need for items to be sterilised in packages and presented sterile at the point of use may be zero. On the other hand, in a specialist periodontal or oral surgery practice, instruments should be routinely wrapped and sterilised so they can be used in surgical procedures as well as in non-surgical procedures. A general dental practice performing mostly restorative dentistry sits between these two extremes.

Dental practices must be mindful of accreditation requirements in relation to packaging of semi-critical items. Note that for public sector clinical facilities and hospital-based clinics, the requirements of the National Safety and Quality Health Service Standards (2nd edition), published by the Australian Commission on Safety and Quality in Health Care in 2017, are relevant. This point is discussed below.

For practices that perform periodontal closed debridement, as well as periodontal surgery or implant placement, having the inventory of scalers and curettes packaged allows versatility for use in both surgical and non-surgical patient appointments.

Some private dental practices may choose to delineate instruments for semi-critical (routine non-surgical) dentistry

from those used in surgical procedures or at critical purposes sites. However, a high level of staff training is essential for this segregated approach, as mistakes can occur when two different systems are used in parallel. Instrument processing mistakes are often the result of poor training and inadequate supervision. In a multi-operator dental facility, it is critical to put in place processes to ensure consistency in instrument processing, such as assigning one individual to the supervision and oversight of instrument reprocessing. Wrapping (bagging) all instruments reduces one important variable from the equation and protects the cleanliness of items.

Instruments organised in cassettes can be easily wrapped as a single set; this may be far more convenient than individually wrapping every instrument.

As mentioned earlier, instruments that must be sterile at the time of use (i.e., critical instruments penetrating normally sterile tissue), must be bagged or wrapped prior to sterilisation. Following sterilisation, critical instruments must remain bagged or wrapped and must then be stored appropriately until use. In an emergency situation, a critical instrument may be steam sterilised unbagged and then transported to the operatory in a sterile container for immediate use.

It is recommended that semi-critical instruments are stored in bags or in cassettes, since both these methods facilitate storage and protect against contamination from aerosols.

Paper bags/wraps used for steam sterilisation are required to conform to AS 1079.3-1994 *Packaging of items (sterile) for patient care, Part 2: Non-reusable papers – For the wrapping of goods undergoing sterilisation in health care facilities* or Part 5: *Single-use, non-woven wrapping materials – For goods undergoing sterilisation in health care facilities*. Textile linen wraps must conform to AS 3789.2:1991 *Textiles for health care facilities and institutions, Part 2. Theatre linen and pre-packs*. Paper and synthetic packaging is designed to be used once and then discarded, as contact with steam alters its properties. Packaging and wrapping materials must permit the removal of air, the penetration of steam into the pack, and the removal of steam and water vapour after sterilisation. Likewise, cassettes used for packaging instrument sets must be perforated to allow for penetration of steam and efficient drying.

Instruments with hinges or ratchets must remain open and unlocked. Sharp instruments should be packaged in such a way as to prevent perforation of the pack.

Packs or bags must be sealed prior to processing. This can be done using a heat-sealing machine or with the use of self-sealing bags. String, domestic adhesive tape, staples, and elastic bands are not suitable for sealing packs.

Colour-coded tapes (including coloured electrical tape) on individual instruments for identification must not be used as these can prevent the penetration of steam under the tape, may harbour microorganisms in their adhesive layer, and may detach from the instrument during surgery, compromising patient safety.





There are specifically designed silicone rubber rings that can be used to identify instruments or instrument cassettes; these do not impede cleaning or sterilisation. If used, follow the instructions for use. It is also possible to etch the surface of instruments for the purpose of identification.

For packages where the contents cannot be seen, adhesive stickers, felt-tipped non-toxic marking pens, and water-resistant ink stamps may be used for labelling. When labelling laminated (paper-plastic) pouches, the labelling information is normally placed prior to sterilisation. Some steam sterilisers can print labels that will be applied at the end of a cycle. If using this approach, the labelling procedure must not compromise the integrity of the package (e.g., because of rough handling).

The information contained in labels placed on wrapped critical items must include the date of processing, the identification of the steam steriliser used, and if relevant, a batch identifier. It is not valid to state an expiry date on a packaged sterilised item, since the effective storage life is event-related. The date of processing is useful for stock rotation purposes.

Further information on storage of sterile packages can be found in the ADA's *Practical Guide to Infection Control*.

## 6. Batch Control Identification (BCI)

Batch Control Identification (BCI) assists in risk management. It is essential for critical items as these may enter or penetrate into sterile tissue or the bloodstream. Critical items include those used during surgical dental procedures such as extractions, periodontal surgery, and endodontic procedures on vital pulp tissue. Critical items include dental forceps and elevators.

Some private dental practices will not need to undertake BCI because they do not perform procedures where reusable critical sterilised instruments and equipment are used, or they only use pre-sterilised single-use or disposable instruments and equipment for surgical procedures. BCI is not required where sterile single-use

instruments are used, since the sterilisation has been undertaken by the manufacturer. Likewise, recording of batch codes or lot numbers for instruments and supplies (e.g., drapes, gauze) that come pre-sterilised from the manufacturer is not required. However, it is necessary to record in the notes the lot number or batch information for all commercially prepared implantable items (e.g., dental implants). Ethylene oxide sterilisation and sterilisation by gamma irradiation are commonly used on a commercial scale to produce disposable sterile items for use in dentistry. These processes can be verified.

As a quality assurance or risk reduction measure, a system of BCI must be used for all packages of critical items that have been processed, as a minimum requirement. These batch numbers are to be recorded in the patient's notes at the time of the procedure. The treating dental practitioner must not delegate responsibility for the accuracy of this information to another person. They must either enter the BCI information themselves or check if the information has been entered accurately by another person.

The recorded batch information links a critical item used on a patient to a specific steam sterilising cycle. This allows dental practitioners to demonstrate that the critical dental instruments they have used on the patient have been through a particular steriliser cycle with verifiable performance data showing satisfactory achievement of the required parameters.

The use of BCI is mandatory for all critical items.

When using BCI, the batch code put onto a sterilised package of critical items must include the date of processing, cycle or load number and if more than one steam steriliser is in use its identification number. Batch information can be recorded on packages manually using non-soluble permanent marker ink, provided that the ink is able to tolerate steam sterilising and does not become unreadable. A manually generated batch code may be a simple incremental sequence of numbers, such as those produced from a labelling gun. Alternatively, it may be a composite of a number sequence with codes for the date and the cycle or load number, and the steam steriliser identifier (if the practice has several steam sterilisers).

If a batch code is applied using adhesive labels, such as those applied with a labelling gun, the information on the label and any adhesives used must be able to tolerate steam sterilising. Several segmented (piggyback) adhesive label systems are available, where one part of the label is peeled off the pack when setting up for the procedure and placed directly under the day's entry on the patient's hard copy chart. In addition, systems also exist whereby batch identification information is printed with barcodes or QR codes, allowing the codes to be scanned for entry into electronic patient records.

Because of the requirement to capture batch code information at the time of undertaking a critical procedure, it is good practice to check the chemical indicators on packages of sterilised items prior to opening. Instruments can then be dispensed into the sterile field and empty packages placed onto a separate clean area (not

immediately into the waste), so the batch number information can later be recorded into the patient's treatment records (or checked) by the clinician responsible, as part of writing up procedure notes. Once this is done, the empty packages can be discarded.

Batch lots for dental implants must also be recorded into the patient's notes.

#### **Including batch code data within steriliser cycle records**

The steriliser cycle record book is an important legal written record and will be a key piece of evidence if claims are made about inadequate reprocessing practices. Typically, a hard copy cycle record book is used together with signed hard copy printouts to record the key characteristics of each cycle, as follows. Prior to activating the steriliser cycle, the loading operator will enter the following information into the cycle record book: (1) date, (2) cycle number, (3) load type/description, (4) cycle program selected, and (5) identification of the loading operator. For the latter, the full name, initials, or an operator code may be used.

At the end of the steam steriliser cycle, the unloading operator then checks the sterilised load and enters the remaining information: (6) whether physical parameters were satisfactory (based on checking the printout or checking the data display in cases where the data is stored on a memory card), (7) that the chemical indicators included in the load show a pass result, (8) whether the sterilised packages are conforming (i.e., they have intact seals and are dry), and (9) identification of the unloading operator, who is signing off that items in this load are suitable for use.

Few sterilisers have suitable software that captures and records all components of information in a secure manner. Consequently, practices should continue to use hard copy cycle record books. It is important that the loading operator does not complete this record book while still wearing contaminated gloves. They should not push the cycle start button until the recording of the loading data is complete. Likewise, items must never be returned to the clinic from a steriliser chamber until all items have been checked for correct sterilisation, and the appropriate sign-off recorded in the cycle record book. This sequence is designed to eliminate the situation in which a load is returned for use when it has not been properly sterilised.

By completing the record, the unloading operator is stating that the sterilised load is suitable for use, which is a tangible contribution to quality and safety in the practice. If the unloading operator identifies issues such as an incorrect cycle, an overloaded chamber, or wrongly positioned items when the chamber is opened, the cycle record book identifies who the loading operator is for follow-up with regard to these problems.

Further information on BCI can be found in the ADA's *Practical Guide to Infection Control*.

#### **Key compliance items for reprocessing stages prior to sterilisation**

- Ensure there is a method to safely transfer items from the operatory to the reprocessing area (e.g. puncture proof, lidded container).
- Determine how each instrument used in the practice will be appropriately reprocessed (each stage required) and include this in the infection control manual.
- Determine how items will be managed if they cannot be immediately reprocessed.
- Review the layout of the reprocessing area to ensure it allows effective and efficient instrument flow throughout the pre-sterilisation processes.
- Ensure the practice Infection Control Manual contains up to date information on the use and maintenance of reprocessing equipment.

## **7. Sterilisation using steam**

Sterilisation is the process of rendering an item free of all forms of viable microorganisms, including spores. In office-based dental practice, the most efficient and simplest means of sterilising dental instruments is steam under pressure (commonly called steam sterilising or autoclaving). It involves the combination of heat and moisture maintained at the correct temperature and pressure for a sufficient length of time to kill all microorganisms, with the probability of survival being less than 1 in 1 million. This is also known as the sterility assurance level (SAL). For effective sterilisation using steam, all air in the steriliser chamber must be removed and replaced by steam.

Dry heat sterilisation is not recommended for routine sterilising of dental instruments and equipment. Likewise, ultraviolet light and boiling water do not sterilise instruments, and must not be used for sterilisation. However, boiling water may be suitable for low-level thermal disinfection of certain prosthetic items such as polishing buffs.

Benchtop steam sterilisers (also called autoclaves) are widely used for sterilising instruments in office-based dental practice. Most instruments (including rotary handpieces and some piezoelectric ultrasonic scalers) are designed to withstand steam sterilisation. If an item is specified as being suitable for steam sterilisation by the manufacturer, and the instructions from the manufacturer are to undertake sterilisation using steam, then that is what must be done. The item cannot be processed using thermal disinfection or high-level (instrument-level) disinfection.

All steriliser used in dental practice must be listed on the ARTG. They must be operated according to AS/NZS 4815:2006 *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* or AS/NZS 4187:2014 *Reprocessing of reusable medical devices in health service organisations*, and in line with the instructions for use.

There are three types of sterilisation cycles:

- **N cycles** – (N indicates 'none wrapped, none hollow'). These cycles can only be used for unwrapped, solid items. Steam pushes the air downwards using gravity and forces it out a port in the bottom of the chamber. Such sterilisers would only be suitable for a dental prosthetist or a dental practice that did not do exposure prone procedures and did not sterilise any hollow items.
- **S cycles** – (S indicates 'specified'). These cycles are intended for processing certain load types and load configurations specified by the manufacturer. They are not 'general purpose' sterilisers and can only be used for those specific loads which the manufacturer has verified as being suitable. A range of bespoke (dedicated) S cycle units have been developed, including units for sterilising dental handpieces and cassette-type compact sterilisers that use induction heating for rapid processing. It is essential that staff carefully read the instructions for these sterilisers so that loads match those specified as being suitable. S cycles use various processes for active air removal, overcoming the limitations experienced in N cycles which employ gravity displacement. This is why bespoke sterilisers with S cycles can sterilise restorative dental handpieces.
- **B cycles** – These are used for type 'A' hollow objects, where the ratio of the length of the hollow portion to its diameter is more than 1:5. In such items, air removal is more challenging. Air is exhausted from the chamber by a mechanical vacuum pump to create negative pressure (a vacuum) before steam is then introduced into the chamber. Sterilisers that run B cycles require specific performance tests, including air leak tests and air removal tests.

## 8. Maintenance and testing

All steam sterilisers must be commissioned on installation.

### Verification of the sterilisation process

In order to ensure appropriate sterilisation, validation of the sterilisation process is undertaken to ensure the desired performance is being achieved. This validation process involves the following steps:

1. Commissioning – installation qualification (IQ) and operational qualification (OQ).
2. A commissioning report includes installation documents and operation verification. This work is performed by the service technician when a new or repaired steriliser [e.g. after a major or critical component has been replaced/repared] is installed in the practice.
3. Performance qualification (PQ).
  - a. Physical qualification (by a qualified instrument technician or manufacturer's technician).
    - Calibration report – this addresses the accuracy of thermocouples used to measure temperature (undertaken annually).

- Penetration report – this checks the physical attributes of the steriliser. This record is obtained after major repairs or when pack contents, packaging materials, or loading methods change significantly.
- b. Microbiological report to confirm functioning of the steriliser using a biological indicator (also known as a spore test).
- c. The validation report summarises satisfactory completion of commissioning, operational, and performance qualification. It provides validation of the total process.

Further information on validation can be found in the ADA's *Practical Guide to Infection Control*.

### Monitoring of cycles

Sterilisation cannot be assumed to have been achieved without appropriate testing and load checking. For steam sterilisation, time, temperature, and pressure must be measured with continuous, automatic, permanent monitoring (e.g., use of a process recorder, data printer, or data logger). Where an older steam steriliser with no recording device is used, it must, where possible, be fitted with mechanisms to electronically record sterilising parameters. Otherwise, the parameters must be read from the relevant gauges and then documented at intervals of 10 seconds. Alternatively, a biological indicator (spore test) or chemical indicator (Class 4 or greater) can be used for each load. The processed chemical indicator must achieve all sterilisation parameters applicable to the indicator used, and that information must be recorded. Hard copy prints that are checked and signed off provide a valuable record of the cycle parameters. Given their importance, each practice should develop a protocol around handling the situation where the printer has malfunctioned or has no paper (e.g. including Class 6 chemical indicators inside each pouch or package). If data from the steriliser is recorded onto a memory card or sent to a file server, there must be a process for reviewing this data – ideally for each cycle at the time, but at least once every day.

The everyday performance of a steam steriliser must be monitored by periodic testing, including daily and weekly tests. The details of these tests are presented in AS/NZS 4815 and AS/NZS 4187 and are described in the ADA's *Practical Guide to Infection Control* under the topic of monitoring of steriliser cycles. The sections below discuss the use of chemical indicators and the process of validation.

### Operating the steam steriliser

Clinical support staff must be trained in the correct operation of a steam steriliser. An operator's manual must be available for each steam steriliser, and the unit must be used according to the manufacturer's instructions.

Before steam sterilising an instrument, the operator must verify the item is suitable for the process. For example, some items are made of low melting point plastic and cannot withstand the process. Likewise, there must not be any attempt to steam sterilise disposable single-use items.

Only steam sterilisers with a drying cycle can process wrapped or bagged items. If the steam steriliser does not have a drying cycle, it can only be used to sterilise unwrapped items.

### 9. Steam steriliser performance tests

Steam sterilisers are complex items of equipment and may be affected by mechanical faults; they are also prone to errors from incorrect use by operators. It is necessary to regularly monitor the sterilisation process to ensure the process has met all parameters and that the reprocessed instruments have been sterilised.

Detailed information on assessing performance can be found in ISO standard 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Follow the manufacturer's instructions for use for each steam steriliser in terms of the recommended start-up sequence for that steriliser. Not all sterilizers require a warm up cycle before the vacuum test or air removal test. The figure below shows one suggested way to sequence the leak rate (vacuum) test and the air removal and steam penetration test at the start of the day. Make sure that your standard operating procedures or manual makes it clear what steps are needed at the start of the day, and that it aligns with the manufacturer's instructions.

For a pre-vacuum steriliser which runs B cycles, a range of tests must be carried out each day before the first active load.

These include:

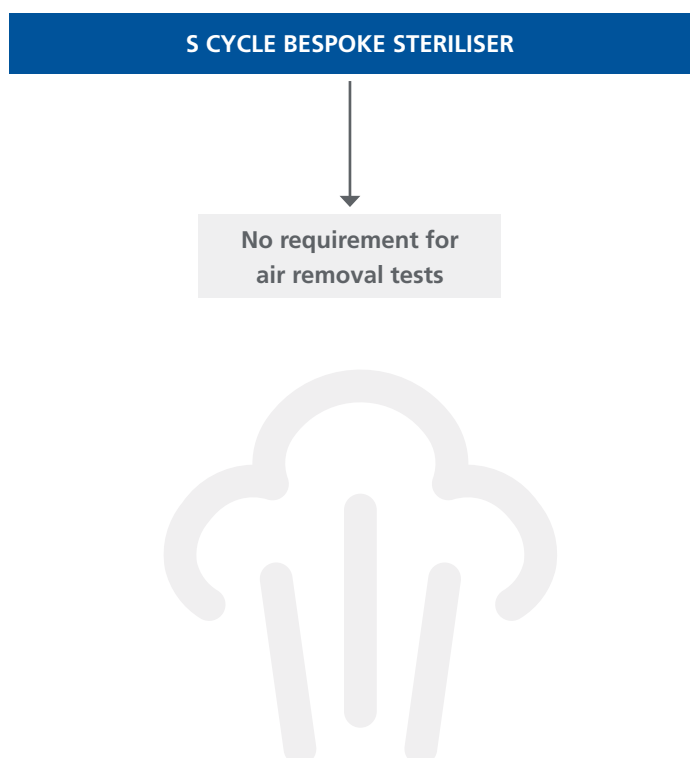
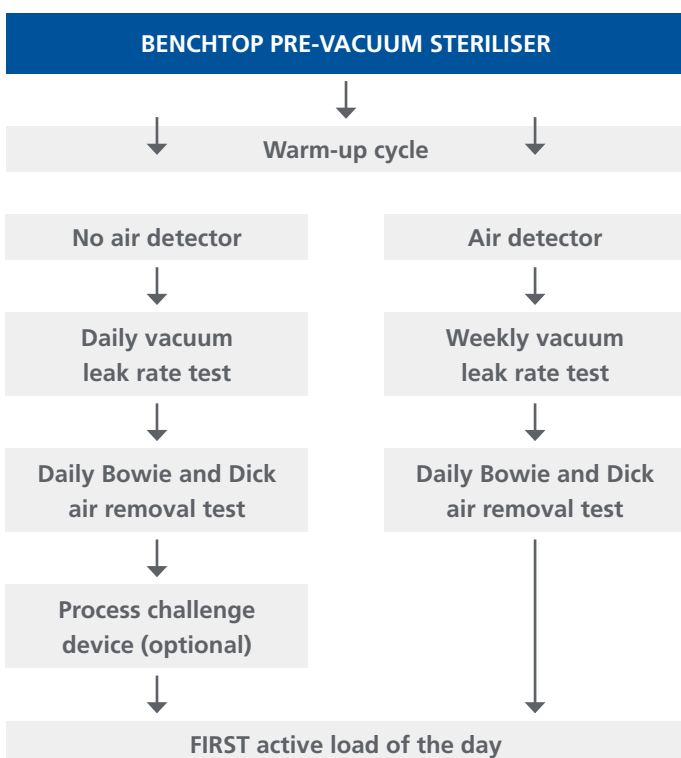
- **Leak rate test** (vacuum test) – This tests the integrity of the door seals. This test must be performed prior to commencing the first sterilising cycle of the day. A high leak rate means that there is a damaged door seal. If the steriliser incorporates

automatic air leak detection, then this leak rate test is only performed weekly. In the absence of automatic air leak detection, this test is run every working day. It is important that each dental practice checks whether their steam steriliser has air detection capability.

- **Air removal and steam penetration test** (Class 2 chemical indicator) – A daily air removal and steam penetration test must be performed on steam sterilizers that utilize a vacuum for air removal prior to sterilisation. For steam sterilisers running B cycles with chamber sizes greater than 10 litres, use tests that conform to EN 867.5: 2001 Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S.

The Bowie-Dick type test provides a challenge that assesses air removal and steam penetration for porous loads. This test must be run on an empty chamber, at the start of the day, in a dedicated cycle, before a normal load with instruments is sterilised. This test is currently only necessary if porous loads are being processed (such as gauze, drapes, cotton rolls) if working under AS/NZS 4815:2006, but is required daily regardless of the loads being processed if working under AS/NZS 4187:2014. See the diagram below for the recommended process under the 4187 standard.

A process challenge device (PCD), also known as a Helix test, is used to test air removal and steam penetration in hollow loads. Under AS/NZS 4815:2006, when pre-vacuum sterilisers are used to process solid or hollow loads using a B cycle, a daily Helix test must be conducted. It is important to follow the manufacturer's instructions for use regarding the correct method of using Helix tests as this may vary between brands.





Further information on monitoring of steriliser cycles can be found in the ADA's *Practical Guide to Infection Control*.

### **Loading**

A steam steriliser can only work effectively if steam can circulate freely and touch every surface of every instrument. Steam steriliser trays should not be crowded; items must not be densely packed, must not touch each other, and must not be layered on top of one another. Correct loading reduces damage to packs and their contents and maximises the efficient use of the steam steriliser by reducing the chance of failed loads.

To ensure correct air removal, items should be loaded into the chamber according to the instructions for use for that steam steriliser.

To reduce the risk of items awaiting sterilisation being mistaken as having been sterilised and thus being recirculated back to the clinic, these items must be stored in a dedicated 'pre-sterilisation' area, not in the chamber of the steam steriliser.

If non-bagged items are loaded, a Class 1 chemical indicator must be placed in each loading tray being processed.

For every wrapped item, a Class 1 chemical indicator must be included on the outside of the package as a visual check that the item has been through the sterilising process.

### **Drying**

Items at the end of the steam sterilising process should be dry, not damp or wet. Damp items are indicative of a faulty drying cycle. It is not acceptable to use a fan to dry items that are damp, nor is it acceptable to boost the local air conditioning to forcibly cool items.

Packaged or unpackaged items must never be dried by opening the door of the steam steriliser before the drying cycle is completed.

In a steam steriliser that does not have a drying cycle, only unwrapped items may be processed. At the end of a cycle, to avoid contamination and thermal injury, these items should be allowed to cool in the chamber before being handled.

Trays of instruments and wrapped items removed from the steriliser should be placed on racks and not directly on the bench. This prevents water condensation occurring either around or inside the cooling packages affecting the pack or load integrity.

### **Checking the completed load**

A number of variables influence the process of sterilisation:

1. quality of cleaning (residual bioburden);
  2. choice of packaging materials;
  3. packaging technique;
  4. steriliser chamber loading technique;
  5. sterilant quality (levels of ions and lubricants in the water); and
  6. cycle parameters (time, temperature, steam wetness).
- Once the sterilising process (including the drying cycle) is complete, a number of checks must be made, and the results recorded.

The operator must check whether the physical parameters were satisfactory by checking the printout or data display for readings of pressure, temperature, and time.

For unwrapped loads of dental instruments and equipment, steam sterilisers must reach a holding temperature of 134–137 °C and must maintain this for three minutes. For readings outside the specified limits, the sterilisation cycle must be regarded as unsatisfactory, and all items must be re-packaged and re-sterilised. If a second cycle is unsatisfactory in the same manner, the steam steriliser has a significant fault and must not be used until the problem has been rectified by a technician.

Printouts must be retained for inspection and monitoring for a period of at least seven years. Modern steam sterilisers have an integral printer or data logger for routine monitoring.

### **Visual inspection of sterilised wrapped items**

When unloading the chamber, the unloading operator must visually check each package of wrapped items, as follows:

- Check the package for damage. There cannot be any items penetrating through the packaging.
- Check that the seals are intact along their length, with no interruptions.
- Check that the package is dry.
- Check that the external (Class 1) chemical indicator has made the required colour change.

If a paper-laminate pouch has been used and there are any internal chemical indicators that have been included (Class 4, 5, or 6), check that these chemical indicators have made the required colour change; this shows the required parameters have been achieved. Remove from circulation and quarantine any packs where the internal chemical indicators reflect insufficient exposure to steam, as this identifies a flaw in the steam sterilising process. Defective packages must NOT be used in the clinic. Pay particular attention to a situation where most items are satisfactory, but one pack shows inadequate colour change; this may indicate issues with air trapping from incorrect loading.

Quarantine any damp or wet packages that have been placed on contaminated surfaces and any packages that have been dropped on the floor or show loss of integrity. In all these cases, the affected instruments are to be considered contaminated and must be cleaned again, and then reprocessed in full, from cleaning through to packaging and sterilising.

Record the identification of the unloading operator who is signing off that items in this load are suitable for use.

### **Retention of cycle data from steam sterilisers**

Practices must retain data from steam steriliser cycles for a minimum of seven years. This requirement is the same for hard copy printouts and electronic data downloaded from a memory card. Printouts generated by thermal printers tend to fade with time and become illegible, so these need to be transferred into digital format (photographed or scanned) or photocopied to give a stable record. Printouts from ink printers do not fade and can be



stored over the long term. Hard copy printouts should be signed off by the unloading operator who has checked them, as part of the normal process for releasing a load of sterilised items.

Some modern steam sterilisers offer cycle data capture onto a memory card. This data must be periodically downloaded from the flash memory card and regularly backed up. It is good practice to use two memory cards and fully back up the contents of each card every week. The longevity of memory cards used in sterilisers is likely to be less than those used in other devices because of higher ambient temperatures. Some sterilisers can connect to a computer network for uploading cycle data onto a server. This approach overcomes functional issues with memory cards.

In addition to steriliser cycle records (in electronic and hardcopy format), other records to be retained include:

- a. results of performance tests of equipment. This includes daily performance tests for ultrasonic cleaners and instrument washers;
- b. employee training records;
- c. incident reports, e.g., non-conforming products or workplace health and safety incidents;
- d. quality and procedure/operational manuals;
- e. steriliser maintenance records; and
- f. certification of validation.

#### Key compliance items for sterilisation using steam

- Ensure all team members involved in reprocessing are familiar with the proper use, packing and maintenance of steam sterilisers.
- Check that the daily, weekly and annual processes used to ensure that steam sterilisation processes are effective based on the specific steriliser and indicators in use have been documented.
- Check that all dental team members involved with inspecting sterilised instruments are aware of the requirements for passing a load and what to do when this is not the case.
- Verify that steam steriliser cycle data is stored and accessible for a period of at least 7 years.

## 10. Steam steriliser monitoring tests

### Chemical indicators

Regular monitoring of the steam sterilisation cycle is necessary to ensure the sterility of reprocessed instruments. This is done using physical indicators (e.g., printouts of cycle parameters) in combination with chemical indicators to show that certain temperatures, times, and steam exposure conditions have been reached during the sterilising process.

Physical and chemical indicators are designed to show whether or not the correct sterilisation parameters have been achieved. As part of the formal validation process, the exposure parameters have been determined using a 'most difficult, worst case' scenario with the most challenging load configuration. Provided that cycle parameters have been followed and the load has been correctly sterilised (as shown by the results of the physical and chemical indicators), wrapped sterilised instruments can be released for use in the clinic. This is known as parametric release and must be recorded and signed off by the person performing the task.

Practices must have a risk management process in place to ensure the parametric release of instruments can be confirmed, particularly if there is no cycle printout or detailed screen which enables staff to check all three parameters (time, temperature, pressure).

Chemical indicators provide information about conditions in the steam steriliser at the specific locations where they have been placed, whether sitting loose in the chamber, included within packs, or inside a process challenge device.

Some indicators, such as Class 1 types, are only sensitive to changes in temperature, whilst others, such as Classes 5 and 6, are sensitive to variables such as temperature, time, and water (as delivered by saturated steam).

### Class 1

A Class 1 indicator must be used on the outer surface of every individual pack of wrapped instruments to show exposure to reprocessing. These indicators are only sensitive to changes in heat; they do not measure exposure to steam. These indicators may be built into the package, as dyes which change colour, or applied as tape which undergoes a colour change. Class 1 indicators do not provide any insight into the conditions inside a package or pouch.

A Class 1 indicator should be used in each load of unbagged, semi-critical or non-critical instruments. The indicator will show a fail result if the load has not been processed at all, or when there has been a gross malfunction of the steam steriliser.

### Class 2

A Class 2 indicator is a specific test used with a pre-vacuum steriliser to assess air removal under a specific challenge. They may be either a Bowie-Dick (B-D) type test (used alone in an empty chamber to assess air removal from porous loads) and/or a Helix process challenge device (PCD), (used alone in an empty chamber to measure the effectiveness of air removal from hollow items).

The following key points describe how these are used:

For a pre-vacuum steam steriliser, a suitable daily air removal test (B-D or Helix PCD, or both) is required in addition to the daily or weekly air leakage test.

If working under AS/NZS 4815:2006:

- A Bowie-Dick type test is recommended for use in a dedicated cycle at the start of day when porous items are to be processed later that day (e.g., loads of drapes, cotton rolls, gauze post-extraction packs, cotton wool, etc.). If porous loads are not being processed, there is no requirement to perform a daily Bowie-Dick type test.
- Use a Helix PCD once per day. This is usually performed in an empty chamber. Follow the instructions for use for the specific Helix test being used.

If working under AS/NZS 4187:2014:

- Perform a Bowie-Dick type test at the start of every day in a dedicated cycle, regardless of the loads being run.
- The use of a Helix PCD in a later cycle is optional rather than mandatory.

For bespoke sterilisers running only S cycles, which do not use a vacuum pump for air removal, neither of these tests are needed. With both Bowie-Dick and Helix PCD tests, a pass result requires even colour change across the entire surface of the indicator. A fail result could be due to problems with air removal (including failure of the vacuum pump) resulting in air and other gases remaining in the chamber, and thus, causing insufficient steam penetration onto the indicator surface.

### Class 3

A Class 3 indicator responds to only one critical variable (i.e., temperature). These indicators have relatively poor accuracy and are only used with dry heat sterilisers. They have limited value in general dentistry where sterilisation is undertaken using steam rather than dry heat.

### Class 4, 5, and 6 chemical indicators

These indicators are designed to be used either loose in the chamber (for an unwrapped load) or included within packages or pouches of instruments. Their purpose is to provide evidence of steam exposure.

For wrapped items, these chemical indicators demonstrate that steam exposure within the package has met the stipulated conditions. Each class of chemical indicator has a different level of precision for measuring temperature and exposure time, with Class 4 being the least precise and Class 6 being the most precise. The tolerance for measuring temperature is 2 degrees for Class 4, but only 1 degree for both Class 5 and Class 6. The tolerance for measuring exposure time is 25% for Class 4, 15% for Class 5, and 5% for Class 6.

The terminology used with these indicators can be confusing. Typically, Class 4 indicators respond to two variables (hence may be called 'multi-variable' indicators), while Class 5 and 6 indicators respond to time, temperature, and steam wetness

(hence may be called 'integrating indicators') and surpass the exposure parameters for biological indicators (spore tests) (hence may be called 'biological emulators'). This terminology should be avoided. Instead, indicators are to be recognised and referred to by their class, since this indicates their tolerance. Class 5 and Class 6 indicators are routinely labelled with their class descriptor; however, this is not the case for Class 4 indicators. Unless there is documented evidence to the contrary, users should regard any unknown and unlabelled internal chemical indicator that has been included in a wrapped item as a Class 4 indicator.

Under AS/NZS 4815:2006 *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*, a Class 4 chemical indicator is the minimum that must be included inside every package of a wrapped load when the reprocessing conditions have not (or not yet) been verified by a full qualification process involving biological indicators used in three replicate cycles. This situation may occur when a brand new or loaned steriliser is being used, when the printer associated with a steriliser has failed, or when a new brand of packaging material is being used. In these situations, there is a lack of formal evidence of effectiveness; thus, the use of internal chemical indicators is mandatory. This requirement applies to all non-validated loads, regardless of whether the instruments in the pouches are intended for use in routine dental procedures in a semi-critical site, or whether the instruments are intended for use in a critical site where they must be sterile at the point of use.

When reading Class 4, 5, or 6 chemical indicators, ensure that the colour change meets the stipulated requirement. If the colour change is incomplete, do not use the items in the clinic; instead, re-clean, re-package, and re-sterilise them (i.e., repeat the full reprocessing sequence).

When the internal chemical indicators inside a package or pouch show a fail result, this could be due to insufficient air removal causing persisting cool air pockets; this may be caused by an overcrowded chamber, incorrect loading, or incorrect wrapping. Air pockets occur less often in pre-vacuum steam sterilisers than in sterilisers that use other methods of air removal.

Further information on the use of chemical indicators for monitoring of steriliser cycles can be found in the ADA's *Practical Guide to Infection Control*.



## Storage and use of chemical indicators

Chemical indicators are designed to be read at the end of a cycle, and the result obtained is compared with the reference colour change chart provided by the manufacturer. Once checked, chemical indicators can be discarded. There is no requirement to keep and store these indicators. The colour change chemistry used within chemical indicators is not intended to provide results of archival quality if these indicators are stored for several years. This is particularly relevant to Class 5 and 6 indicators, which use sophisticated multi-step chemical reactions. When indicators are stored in record books, acid released from the paper of the record book can permeate into the indicator and cause colour changes. Thus, do not keep ANY chemical indicators (Classes 1 through to 6) as part of the records of the practice.

### Key compliance items for chemical indicators

- Ensure all dental team members involved with reprocessing know which chemical indicators are being used and their purpose.
- Consider protocols for the use of additional chemical indicators when the reprocessing conditions have not (or not yet) been verified by a full qualification process (such as when a loan unit is being used or after a temporary printer failure).

## Biological indicators

Whenever instruments are packaged, it is essential to determine what steam steriliser cycle parameters are required for successful air removal and steam penetration. Validation of the conditions is necessary when there is a change in the type of packaging material used. Validation must also be repeated annually, even when there has been no change in the type or method of instrument packaging. This test is typically undertaken by a technician.

### Qualification and validation

When there is a change in the brand of packaging, and annually (regardless of consistent processes being used), it is necessary to undertake the process described below to establish what steam steriliser cycle parameters are required for successful air removal and steam penetration (validation).

Validation of cycle parameters involves using multiple biological (spore) tests. Biological indicators (spore tests) contain highly heat-resistant bacterial endospores. Killing these demonstrates that sterility has been achieved. For steam sterilisers, the spores of *Geobacillus stearothermophilus* are used. These spores are heat resistant (and thus, difficult to kill) and do not cause human disease.

For long thin pouches, it is necessary to use three biological indicators in each test pack, one placed at each end and one in the middle of the pouch. With larger packs, one indicator should be placed in each corner and one in the centre of the pack. The intention is to select the largest and most difficult pouch or package for this performance test. A test pack with multiple indicators must be prepared in triplicate so that one can be processed on each of three consecutive cycles. A tenth indicator is not sterilised, but rather, is used as a positive control. This control will show growth (colour change), demonstrating that activation and incubation of the spore tests have been undertaken correctly.

The packages containing the spore tests are placed in location within the steam steriliser chamber; they are to be placed in either the known (from manufacturer information) or shown (from a heat distribution test run using thermocouple probes) 'cold spot' where the chamber temperature is the lowest. Typically, this location is towards the bottom of the chamber. The rest of the chamber is loaded with packages as per normal.

After completion of three cycles, 10 biological indicators, nine which have been processed and the tenth as a control, are activated (by crushing the end of the vial to release the liquid growth medium) and incubated at 55–56 C for 24–48 hours, then checked for growth. When spores survive and germinate, there is a colour change in the liquid medium, indicating a failure of sterilisation. Correct steam reprocessing parameters will cause inactivation of ALL biological indicators in test items in the three successive loads. Growth should only be seen in the positive control. If there is no growth in the control, this indicates a failure to activate or incubate the spores, and thus, all results are invalid; in this case, the test sequence must be repeated in full. The results from the spore tests must be recorded in the steriliser cycle book. The used spore tests (including any that show growth) are discarded into the sharps waste.

The results of performance qualification (PQ) tests must be recorded with sufficient detail that can inform future tests of the same type. The data to be recorded includes:

- date of the test;
- brand and type/description of the packaging system used;
- how the test packs were assembled, and where they were placed in the chamber (this could be done using photographs);
- type of biological indicator used and the batch number. It is important to check that the biological indicators used are within their expiry date;
- location and identification number of the steam steriliser (if there are multiple steam sterilisers in the practice);
- name of the operator running the performance qualification; and
- the cycle parameters that were tested and shown to be suitable.

For steam sterilisation of unwrapped instruments (i.e., those that do not require packaging), air removal problems are minimal. For such loads, verification of the parameters using biological indicators is not necessary.

For further information on the use of spore tests, see the ADA's *Practical Guide to Infection Control*.

#### Key compliance items for biological indicators

- Determine if and when validation of steam sterilisers will occur.
- Ensure technicians using biological indicators for validation are familiar with the protocols in these Guidelines and that the data to be recorded is maintained.

## 11. Disinfection

Disinfection does not ensure the same degree of safety to patients as achieved with sterilisation because it does not always destroy all microbial life forms – some resistant forms, such as bacterial endospores, may survive.

Disinfectants are regulated by the TGA in several categories. The requirements of disinfectant manufacturers have recently been changed by the TGA, and these changes will force greater discretion onto clinical use applications. Any instrument-level disinfectants used must be TGA-registered and must be used according to the manufacturer's specific directions. The three significant categories of disinfectants are:

1. Instrument disinfectants (four subcategories as follows):
  - a. sterilants;
  - b. high-level instrument disinfectants;
  - c. intermediate level instrument disinfectants;
  - d. low-level instrument disinfectants.
2. Surface disinfectants (there are two regulated and one exempted category as follows):
  - a. hospital-grade disinfectants (with or without additional claims);
  - b. commercial grade disinfectants (with or without additional claims);
  - c. sanitisers (exempt from regulatory supervision).
3. Disinfectant wipes.

Disinfection undertaken with an instrument washer with a thermal disinfection cycle is not a sterilising process and must not be used as a substitute for steam reprocessing and sterilisation where the items can withstand steam sterilisation. Disinfection using a liquid sterilant or high-level instrument disinfectant may be undertaken for non-critical instruments and some semi-critical instruments (such as those used in dental prosthetics) that cannot be steam sterilised.

### Thermal disinfection using washer disinfectors

To achieve disinfection, an instrument washer (also referred to occasionally as a washer disinfectant (WD)) must employ a cycle that holds items at a high temperature for a sufficient time. Only WDs that are regulated by the TGA and which conform to the requirements of AS/NZS 4187:2014 shall be used for this purpose. The applied heat destroys pathogenic non-spore-forming vegetative organisms according to a formula set out in AS/NZS 4187:2014. Thermal disinfection can be used for some prosthetic instruments, polishing buffs, and brushes since instruments used in dental prosthetics are semi-critical or non-critical. An alternative approach is to use single-use disposable instruments for dental prosthetics, as this eliminates the need to reprocess instruments.



Items to be thermally disinfected must be cleaned prior to disinfection. If an item is not clean, it cannot be disinfected. The required cleaning steps are undertaken within a WD. Items can be placed into a WD without prior cleaning or while still wet (if previously rinsed). Performance tests (known as soil tests) must be undertaken to document the performance of each cycle. The chamber of the WD must be cleaned regularly. Most WDs connect directly to mains water and mix this water with highly alkaline detergents for washing items. Incoming water must not be too 'hard' or this will reduce the WD performance in the cleaning phase of the cycle. In some locations, the reticulated water is too 'hard' and needs to be treated using a water softener to allow the water to be suitable for use with detergents in the WD. It is important that the quality of the feed water used for washing and rinsing matches the manufacturer's specifications. Note that the same water hardness problems affect manual cleaning of items. It is not appropriate to use small electric ovens (portable cooktops) or domestic microwaves as a means of thermal disinfection of instruments in dental practice.



## Chemical disinfection using instrument disinfectants – high-level (instrument-level)

For practical purposes, there is no place in dentistry for the routine, everyday use of high-level chemical disinfection for devices, dental impressions, or instruments (e.g., use of glutaraldehyde or ortho-phthalaldehyde). Instrument disinfectant products should never be used on surfaces. This is due to concerns about safety and effectiveness of glutaraldehyde.

High-level (instrument-level) chemical disinfectants should only be used when thermal disinfection is unsuitable (e.g., some prosthetic or laboratory items – surgical guides or surgical templates). This includes whether the agent needs to be diluted or mixed with an activator, and how items are to be rinsed and then handled after disinfection. As with thermal disinfection, items must be cleaned thoroughly prior to using high-level disinfection.

Instrument disinfectants cannot be mixed with other disinfectants. Instruments must not be stored in these disinfectant solutions for any time extending beyond the intended soaking time required to achieve the specified sterilisation or high-level disinfectant outlined on the specific product label conditions.

The use of an instrument disinfectant must be undertaken with all due caution, including full training of staff with respect to both the intended purpose and the safety requirements set out in the product Safety Data Sheet. This includes the use of appropriate PPE, ventilation conditions, discard requirements, and the use of potency test strips as recommended by the instrument disinfectant product manufacturer. All instrument disinfectants are fully regulated by the TGA and are registered on the ARTG. Ultraviolet cabinets must not be used for instrument disinfection.

### Surface disinfectants and disinfectant wipes

New requirements from the TGA have altered the level of oversight for disinfectants. Dental practitioners should take great care in reading and understanding the efficacy claims of surface disinfectants, particularly claims around inactivation of SARS-CoV-2 (the virus responsible for COVID-19) or other viral or bacterial pathogens.

Any compliance concerns over product potency, use conditions, or safety and efficacy should be addressed to the manufacturer in the first instance. For any complaints or concerns over product performance, potency, safety, or efficacy, a complaint should be lodged directly with the TGA via the TGA website under the Medical Device section.

#### Key compliance items for disinfection

- Ensure disinfectants are being used according to the manufacturer's instructions for their intended purpose and safely stored.

## 12. Storage of processed instruments

The shelf life of a packaged sterilised item is not fixed in time but reflects the conditions of storage, particularly temperature, ventilation and humidity control (as described in AS 1888.2 *The use of ventilation and airconditioning in buildings Part 2: Ventilation design for indoor air contaminant control*). This is called an 'event-related' shelf life.

During storage, packs also can be contaminated by:

- over-handling – this can happen through excessive transferring from one place to another or during rotation of stock, from over-stocking of storage areas, or from bundling packs together using rubber bands;
- moisture – if the pack is placed on a wet benchtop or splashed with water or other liquids; or
- penetration – if instruments break through the wrapping of the pack and breach the surface.

A package is considered to be non-sterile when it:


- is damaged or open;
- comes out of the steam steriliser wet or is placed on a wet surface; or
- is dropped onto the floor or placed on a contaminated surface.

It is essential to store items away from the contaminated zone in order to avoid them being exposed to splashes of fluid and aerosols produced during clinical treatment or instrument reprocessing. The correct storage of processed instruments will protect them from environmental contamination. In dental practice, the major source of environmental contamination of processed items is splashes of fluids and aerosols of airborne bacteria and viruses which settle over time.

For this reason, unwrapped instruments, wrapped instruments, and instruments in cassettes must be stored in such a way that contamination from splashes and aerosols does not occur. Keeping sterilised instruments in closed drawers, closed cupboards, or sealed containers achieves this. Locating the stored items at an appropriate height, or using cupboards with transparent doors, allows the contents to be seen easily.

Care is necessary when moving packages of instruments within drawers so as to reduce the chance of a surface breach caused by instruments perforating the paper or textile of the package. Staff must also ensure proper rotation of sterile stock using the older processed items first.

Storage areas for wrapped sterilised instruments must be dedicated to this purpose only and must be kept free of dust, insects, and vermin. Ideally, wrapped sterilised instruments will be stored in enclosures (such as drawers or cupboards) that prevent the occurrence of environmental contamination. Special requirements are necessary if open shelves or racks are used for storage of wrapped sterilised instruments. For open shelving –



items must be at least 250 mm above floor level and 400 mm away from ceiling fixtures, away from open windows and protected from direct sunlight. This avoids wrapped sterilised instruments becoming contaminated by dust or being degraded by sunlight. It also facilitates environmental cleaning.

The area used for storage must be of sufficient size so that items are not packed densely on top of each other. If it is too small, too high, crowded, or awkward, access may be difficult, and this increases the likelihood of the integrity of the packaging being compromised. The storage area must not have high humidity, as this increases problems due to dampness.

Unwrapped semi-critical and non-critical items must be stored dry and in a way that will prevent contamination from dust or splashes prior to use. This can be achieved by storing items in:

- instrument cassettes, which are then placed into drawers or cupboards;
- trays in closed drawers; or
- trays or cassettes kept in sealable plastic containers with lids.

Cardboard boxes must not be used as storage containers for instruments as these are porous, cannot be adequately cleaned, and may harbour organisms.

As part of environmental cleaning, areas that are used for instrument storage (wrapped or not) require periodic cleaning, e.g., monthly or three-monthly, according to the local cleaning policy. At this time, drawers or containers are cleaned with detergent and water.

As discussed earlier, before opening any wrapped package of sterilised instruments, it is essential for the dental practitioner to check the package to ensure the item has been sterilised and the barrier wrap has not been compromised during storage. If there is any doubt about the sterility of the package or the instrument pack has been compromised, the instruments cannot be used in patient treatment. Packages showing evidence of damage must not be used. Instead, the instruments must be put back through the cleaning, packaging, and sterilising process once again.

#### **Key compliance items for storage of processed instruments**

- Note any circumstances in which items may become contaminated or non-sterile prior to use and determine what changes may be required to storage arrangements to avoid this.
- Verify that any unwrapped semi-critical or non-critical items are stored in a way that prevents contamination prior to use.

# Section E. Documentation and practice protocols for infection prevention and control

## 1. Maintaining records of instrument reprocessing

Dental practitioners must maintain records relating to instrument reprocessing activities; these records must include both cleaning and sterilisation. Sterilisation records include maintenance records for the steriliser, ultrasonic cleaner, and instrument washer, as well as the regular performance tests on these key items of equipment (such as the foil or pencil test for the ultrasonic cleaner, soil tests for the instrument washer, and air leakage tests and air removal tests for pre-vacuum steam sterilisers).

Additional records must be kept for the steam steriliser, including the results of annual calibration, annual performance qualification using biological indicators (spore tests), and daily cycle data from air removal tests, as well as the records of individual steriliser cycles.

Maintenance of this portfolio of records provides evidence of quality management processes and allows for BCI of critical instruments. The length of time that documentation must be kept varies and depends on the state or territory where the practice is located, but typically, it is a minimum of seven years. Note that records must be readable over this period of time. This will be an issue if the printout from the steam steriliser uses thermal paper, as the printout fades with time and becomes unreadable. As discussed earlier, solutions include scanning or photocopying thermal printouts.

For every steam sterilising cycle (including those that do not have packs of critical instruments), the recorded entry for the cycle in the steriliser log must include:

At the time of loading the chamber:

- the steam steriliser number or code (if there is more than one steriliser in the practice, in order to identify the machine the item was sterilised in);
- the date;
- the cycle or load number on that date;
- a summary of the contents of the load, e.g., wrapped or unwrapped items;
- which cycle parameters were used (time and temperature) – ensuring these are appropriate for the load type being processed – whether wrapped or unwrapped;
- batch numbers of packs included in the load (if any); and
- identification of the loading operator.

At the time of unloading the chamber:

- check for the correct physical readout data (on the digital display or on the printout) for the cycle;

- check of the chemical indicators used in the cycle (this includes checking all external Class 1 chemical indicators as well as any visible internal chemical indicators);
- check of packages (if present) for the integrity of the seals;
- check of packages for dampness; and
- identification of the unloading operator.

After the last dot point has been completed, the unloading operator has now authorised release of the load (parametric release) for use in the clinic.

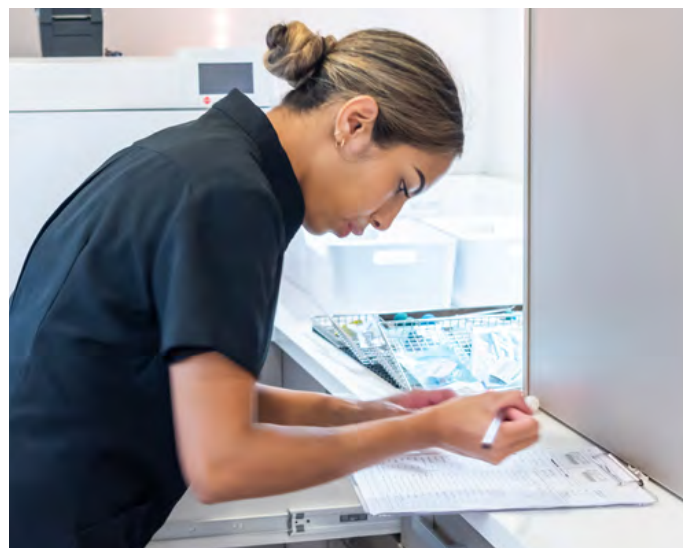
### Other documentation for the steam steriliser

Following installation of a new steam steriliser, a certificate of calibration, installation qualification (IQ) and operational qualification (OQ) should be issued by the technician carrying out the process. This must be kept as part of the documentation for the dental practice.

It is also necessary to keep a record of servicing and repairs to the steriliser, as well as records of any upgrades to its hardware or software.

### Key compliance items for documentation of sterilisation processes

- Ensure calibration and performance qualification for steam sterilisers are scheduled with a trained technician.
- Verify that installation and maintenance records as well as daily, weekly and annual process documentation are being maintained.



## 2. Infection prevention and control for dental practitioners and clinical support staff

### Immunisation

As discussed in the introduction, dental practitioners and clinical support staff are at risk of exposure to many common vaccine-preventable diseases (VPDs) through contact with patients and the general community. Immunisations substantially reduce the potential for acquisition of disease, thereby limiting further transmission to other dental staff and patients.

All dental practitioners and clinical support staff are to be advised of the need to have particular immunisations. The list of immunisations required for HCWs is provided in the current edition of the [Australian Immunisation Handbook](#)<sup>10</sup> and is summarised below.

- A history of successful immunisation against HBV. This is shown by having developed antibodies to hepatitis B surface antigen in a blood test taken after the initial course of three injections.
- Varicella (if seronegative).
- Measles, mumps, and rubella (MMR) (if non-immune).
- Pertussis (whooping cough).
- Viral influenza (required every year to cover new circulating strains of these viruses).

The Australian Technical Advisory Group on Immunisation (ATAGI) recommends that healthcare workers at risk of exposure to persons infected with SARS-CoV-2 be prioritised for COVID-19 vaccination.

Those working with remote Indigenous communities are advised to also undergo vaccination for hepatitis A, while those at high risk of exposure to drug-resistant cases of tuberculosis should also undergo vaccination with bacille Calmette-Guérin (BCG) after being tested for their immune response to tuberculosis using an appropriate challenge test. This is a specialised topic and is covered in depth in a chapter within the ADA's *Practical Guide to Infection Control*.

All dental practitioners and clinical support staff require immunisation against HBV, unless they have documented evidence of pre-existing immunity (from natural infection or prior vaccination) prior to commencing work. Any staff who are new to dental practice must be assessed for their HBV status. It is essential that staff who are undergoing vaccination for HBV are tested for antibody levels after the full course of three injections has been completed in order to demonstrate immunity and to identify poor responders who require additional vaccinations. There are specific protocols for this, which are specified in the [Australian Immunisation Handbook](#).

Dental practices should have education programs to support their immunisation strategy, and all dental staff must be advised of the potential consequences of non-immunisation. Consequences include an increased likelihood of acquiring infections in the workplace, increased probability of spreading infections to family members and close contacts, and restrictions on being able to work chairside when patients have active infections. While a staff member has the right to refuse vaccination, this refusal must be documented with their reason for refusal noted and signed by him/her.

### Immunisation records

The practice must develop and maintain regularly updated immunisation status and allergy records for dental staff. It is recommended that dental staff also maintain their own personal immunisation and screening records.

Staff should be asked to declare their vaccination status for hepatitis B, influenza, and other infections of relevance to the healthcare setting when commencing employment. This information needs to be updated when staff receive further vaccinations (e.g., for viral influenza) or when they receive booster injections. The rationale for asking for hepatitis B vaccination status is that past successful vaccination confers lifelong immunity, even if and when serum antibody levels wane, since there is lifelong immunological memory in lymphocytes, something not easily tested for using commercial tests.

It is highly recommended that when employing new staff, they are asked to complete a statement of their immunisation status and vaccination history. It is not appropriate to ask them for details of their immune status (i.e., actual levels of antibodies for all the listed conditions above).

For further information on immunisation requirements, consult the current edition of the [Australian Immunisation Handbook](#).

### Key compliance items for immunisation

- Ensure all dental team members are aware of immunisation required for HCWs, and have an opportunity to declare their immunisation and allergy status regularly.

### Education

Dental staff must be provided with comprehensive training in the full range of infection prevention and control procedures they are expected to know about and follow in their day-to-day work. Regular refresher training is also appropriate to ensure infection prevention and control measures are being complied with and understood.

10. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, [immunisationhandbook.health.gov.au](http://immunisationhandbook.health.gov.au).



New clinical dental staff should complete an induction program. This pre-service training should include the practical implementation of workplace health and safety and infection prevention and control measures used in the practice.

This induction program should contain the following:

- general orientation to the physical environment of the practice, including the clean and contaminated zones, as well as the flow of instruments in the operatory and reprocessing room;
- practice expectations in terms of infection prevention and control and safe working procedures, as laid out in the practice's *Infection Prevention and Control Manual*;
- practice expectations and recommendations for vaccination prior to commencing work;
- reporting requirements for sharps injuries and workplace incidents;
- policy on wearing and cleaning uniforms, use of PPE (including shoes and clothing), and hand hygiene;
- emergency procedures for fire and medical emergencies;
- first aid procedures;
- management of waste streams and hazardous substances, and the locations of containers for various types of waste;
- confidentiality of patient information;
- hand hygiene procedures;
- policies in terms of hair, footwear, and jewellery (such as 'bare below the elbows');
- surgical technique and preparation as well as scrubbing, gowning, and gloving;
- procedures for changeover between patients; and
- procedures for instrument cleaning and sterilisation.

To supplement and update the information provided during the initial induction, regular staff meetings should be held to discuss infection prevention and control matters. There should be a short summary record kept of these discussions. Likewise, staff attendance should be recorded for external (including online) infection prevention and control training.

#### Key compliance items for education

- Review how members of the dental team are equipped with skills and knowledge in infection control topics, and what strategies are being used to maintain and document this.

### 3. Exposure incident protocol

In the healthcare environment, the term 'exposure incident' refers to any incident where a contaminated object or substance breaches the integrity of the skin or mucous membranes or comes into contact with the eyes. This includes:

- penetrating injuries of the skin caused by a sharp item (e.g., a sharps injury caused by dental instruments, burs, needles, scaler tips, wires, and scalpel blades);
- an injury involving direct skin contact with blood or saliva visibly contaminated with blood and where there is compromised skin integrity, such as a cut, open wound, abrasion, or dermatitis;
- bites or scratches inflicted by patients; and
- direct contact between blood or body fluids and the mucous membrane of the mouth, nose, or eyes.

While the site of a penetrating injury can become infected with microorganisms, the major concern to dental practitioners and clinical support staff is the risk of transmission of HIV, HBV, and HCV by contaminated blood from a patient. For exposures involving the skin, the larger the area of skin exposed and the longer the time of contact, the more important it is to verify that all of the relevant skin area is intact.

To comply with work health and safety legislation, all exposure incidents must be recorded and followed up.

Counselling is needed and may be undertaken by a designated medical practitioner or infection control practitioner. Services such as sharps injury telephone hotlines may also be of value.

Follow-up tests must be offered after a significant exposure incident, and blood samples for testing should be obtained from the source (i.e., the patient) wherever practicable. These tests include HBV surface and envelope antigens, HCV antibody, and HIV antibody (and in some cases, viral load). Where the source is positive, follow-up tests of the injured person will need to be repeated at intervals in order to assess whether seroconversion has occurred.

Post-exposure prophylaxis for HIV and guidance in the use of antiviral agents in the early management of HIV and Hepatitis C infection may be available from public hospitals. The use of prophylactic antiviral agents is restricted according to a formal risk assessment that would normally be overseen by a specialist in infectious diseases.

For further information see Appendix: *Blood and Body Fluid Exposure Protocol*.

### 4. Infection prevention and control manual and other practice management issues

Each practice owner has a duty to:

- facilitate the collection of a detailed medical history to establish if a patient may be more susceptible to infection, and therefore, may require special measures to prevent infection (e.g., patients with leukaemia or neutropenia may require antibiotic prophylaxis); and
- ensure adequate physical facilities are maintained and conduct regular quality checks to ensure all equipment is always in sound working order.

Employers and practice owners should:

- maintain awareness of new vaccine-preventable diseases (such as new forms of viral influenza) and ensure dental staff at risk are encouraged to be fully immunised when these vaccines become available (including annual influenza immunisation);
- offer testing following occupational exposure such as a sharps injury;
- ensure dental staff are adequately informed of the rights and responsibilities of patients, especially in relation to their right to refuse to provide information on their infection status or to be tested for a BBV;
- develop a comprehensive infection prevention and control manual for the practice, and keep this up to date;
- provide measures that protect staff from infections, including PPE and immunisation, and implement effective reporting systems for breaches of protocols and safe work practices;
- inform dental staff of the health screening policies of the practice at the time of their employment;
- inform employees of local work health and safety policies, including the use of PPE;
- allow patients to access the practice's infection prevention and control strategies and provide information about procedures for dealing with concerns about infection prevention and control procedures; and
- provide all dental staff with a specific program of education and training in infection prevention and control principles, policies, and procedures.



## 5. Infection control manual

Each practice must develop a comprehensive infection prevention and control manual that outlines pertinent information for the daily routines of the practice. It must describe the infection

prevention and control procedures of the practice in sufficient detail such that it can be used as the foundation for training new staff who join the practice. The ADA has developed a suitable infection prevention and control manual that serves as a template and can be adapted to the specific requirements of an individual dental practice.

All staff in the practice must know who is responsible for ensuring certain activities are carried out and to whom they should report any accidents or incidents.

The content for this manual must include:

- methods of hand hygiene (both routine and surgical (where relevant));
- PPE requirements;
- setting up the treatment area between patients;
- environmental cleaning protocols;
- surface management, including barrier protection and cleaning between patients;
- protocol to be followed after an exposure incident such as a sharps injury;
- handling and disposal of sharps;
- waste disposal;
- processing of reusable items (cleaning, packaging, sterilisation, disinfection, storage);
- processing of radiographs in a manner so as to avoid cross-contamination;
- quality control mechanisms, including documentation for the maintenance and monitoring of equipment;
- immunisation requirements;
- use of single-use items;
- recording of information during patient treatment in a manner so as to avoid cross-contamination;
- use of computers and computer-run equipment during patient treatment in a manner so as to avoid cross-contamination;
- management of waterlines used in direct patient contact; and
- handling allergies to latex and glove materials in dental patients and dental staff.

Practice infection prevention and control manuals must be regularly updated as new guidelines are produced by the DBA, the ADA, or the NHMRC.

### Key compliance items for infection control manual

- Ensure the practice Infection Prevention and Control Manual is up to date and consistent with these Guidelines.
- Implement systems that facilitate ongoing review and compliance with the protocols documented in the infection control manual.

# Section F. Special areas and their particular dental infection prevention and control requirements

Aspects of dental care, or particular settings in which dental care is provided, present specific challenges to dental practitioners and clinical support staff in implementing effective infection prevention and control measures.

## 1. Dental radiology and photography

Items or materials placed in a patient's mouth and subsequently removed for processing must be considered biologically contaminated and must be handled in a safe manner. Gloves must be worn when taking radiographs and handling contaminated film packets or sensors. Other PPE (e.g., masks, protective eyewear) must also be used in case of spattering of blood or other body fluids. It is recommended that heat-tolerant or disposable intra-oral radiograph devices are used (unless using digital radiography) wherever possible. Semi-critical items (e.g., film-holding and positioning devices) must be cleaned, and either heat sterilised or barrier protected, before use on subsequent patients.

Exposed radiographs need to be transported and handled carefully to avoid contamination of the developing equipment. Following exposure of the radiograph, dry the film packet with a paper towel to remove blood or excess saliva before placing it in a container (such as a disposable cup) for transport to the developing area, where it will be decontaminated. Use protective barriers on developing equipment where possible. When these surfaces become contaminated, they must be cleaned.

There are several ways to handle intra-oral radiography to avoid cross-contamination. For example:

- Remove gloves and perform hand hygiene to ensure clean hands are used to position the tube and operate the x-ray controls; or
- Use gloved hands to position the tube and operate the controls, and then clean all the contaminated surfaces of radiography equipment (e.g., x-ray tube head and control panel) at the end of the appointment; or
- Use gloved hands but operate the x-ray controls through a barrier that is changed at the end of each appointment.

Digital radiography sensors come into contact with mucous membranes and are considered semi-critical devices. They must be cleaned and then covered with a barrier before use on subsequent patients. Follow the instructions for use in terms of appropriate products and methods to be used for this cleaning so as to ensure that the sensor is not damaged.

Most state regulations accept radiographic film packets and barrier envelopes contaminated with saliva or blood for disposal as general waste. However, some jurisdictions require these to be treated as contaminated medical waste – this means that they must be placed in yellow containers or plastic bags appropriately

marked with the international biohazard symbol and collected and disposed of by a licensed waste contractor.

## 2. Specialised intra-oral equipment and devices

Specialised intra-oral equipment and devices include:

- handle and tip of the curing light used for photopolymerisation of dental materials;
- intra-oral scanners used for digital impressions and CAD/CAM;
- keyboards, mice, touchpads, and other computer peripherals associated with CAD/CAM systems and other electronic devices;
- air abrasion units;
- intra-oral cameras and image capture devices;
- lasers;
- apex locators;
- electronic periodontal probes;
- occlusal analysers; and
- electrosurgery units.

Several factors need to be considered when determining whether a barrier is needed (or not) on a piece of dental equipment.

The first point relates to the responsibilities of importers/suppliers, who must comply with the legislation covering the sale of these items of equipment. These responsibilities include providing accurate, evidence-based advice on reprocessing, as per the Essential Principles under the Medical Devices Regulations (Commonwealth) adopted by the TGA. These reprocessing considerations will form a central part of the directions for use, as will any advice to clinicians specifically with regard to the Spaulding classification (sterile – then sterilise; mucosal contact – then high-level disinfection; intact skin – then cleaning or low-level instrument disinfection). In other words, the importer/sponsor will already have cleared this topic with the TGA during the registration of the device.

The need for any one dental practitioner to determine whether or not a barrier is needed, or whether the item can be cleaned, disinfected, or sterilised, should be small since all TGA-approved specialised devices used in clinical practice are required to come with instructions from the manufacturer on how to ensure appropriate control of cross-infection. Some devices will have parts that can be steam sterilised and other parts that need to be covered (e.g., sheaths for intra-oral cameras and digital imaging sensors). If the manufacturer recommends and supplies a dedicated barrier that covers the parts of the device that may come into contact with saliva, then failure of that barrier during operation is unlikely to occur.

In the event that a manufacturer or supplier is unable to provide suitable advice with regard to routine reprocessing and maintenance of an item, a complaint should be made directly to the TGA as the regulator, via the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) then search 'medical devices' and then 'lodge a complaint'.

A range of options exist for surface management of specialised devices such as intra-oral cameras used in patient examination and intra-oral scanners used to record digital impressions. A common approach used for intra-oral cameras and scanners which cannot tolerate heat sterilisation is protection with a single-use barrier (such as a disposable sheath); this is important due to their exposure to saliva and potentially blood. Options such as steam sterilisation, thermal disinfection, or cleaning with detergent followed by immersion disinfection are likely to damage the specialised optical and electronic components. Follow the instructions for use as to the appropriate barrier and/or cleaning/sterilisation procedures required for these devices. Some devices can be sterilised using hydrogen peroxide gas plasma sterilisation, which does not use heat.

Likewise, follow the instructions for use for how to manage equipment with touch panels. Some lasers and surgical motor controllers have touch panels for operation, for which there are adhesive stick-on covers that completely cover the panel so that no wiping is required afterwards; the covers are simply pulled off and discarded. There are other situations where wiping would not be appropriate, and a disposable barrier should be employed.

In summary, if the manufacturer states that a barrier is required, use a barrier (typically the manufacturer would also supply or specify the type of barrier). If the manufacturer states that the item is to be sterilised, then sterilise the item – do not simply cover it with a barrier. An important example is piezoelectric ultrasonic scalers, many of which are designed to be sterilised. Likewise, many modern dental chairs have membrane switches designed to be cleaned by wiping over using specified products – in this case, use the specified products for cleaning the area and do not use a barrier.

The second aspect relates to the responsibility of registered dental practitioners to follow the manufacturer's instructions (as per the TGA approval process described above).

Most modern equipment has been designed to be cleaned, with minimal use of barriers. For example, on most modern dental chairs, the suction tubing is very smooth (rather than ribbed) and has been designed for wiping. Follow the instructions for use with regard to how such surfaces are to be managed.

Older dental equipment may need barriers when the surfaces to be protected are very hard to clean (e.g., because of their complex shape) or where appropriate instructions from the manufacturer are lacking. Apply the principles articulated in these *ADA Guidelines for Infection Prevention and Control* for any situation not covered by instructions from the manufacturer. This will be an uncommon situation. Professional judgement will be needed. Consider the situation at hand with the device

and decide whether the suggested barrier will be adequate and will not introduce additional risks. If a staff member devises an improvised barrier using cling (polyethylene) film, aluminium foil, or a sandwich bag, the result is dependent on this device; in some cases, this may work, but in other cases, its integrity may be compromised because of poor fit or limited adaptation.

When replacing barriers, remove the contaminated barrier while gloves are still on, then check the surface for any visible contamination. If there is any saliva or blood contamination, the surface needs to be cleaned by wiping with a neutral detergent before the next barrier is put in place. At the end of the day, surfaces that were covered with barriers during patient treatment should be cleaned by wiping.

### **Curing light**

Curing light tips are semi-critical items. Steam sterilisation of the tips causes the optical performance to degrade. Barrier protection is an appropriate level of infection prevention and control for all curing light tips, as the equipment is not intended to contact mucosa. This barrier will also prevent adhesive materials from contaminating the end of the curing light tip. The handle of the curing light and the tips must always be cleaned prior to placing new barriers. A new barrier must be used for each patient.

### **Air abrasion, electrosurgery units, and lasers**

High-volume suction devices are essential when using electrosurgery units, dental lasers, and air abrasion/particle beam or powder jet devices as these create bio-aerosol hazards. Air abrasion devices used in restorative dentistry create alumina dust, which can be a respiratory irritant for dental practitioners, clinical support staff, and patients. Powder jet devices used to remove stains from teeth and to clean the surfaces of dental implants use powders such as sodium bicarbonate, calcium carbonate, glycine, or trehalose, in a water spray. While such powders are not considered to pose a significant occupational risk, all powder jet devices generate large amounts of splattered fluid and aerosols. Having high-velocity evacuation located close to the tip of the unit is essential.

Some pathogenic viruses such as human papillomavirus (HPV) are not inactivated by laser or electrosurgery procedures and remain viable within the plume (smoke) created from vaporisation of soft tissue lesions such as intra-oral warts or dysplastic oral mucosa. As discussed in AS/NZS 4381:2015, when ablating or excising such lesions, use of a disposable surgical mask with demonstrated superior filtration performance in the 0.1–0.3-micron range is appropriate. Alternatively, use an N95 surgical respirator.

Aside from HPV, other viruses and bacteria are rendered non-viable by laser or electrosurgery, even though fragments may be present in the plume. Blood-borne viral diseases such as HIV or HBV are not transmitted through the inhalation of aerosols or plume. Correct placement of high-volume suction and the use of high-filtration surgical masks can prevent inhalation of particles. These will remove gases (e.g., hydrogen cyanide, benzene, and formaldehyde) that are irritant and noxious. Evacuation systems



which remove plume must always be employed when using electrosurgery units or surgical dental lasers.

### 3. Implants

For surgical procedures involving placement of implants, both the instruments and the implants must be sterile at the time of use. Surgical aseptic technique must be employed. Explanted devices and components must not be reprocessed and reused in the same or other patients. All items in an implant kit marked as single-use are to be discarded at the end of the appointment.

### 4. Impressions

To remove contamination from impressions, thoroughly rinse them with cold running water to remove saliva and traces of blood. Then, apply a diluted detergent. This can be done by immersion in a solution of detergent or by spraying the diluted detergent onto the impression (e.g., in a plastic bag). The detergent will have a surfactant action which assists in removing the remaining microorganisms from the impression. Thorough rinsing is then undertaken to remove the detergent. This second rinsing step must continue until all visible contamination is removed. Once this is completed, the impression is deemed to be decontaminated.

A range of commercial products have been developed for the treatment of impressions. If using these rather than a plain detergent, follow the instructions for use exactly, and pay particular attention to shelf life and dilution ratios.

Where a risk assessment indicates that additional treatment may be needed (e.g., a patient is known or suspected to be colonised with multi-resistant organisms such as MRSA), additional chemical treatments may then be undertaken. A common protocol for additional treatment is immersion in a weak (0.5%) sodium hypochlorite solution for 3 to 15 minutes, as this does not cause deterioration of the impression material. Note that higher concentrations or longer exposure times will degrade the quality of the impression and the resulting cast. Other commercial solutions designed for impression disinfection can also be used, as per the instructions for use.

Once decontaminated, impressions can be scanned or can be used to pour up study models. If sent to an external (off-site) laboratory, impressions need to be packaged correctly and labelled as having been decontaminated.

### 5. Dental laboratory and dental prosthetics

Single-use dental laboratory and dental prosthetic items should be used where appropriate. Do not attempt to reuse single-use impression trays. Metal reusable trays must be cleaned to be free of all residues of impression material, as part of their reprocessing.

Use standard precautions when taking impressions or when inserting dentures or appliances, and when performing any intra-oral adjustments.

All materials transported to and from dental laboratories must first be cleaned and then placed in a sealed bag or container.<sup>11</sup> Check with local authorities about whether items need additional processing other than decontamination (as described in the previous section) prior to transport or posting.

Wear gloves during cleaning of the clinical work area. Never touch saliva-contaminated items with ungloved hands.

Keep bulk supplies of impression materials and prosthetic supplies (such as wax) away from potential contamination from dust, splashes of water, or patient fluids.

Employ safe working practices in the dental laboratory to prevent environmental contamination of items of laboratory work. Perform hand hygiene before working with clean items such as articulators and surveyors. Never place contaminated casts onto these.

Before inserting dental prostheses, or intra-oral or extra-oral appliances, clean them thoroughly to remove any environmental contamination.

Reprocess semi-critical items used in dental prosthetics that come into contact with saliva using one of the following three methods:

- Clean them with an ultrasonic cleaner and then sterilise them in a steam steriliser; or
- Use a WD that has a thermal disinfection cycle, for both cleaning and thermal disinfection; or
- Clean the item (e.g., with an ultrasonic cleaner) and then use a high-level (instrument-level) disinfectant. This third option applies for heat-sensitive items that cannot withstand steam sterilisation or thermal disinfection. After being thoroughly cleaned, the item is then immersed into a TGA-approved high-level (instrument-level) disinfectant, such as OPA, exactly as stated in the instructions for use. These agents can be used to disinfect surgical guides for implant surgery. After disinfection, items must be rinsed thoroughly to remove all traces of disinfectant.

Non-critical items (i.e., those that come into contact with intact skin, but not saliva) can be cleaned using detergent.

Areas for laboratory work (such as areas for pouring up models or grinding models) must be well separated from patient treatment areas and from the reprocessing area. Ideally, there should be physically separate areas for patient treatment, laboratory work, and instrument reprocessing. When these areas are in the same room, patients cannot be treated at the same time as undertaking laboratory work or reprocessing instruments.

When polishing appliances or prostheses that have been worn in the mouth, or when repairing or relining appliances, prevent contamination of the polishing lathe by dispensing single-use pumice, and then clean the pumice tray after each use.

11. Some state/territories specify disinfection plus cleaning; check with local authorities about transport process requirements.

## 6. Handpiece management

All dental handpieces must be cleaned and lubricated in accordance with the instructions for use and must be sterilised after each patient. Similarly, ultrasonic scaler tips must be sterilised between patients. The handpiece of piezoelectric scalers must be sterilised between patients if specified by the manufacturer (not just covered with a barrier or wiped down after use).

Burs must be removed from restorative handpieces and the exterior surfaces of the handpiece must then be cleaned thoroughly using a detergent-based product before reprocessing it. Never clean or immerse the handpiece in disinfectant solutions or in the ultrasonic cleaner. Never fully immerse dental handpieces or ultrasonic scaler handpieces in water at any stage when they are being reprocessed. Note that few brands of restorative dental handpieces are compatible with WDs, so do not use these unless so instructed by the manufacturer.

For restorative handpieces and surgical handpieces, follow the manufacturer's instructions for approved methods of lubrication of the internal aspects. This is normally done prior to steam sterilising. Two common approaches are as follows:

Using dedicated systems that perform automatic lubrication of dental handpieces. These use low viscosity lubricants and achieve better lubrication than manual methods. They also reduce concerns from excess oils being released during the sterilisation cycle or during use in the clinic. They achieve greater consistency in outcomes than pressure pack units. Thus, it is strongly recommended that these dedicated systems are used.

If performing manual lubrication using a pressure pack (spray can) unit, following this approach, care must be taken to ensure that excess lubricant is completely drained from handpieces prior to sterilisation otherwise the excess lubricant on packages compromises the sterilisation process. To enable the complete removal of lubricant from handpieces, either run the handpiece briefly or allow the handpiece to completely drain while sitting vertically prior to packaging and undertaking the sterilisation process. If draining the handpiece, allow it to sit vertically until no further lubricant is visible. If using a steam steriliser that condenses the steam and reuses water for later cycles, it is essential to prevent the accumulation of residues of lubricants, as these cause deterioration of the quality of steam and superheat the steam, making it unable to condense onto the surfaces of instruments. For such sterilisers, completely replace the deionised water every week after draining out the water reservoir and flushing it with deionised water.

Following sterilisation, handpieces used for restorative dentistry must be stored in such a way that they are not contaminated by splashes or aerosols. They should not be fitted to the dental unit until required for use on a patient. Once fitted to the dental unit, they are deemed to have been exposed to contamination during treatment, and thus, they must be reprocessed at the end of the appointment, even if not used on the patient.

For steam sterilisation of restorative dental handpieces, there are two options:

1. Use an S cycle steriliser with active air removal that has proven performance for steam sterilising dental handpieces and is approved for that purpose by the TGA. When using such a unit, ensure the load configuration is exactly as specified by the manufacturer.
2. Use a B cycle steriliser with vacuum air removal.

It is not acceptable to use an N cycle steriliser, since air removal from hollow areas of the handpiece is insufficient.

Surgical handpieces must be wrapped and then steam sterilised using a B cycle in a pre-vacuum.

For further information on handpiece management see the chapter on this topic in the *ADA's Practical Guide to Infection Control*.

## 7. Specimens

Place biopsy specimens into a sturdy, leak-proof specimen container labelled with the patient's name, and then place this in a zip lock bag labelled with the biohazard symbol. The outer bag reduces the chance of leakage during transport, should the specimen container leak. Gloves must be worn when handling pathology specimens and specimen containers. If the biopsy specimen container is visibly contaminated, transfer it to another container, or clean and disinfect the outside of the container before placing it into the transport bag.

## 8. Endodontic irrigants

Practitioners should ensure that sodium hypochlorite products used in the root canal as endodontic irrigants are approved by the TGA for the particular clinical use. Approved products for endodontics differ from domestic products in many ways (chemical composition, pH, tissue dissolving capabilities, and antimicrobial effectiveness).

Domestic sodium hypochlorite products, approved by the TGA for low-level disinfection (sanitising), may be used to decontaminate gutta-percha points, plastic-enveloped radiographic films, or dental impressions undertaken on the bench. Domestic sodium hypochlorite products cannot be used for irrigation of root canals during endodontic treatment.

The status of a product can be checked with the supplier. Labels also disclose registration on the ARTG.

## 9. Gutta-percha points

Immediately prior to use, gutta-percha points can be disinfected on the bench by one-minute immersion in a sodium hypochlorite solution with a concentration between 1.0 and 5.25%. This could be either a domestic sodium hypochlorite product approved for sanitising purposes or an approved sodium hypochlorite endodontic irrigation solution.

## 10. Hand-operated endodontic files

Hand endodontic files (regardless of their metallurgical composition) are single-use items. They are to be disposed of into a sharps container at the end of the appointment. Reprocessing

hand files is not practicable as manual or mechanical cleaning is ineffective and unsafe, and likely to result in a sharps injury. There are no verified protocols for cleaning these items, using any method.

For hand pluggers and other hand-operated endodontic instruments, check the manufacturer's instructions. Typically, these are labelled as single-use items, and must be disposed of after use.

### 11. Rotary nickel-titanium (NiTi) endodontic files

Rotary stainless steel files and hand-operated NiTi files cannot be reprocessed and must be discarded after use. Likewise, rotary NiTi files may be used once and then discarded. If they are to be reused, rotary NiTi files must be reprocessed using the specific protocol below. This could allow for reuse of rotary NiTi files up to three times. However, it is important to check the labelling and the manufacturer's instructions for NiTi files. Those marked as single-use cannot be processed.

If a dental practice intends to reuse rotary NiTi files, they must be cleaned using a verified protocol that combines a specific enzymatic agent with ultrasonic cleaning.<sup>12</sup>

The following protocol has been shown to be effective for all types of rotary NiTi endodontic files. It relies on both mechanical removal of gross debris by plunging the file into a sponge, followed by enzymatic breakdown of dentine residues during a soaking step, and then ultrasonic cleaning in the same enzymatic agent. The protocol comprises the following steps:

- immediately after use, remove stoppers and insert the files into a scouring sponge soaked with chlorhexidine gluconate aqueous solution (e.g., 0.2%);
- clean the files by applying 10 vigorous in-and-out strokes in the sponge;
- place the files in a wire mesh basket and immerse it in a suitable enzymatic cleaning solution (i.e., Empower™) for 30 minutes;
- follow this with 15 minutes of ultrasonic cleaning in the enzymatic cleaning solution;
- drain and rinse in running water for 20 seconds;
- perform wrapping and steam sterilisation.

### 12. Relative analgesia equipment

Reusable relative analgesia masks must be cleaned and sterilised. Manual cleaning of masks and hoses can be performed, or preferably, cleaning can be done using a WD. All sterilisable components can then be processed in a steam steriliser at 134 degrees.

Disposable single-use relative analgesia masks are available and may be more cost effective than reprocessing these items through a WD.

### 13. Nursing home visits

There are many dental patients whose dental treatment must be provided in a nursing home and occasionally, bedridden patients need dental care in a private home, nursing home or hospital. The facilities are often inadequate and can make it difficult to provide treatment. In these settings, standard precautions as a minimum should be followed when providing dental care, including wearing gloves and other protective clothing, and rigorous hand hygiene practices. In some situations, contact transmission-based precautions may also be required if the nursing home patient is at risk of MRSA, VRE or norovirus. Handwashing is essential because of the common presence in nursing homes of resistant microorganisms, norovirus, *Clostridium difficile* and other enteric pathogens that are not readily inactivated by ABHRs in residential aged care facilities and private homes.

Dental practitioners and clinical support staff may need to carry all necessary PPE to the site. During transport, all instruments and materials must be carried in clean lidded metal or rigid plastic containers to prevent damage or spillage. Such containers must be labelled clearly (e.g. clean or contaminated) as appropriate. After use, reusable instruments must be placed in a labelled rigid sealed container for transport back to the dental practice for cleaning and reprocessing. Where possible, instruments should be cleaned immediately after use with detergent and water. If this is not possible, they should be sprayed with a suitable instrument cleaner to prevent hardening of debris before transportation back to the dental practice.

Use of disposable instruments may be cost effective in extra-mural settings such as domiciliary care. These are to be disposed of into an approved sharps container.

After on-site decontamination, items such as impressions, try-ins, and articulators must be transported in sealed plastic containers.

Waste should be separated at the point of generation. General waste should be disposed of in the general waste stream of the nursing/private home or hospital. Sharps and medical waste must be dealt with according to jurisdictional regulations. A designated sharps container, as described in AS/NZS 3816 Management of clinical and related wastes, must be used for sharps waste. This can be transported with other instruments and equipment.

#### Key compliance items for special areas

- Consider which areas of the clinic may pose unique challenges and how you will manage these items/ areas.
- Review instruction manuals published by the manufacturer for items that pose infection control challenges and include any key information in the practice infection control manual.

12. Parashos P, Linsuwanont P, Messer HH. A cleaning protocol for rotary nickel-titanium endodontic instruments. Aust Dent J 2004; 49 (1):20-27.

# Section G. Infectious diseases, allergies, and transmission-based precautions for infection prevention and control

Some situations require additional infection prevention and control measures on top of the standard precautions already outlined. These transmission-based precautions must be applied for patients with known or suspected infectious diseases not managed by standard precautions alone. Details of the diseases and specific precautions are given in the 2019 NHMRC Guidelines, which cover conditions such as viral influenza, tuberculosis, and chicken pox (varicella). These diseases are readily transmitted in a dental practice environment. In each case, the transmission-based precautions are tailored to the specific infectious agent concerned, and may include measures to prevent airborne, droplet, or contact transmission.

## 1. Prion diseases including Creutzfeldt-Jakob disease (CJD)

For all patients with potential Creutzfeldt-Jakob disease (CJD) infection, instruments used during routine dental procedures (including endodontics) that come into contact with oral mucosa, gingiva, dental pulp, and other oral tissues can be routinely reprocessed with no special measures needed because oral tissues have low or zero infectivity due to the absence of prions. Prions are not found in saliva. Any patients with suspected or confirmed prion diseases can undergo normal dental treatment, including dentoalveolar surgery, without additional measures. This applies to those with classical or iatrogenic CJD as well as other prion diseases such as fatal familial insomnia (FFI).

While no special precautions are needed for routine dentistry, maxillofacial surgery involving the central nervous system and the cranial vault needs additional measures, as prions are found in the central nervous system. Details of this are given in the *CJD Infection Control Guidelines 2013* published by the NHMRC. Variant CJD (vCJD) is excluded from the scope of this document as vCJD has not been reported in Australia to date.

## 2. Measles, mumps, and tuberculosis

Infection by airborne transmission of respiratory secretions can occur with pulmonary tuberculosis and measles. Tuberculosis is spread by droplets or by direct contact and has been transmitted as a result of dental procedures. Patients with these diseases should have their dental treatment deferred until they are no longer infectious and have reached the end of any mandatory quarantine period.

## 3. Human viral influenza

As with measles, mumps, and tuberculosis, patients who are currently unwell with viral influenza should have their dental treatment deferred until they are no longer infectious (two weeks after symptoms appear for an adult; three weeks after symptoms appear for a child up to age 13).

A dental practice considering treating these patients should do so only after having conducted a written risk assessment. Most patients for whom contact and droplet transmission-based precautions for influenza are required would normally be quarantined at their home or too ill to consider any treatment other than relief of a severe dental infection. Pain can be reduced through the appropriate use of analgesics until the patient is no longer infectious and has reached the end of any mandatory quarantine period.

Where treatment cannot be deferred (e.g., facial swelling), transmission-based precautions must be used for provision of dental treatment. These are described below.

- Schedule the patient to be seen as the last patient of the day.
- Ensure staff working in the treatment room have been immunised against the current strains of influenza in circulation.
- Have the patient use a suitable antimicrobial pre-procedure mouth rinse (e.g., chlorhexidine gluconate, essential oil mouth rinse, hydrogen peroxide, povidone iodine or ozonated water).
- Wear high-filtration surgical masks that are adapted well to the face. Use of surgical respirators (N95 or N99) is optional; this would apply only to staff who have been fitted (i.e. fit tested) and trained properly in how to wear these respirators, with proper fit checking before use.
- Consider the use of barriers for high-risk items (optional).
- For restorative dentistry, use a dental dam and high-velocity evacuation to reduce the formation of aerosols. For other procedures, use techniques that minimise the production of splashes of fluids and generation of aerosols.
- At the end of the appointment, undertake the surface cleaning process twice (i.e., one full additional cycle of surface cleaning). This could be detergent followed by disinfectant, or two cycles using a product that combines detergent and disinfectant.



## 4. Avian influenza viruses

H5N1 and H7N9 are forms of avian influenza that are highly pathogenic and contagious. Normally, they only infect birds and occasionally pigs. Both have much higher mortality than human influenza strains that do not have avian components. To date, there is limited evidence of person-to-person transmission. Nevertheless, practitioners should be aware of the importance of respiratory illnesses that develop in patients who have recently returned from regions where such conditions occur (e.g., Indonesia and China), particularly within the timeframe of ten days of onset of illness. Patients with suspected avian influenza should not undergo any elective dental treatment. Urgent dental treatment requires both contact and droplet precautions, as described above.

Some novel respiratory pathogens require airborne precautions. These precautions cannot usually be implemented fully in private practice small office settings. Unless airborne precautions can be comprehensively implemented, it is unsuitable for infected patients needing urgent dental care to be seen in such settings. When such pathogens cause pandemics, public health authorities may dictate limits on what health care facilities may see such patients.

Further information on risk reduction for airborne infections can be found in the ADA's *Practical Guide to Infection Control*.

## 5. Staphylococcus aureus

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a bacterium resistant to common antibiotics and, as a result, infections caused by this organism are difficult to treat. MRSA colonises the nose, axillae, and perineum, as well as abnormal skin (such as wounds, ulcers, and eczematous skin). Normally, it is not found in the oral cavity, but occasionally it may be isolated from oral infections, including those associated with dentures.

In office-based dental practice, transmission of MRSA is relatively unlikely as vulnerable patients will recently have had major procedures in a hospital or other large institution and are unlikely to be ambulant or seeking dental care during the immediate post-operative phase.

Patients in long-term care facilities are another group of patients vulnerable to MRSA; however, for most office-based dental practices, this group does not comprise a large proportion of patients.

When treating patients colonised with MRSA, it would be prudent to use a disinfectant on impressions and on dentures or appliances being sent for repair. Double wipe all surfaces touched by the patient and ensure minimal contamination of surfaces during treatment of the patient so as to guard against contamination of the operatory.

Dental staff known to be colonised with MRSA must not undertake or assist with major surgical procedures in hospitals. They should seek medical advice and undergo treatment to ensure they do not cause contamination of the operatory. MRSA carriers are likely to have MRSA on the facial skin, and in particular, the peri-oral skin. Organisms may be distributed by air coming from the nose, and particularly by nose blowing

### Key compliance items for transmission-based precautions

- Review how conditions that warrant transmission-based precautions are screened, how treatment for these patients can be delayed, and what protocols are used when treatment cannot be delayed.
- Determine the circumstances in which referral is warranted due to facility/equipment limitations or risk assessments.

## 6. Allergies to chlorhexidine

Practitioners using chlorhexidine mouth rinses, hand washes, or irrigants should be aware of the potential risks of allergic responses. The chlorhexidine molecular structure has two identical epitopes and can cross-link IgE antibodies on the surface of mast cells and basophils, causing them to degranulate. This leads to histamine release and the possibility of anaphylaxis in sensitised individuals. There have been over 60 reports of anaphylaxis to chlorhexidine in the literature since 1983.<sup>13 14 15 16</sup>


The greatest risk situation is when chlorhexidine gains access to the systemic circulation. This concern underpins advice that chlorhexidine rinses, irrigants, or gels should not be applied onto bleeding sites (e.g., subgingival irrigation during periodontal debridement, or by irrigation into extraction sites).

The NHMRC *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2019) discuss emerging issues with allergy and resistance to chlorhexidine and recommend that its use be limited to clearly defined applications that are evidence-based, so that it is not used injudiciously.

## 7. Latex sensitivity

Suspected natural latex allergy (NLA) in dental practitioners, clinical support staff, or patients must be treated as a serious medical issue. Symptoms may manifest as delayed hypersensitivity such as rash, conjunctivitis, or rhinitis (Type 4), which could then progress with time to an acute allergic anaphylactic reaction (Type 1), which may result in death.

13. Moghadam BK, Drisko CL, Gier RE. Chlorhexidine mouthwash-induced fixed drug eruption. Case report and review of the literature. *Oral Surg Oral Med Oral Pathol.* 1991;71(4):431-4. 14. Beaudouin E, Kanny G, Morisset M, Renaudin JM, Mertes M, Laxenaire MC, et al. Immediate hypersensitivity to chlorhexidine: literature review. *Eur Ann Allergy Clin Immunol.* 2004;36(4):123-6. 15. Nagendran V, Wicking J, Ekbote Am Onyekwe T, Garvey LH. IgE-mediated chlorhexidine allergy: a new occupational hazard? *Occup Med.* 2009;59(4):270-2. 16. Liipo J, Kousa P, Lammintausta K. The relevance of chlorhexidine contact allergy. *Contact Dermatitis.* 2011;64(4):229-34. Reisner D, Khanam J. United Kingdom: Death At the Dentist. <https://www.mondaq.com/x/133104/Healthcare+Medical/Death+at+the+Dentist>.



All patient medical histories and new dental staff employment forms must include questions about NLA and/or sensitivity or allergy to latex/rubber products.

Patients with proven anaphylactic reactions to latex should be wearing a medical alert bracelet and should be carrying self-injectable adrenaline. Staff who have allergies to latex should have this documented in the clinic's allergy records for staff, and should inform the practice so that all necessary accommodations can be made to minimise and prevent exposure to latex in the workplace.

If latex sensitivity is identified, then a 'latex-free' environment should be created for the persons affected. This involves the use of latex-free gloves and removal of identifiable latex products likely to cause a reaction from the operator. Such items include latex gloves, latex prophylaxis cups, latex dental dams, rubber bite blocks, and latex rubber alginate mixing bowls. Non-latex versions of these items are available.

Further information on latex allergies can be found in the ADA's *Practical Guide to Infection Control*.

#### **Key compliance items for allergies and sensitivity**

- Consider the use of chlorhexidine and determine the evidence-based applications for judicious use.
- Ensure dental staff with latex sensitivities are able to work in a latex-free environment by selecting non-latex products.

# Appendix 1. Blood and body fluid exposure protocol

## First aid

- Stop work immediately, regardless of the situation (e.g., even if administering local anaesthetic or undertaking a surgical procedure).
- Allow the wound to bleed and clean it thoroughly with a soap and lukewarm water wash. There is no benefit in squeezing the wound. Do not apply disinfectants as some are irritants and retard healing.
- Flush mucous membranes/conjunctiva with normal saline or water. If contact lenses are worn, remove after flushing eye and clean as usual.
- Further management of the wound is dependent on the nature of the injury.

## Risk assessment

For a large exposure to HIV, an assessment of the risk of transmission is of urgent priority in order to determine whether post-exposure prophylaxis (PEP) for HIV is necessary. Expert medical advice from an S-100 prescriber or an infectious disease specialist is required to determine the need and type of HIV PEP for the exposed person and the necessity, or otherwise, of testing the patient's blood after appropriate pre-testing counselling. Both the risk assessment and baseline tests need to be undertaken as a matter of priority, so that valid baseline results are obtained and PEP, if needed, can be given within 72 hours of the injury occurring.

Each dental practice should have a clear set of written instructions on the appropriate action to be taken in the event of a sharps injury to either staff or patients. These instructions should include emergency contact numbers for expert advice (including the name of a medical practitioner experienced in dealing with such cases). These instructions must be easily accessible and understood, and all staff must follow them.

A full record of the incident must be made, including details of:

- who was injured;
- how the incident occurred;
- type of exposure;
- presence of visible blood on the device causing the injury;
- whether a solid sharp object, hollow bore object, or needle was involved;
- gauge of the needle;
- time the injury occurred;
- what action was taken;
- who was informed and when; and
- details of the patient being treated.

Factors influencing whether an exposure has the potential to transmit a BBV infection include:

- type of exposure (mucosal splash vs. a deeply penetrating skin injury);
- type of body substance (e.g., how much blood is present in the saliva);
- volume of blood or body fluids;
- length of time in contact with blood or body fluids, and
- the length of time that has elapsed since the exposure (as post-exposure prophylaxis for HIV needs to be instituted within 72 hours of the sharps injury).

In addition, to complete an accurate assessment after a sharps injury, the following factors should be considered:

- type of device involved;
- procedure for which the device was used (e.g., into a vein or artery);
- whether the injury was through a glove or clothing;
- whether a deep injury occurred in the exposed person; and
- whether the source patient is viraemic (e.g., with advanced/terminal HIV disease or a high viral load).

Finally, the record of all these details should be signed by those involved in the incident.

## Testing

Testing should be offered following all occupational exposure to blood or body substances, particularly all 'contaminated' sharps injuries (e.g., those involving exposure to blood or blood-contaminated saliva via an instrument, bur, or contaminated wire).

## Baseline tests

Baseline serum is requested from the injured staff member AND the patient (where the source is known). The injured staff member should be tested soon after the injury to establish their serological status at the time of the exposure for:

- HIV antibody;
- HCV antibody; and
- antibody to hepatitis B surface antigen (anti-HBs).

This testing should be completed as soon as possible after the injury (ideally the same day, and definitely within 24 hours), bearing in mind the window period of the tests.

If the source patient is found to be positive for a BBV, it is recommended that additional testing and assessment of the injured person be conducted by an infectious disease physician.

If the injured staff member has ever had a blood test that demonstrates HBV immunity (anti-HBs antibodies) – whether from vaccination or past infection – they are protected, and there

is no need for hepatitis B immunoglobulin after a potential or confirmed exposure to HBV.

### Testing the source patient

When a situation arises where there is a need to know the infectious status of a patient (such as a sharps injury), the patient has a responsibility to provide information or consent for testing so as to enable the practice or responsible health professional to ensure the safe management of the injured staff member.

Informed and voluntary consent must be obtained before taking a blood sample to test for any purpose. When the responsible medical practitioner is obtaining consent, the patient should be offered pre-test counselling to provide details of the test procedure and the long- and short-term consequences of the test results for the patient.

Post-test counselling may also be required, particularly if the result is positive.

The source individual should be tested for:

- HIV antibody;
- HBsAg; and
- HCV antibody.

If the source individual tests positive for either of the hepatitis B or C markers, additional tests would usually be ordered to assess infectivity (e.g., hepatitis B 'e' antigen, HBV DNA, and HCV RNA – the latter two by polymerase chain reaction assay).

### Refusal for testing

If the source patient refuses testing, this refusal should be documented. In this case, treat the situation the same as the 'positive patient' scenario, and consider whether post-exposure prophylaxis and appropriate long-term follow-up should be offered.

### Source negative

Generally, no further follow-up of the exposed staff member is necessary if blood tests show the source patient is negative for HIV, HBV, and HCV, unless there is reason to suspect the source patient:

- is seroconverting to one of these viruses; or
- was at high risk of blood-borne viral infection at the time of the exposure (because they have recently engaged in behaviours associated with a risk of transmission of these viruses).

The window period causes a FALSE NEGATIVE test result. The patient may be infectious, but this is undetectable by testing. Usually, the window period for HIV is up to three months but it can, very rarely, be longer. The use of polymerase chain reaction (PCR) testing for HIV/viral RNA can identify 90% of infections within four weeks, significantly reducing this window period. The window period is six months for HBV and HCV.

### Source positive for hepatitis B

The level of antibodies is important if the source is KNOWN or SHOWN to be positive for HBsAg. If the staff member is immune to HBV (based on their anti-HBs antibodies), then they are protected. If antibody levels are low, a booster injection may be prudent.

If the staff member is NOT IMMUNE (e.g., has never been immunised, did not seroconvert to the vaccine (a non-responder), or has antibody levels to HBsAg less than 10 mIU/mL), the correct treatment is to:

1. Give a single dose of hepatitis B immunoglobulin (HBIG) within 48–72 hours

AND

2. Start a course of HBV immunisation. HBV vaccine should be given within seven days of exposure, and then repeated at one to two months, and then again at six months after the first dose. Following the final vaccine dose, the level of immunity (antibodies to surface antigen) should be checked two to four weeks later.

If this HBV prophylaxis is not undertaken, the risk of transmission of HBV is more than 30% if the source is hepatitis B 'e' antigen positive.

### Source positive for hepatitis C

If the source is KNOWN or SHOWN to be positive for antibodies to HCV, there is no effective post-exposure prophylaxis (PEP) for HCV. The risk of transmission after a sharps injury from a positive source varies according to whether active viral replication is occurring. If the source is HCV RNA negative by polymerase chain reaction (PCR) assay, the risk is 1.8–3.1%. However, the risk increases to 10% if the source is PCR positive.


The injured staff member should be re-tested for HCV antibodies at three and six months, in addition to their baseline test. In addition, regular liver function tests such as alanine aminotransferase (ALT) and aspartate aminotransferase (AST) (e.g., at two, three, and six months) can be undertaken, and possible clinical signs and symptoms monitored by an infectious disease physician or gastroenterologist; specific antiviral therapy should be implemented under specialist guidance.

### Source positive for HIV

If the source is KNOWN or SHOWN to be positive for antibodies to HIV (or is at high risk of seroconverting), the assessment of the injured person needs to take into account the risk of seroconversion as follows:

- After a sharps injury with HIV-infected blood: 0.3%
- After a mucous membrane exposure to HIV-infected blood: 0.09%.





Only a very small proportion of occupational exposures to HIV result in transmission of the virus. The side-effects and toxicity of HIV PEP must be carefully considered against its efficacy. PEP is only indicated if there has been a significant exposure and a proper risk assessment has been undertaken by a medical practitioner experienced in HIV management.

HIV PEP is typically several orally administered antiretroviral drugs and should be administered to the recipient within 24–36 hours after exposure.

PEP will not be offered in the case of exposure to non-bloodstained saliva (as this is not potentially infectious for HIV).

### **Testing for the injured person**

Follow-up blood tests for the injured person should be undertaken at one, three, and six months, and follow-up should be undertaken to detect any febrile illness occurring within three months of exposure (possibly representing an HIV seroconversion illness).

## Appendix 2. Frequently Asked Questions

**Q: What is the difference between alcohol-based hand rub (ABHR) for regular hand hygiene versus ABHR for surgical hand hygiene?**

**A:** ABHR for surgical hand preparation uses both a different product and different technique, which is typically much longer in duration than regular hand hygiene using ABHR. To determine whether ABHR is intended for surgical hand hygiene or regular hand hygiene, you can search for the product using the Australian Register of Therapeutic Goods search function:

[www.tga.gov.au/searching-australian-register-therapeutic-goods-artg](http://www.tga.gov.au/searching-australian-register-therapeutic-goods-artg)

**Q: How do I know if a device needs to have a barrier placed on it?**

**A:** Review the manufacturer's instructions for the item being used. If the manufacturer recommends that a barrier is used, this should be followed.

**Q: Is it mandatory to use an instrument washer to reprocess regular dental instruments (rather than an ultrasonic cleaner or manual cleaning)?**

**A:** Mechanical cleaning of instruments can be carried out in instrument washers (also known as thermal disinfectors) or using ultrasonic cleaners. Mechanical cleaning is preferred to manual cleaning as it is more efficient and reduces the risk of exposure to blood, and the risk of penetrating skin injuries from sharp or pointed instruments. The use of instrument washers is not mandatory unless using items that are expressly required to undergo an instrument washing and thermal disinfection process. However, instrument washers are more efficient at pre-sterilisation cleaning than both ultrasonic cleaners and manual cleaning.

Mechanical cleaners used in dental practices may be instrument washers (which also provide thermal disinfection), ultrasonic cleaners, or combination units which perform both. Not all instruments are suited to thermal disinfection or ultrasonic cleaners, so careful attention should be paid to the manufacturer's instructions to determine the appropriate management of items.

**Q: Is checking the steriliser printout enough evidence for determining the success of the process of sterilisation?**

**A:** Checking the steriliser printout is just one step in the process of checking that a load of instruments has been effectively sterilised. The steriliser printout (or digital record) is a physical indicator that cycle parameters have been reached. This is used in combination with chemical indicators to show that certain temperatures, times, and steam exposure conditions have been reached during the sterilising process.

Provided that cycle parameters have been followed and the load has been correctly sterilised (as shown by the results of the physical and chemical indicators), after inspection to ensure pack integrity, wrapped sterilised instruments can be released for use in the clinic. This is known as parametric release and must be recorded and signed off by the person performing the task.

**Q: What records do I have to keep for a steam steriliser?**

**A:** The manufacturer will determine the appropriate tests that need to be carried out for a steam steriliser and the results of these tests should always be maintained.

The most common type of steam steriliser used in dentistry is a pre-vacuum steriliser which runs B cycles. A range of tests must be carried out and the results recorded.

A summary of the records required for this type of steam steriliser is provided below:

What to record / maintain	When to record
Certificate of calibration and operational qualification	When a new steam steriliser is installed (provided by the technician).
Record of servicing and repairs to the sterilisers and any upgrades to hardware or software	When servicing, repairs or upgrades occur.
Results of annual calibration	Annually (provided by the technician).
Results of performance qualification using biological indicators (spore tests)	Annually (provided by the technician) or when new packaging materials are being used.
Results of leak rate test (vacuum test)	Daily for machines without automatic air leak detection, weekly if using a steriliser with automatic air leak detection (see manufacturer's instructions).
Results of air removal and steam penetration tests	Daily for clinics operating under AS/NZ 4187. When intending on sterilising porous loads for clinics operating under AS/NZS 4815 (or daily by choice).
Results of Helix test	Daily
Results of individual steriliser cycles: <ul style="list-style-type: none"> <li>the steam steriliser number or code (if there is more than one steriliser in the practice, in order to identify the machine the item was sterilised in);</li> <li>the date;</li> <li>the cycle or load number on that date;</li> </ul>	

What to record / maintain (cont'd)	When to record (cont'd)
<p>Results of individual steriliser cycles (cont'd):</p> <ul style="list-style-type: none"> <li>• a summary of the contents of the load, e.g., wrapped or unwrapped items;</li> <li>• which cycle parameters were used (time and temperature) – ensuring these are appropriate for the load type being processed – whether wrapped or unwrapped;</li> <li>• batch numbers of packs included in the load (if any); and</li> <li>• identification of the loading operator</li> </ul>	
<ul style="list-style-type: none"> <li>• correct physical data has been checked (include printouts)</li> <li>• chemical indicator results</li> <li>• integrity of packages (if present)</li> <li>• identification of unloading operator</li> </ul>	After each load

It is important to maintain physical steam steriliser printouts in a way that ensures their long-term legibility by scanning, photographing, or photocopying these items, as steriliser printouts can fade or become damaged over time.

**Q: Do I have to store chemical indicator strips as part of record-keeping?**

**A:** No. Chemical indicators are susceptible to changes during storage and therefore there is no need to keep these as part of record-keeping.

**Q: When do I use a spore test?**

**A:** A spore test is part of an annual microbiological report to confirm functioning of the steriliser, typically provided by a trained technician. Spore tests may also be used when there is a change to the packaging being used to wrap instruments. Additionally, these may be used in each load as an indicator when physical data for the steriliser cannot be accessed (such as a temporary malfunction of a steriliser printer).

**Q: What infection control documents should be available in the practice?**

**A:** Each dental practice should make available to staff the following resources:

- AS/NZS 4815 or AS/NZ 4187 (depending on which standard you are working under)
- NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare
- ADA Guidelines for Infection Prevention and Control
- Infection Control Manual for your practice

For more information see Page 13.

**Q: What are the essential records that I am required to keep to satisfy the Infection Prevention and Control requirements?**

**A:** In addition to records relating to steam steriliser use and maintenance outlined above, the following records should be maintained:

- Performance tests and maintenance records for any instrument washers being used
- Performance tests and maintenance records for any ultrasonic cleaners being used
- Vaccination and allergy status for each staff member
- Workplace injuries and incidents (such as breaches in infection control protocols and how these are managed)
- Any risk assessments or audits undertaken and the results of these
- Induction and training processes (including staff meetings) being used to update infection control knowledge and skills
- Batch control identification (in patient records) when critical items are used.

**Q: What daily autoclave tests am I required to do?**

**A:** Always follow the manufacturer's instructions. In general, if using the most common type of steriliser (pre-vacuum steriliser which runs B cycles), you will need to run:

A leak test: This would usually only be performed daily if the steriliser being used does not have an air detector and automatic leak detection. If automatic leak detection is a feature of the steriliser, a weekly leak test is indicated.

An air removal and steam penetration test.

1. A Bowie-Dick type test. This is typically run first as it runs in an empty chamber without other instruments to test air removal and steam penetration for porous loads. This test is currently mandatory to perform daily for clinics operating AS/NZS 4187:2014 (Amendment 2, 2019) Reprocessing of reusable medical devices in health service organisations.

For clinics under AS/ NZS 4815:2006 (Office-based), this remains mandatory only when processing porous loads that day. However, a clinic may elect to undertake a daily Bowie-Dick type test as a best-practice approach. It is possible that this will become a mandatory daily test for all clinics under a unified standard.

2. A Helix test. This is a test of air removal and steam penetration in hollow loads. As Helix tests vary from one manufacturer to the next, it is important to read the manufacturer's instructions to determine the appropriate timing and placement of this process challenge device.

**Q: Do I need to wear a gown over my uniform/scrubs for routine dental procedures?**

**A:** It is important to distinguish a uniform worn throughout a dental practice compared with PPE. They are not the same. The key concept is that clothing (whether it be a gown, clinic coat or scrubs) worn in contaminated areas of the practice and during procedures that create aerosols, sprays and splatter, should not be worn outside of this area into a clean environment. Solutions to avoid contamination of clean areas may include:

- Wearing a gown or clinic coat over scrub uniforms or street clothes
- Changing out of scrubs worn in contaminated areas prior to leaving contaminated areas.

It is up to each practice to ensure that PPE is worn and removed in a way that avoids contamination of clean areas.

**Q: Is it acceptable to wear over-gloves to retrieve items from a clean area instead of de-gloving and performing hand hygiene?**

**A:** It is no longer considered acceptable to wear over-gloves to retrieve items from a clean area as this poses a high risk of inadvertent contamination of clean areas and items. De-gloving and performing hand hygiene prior to retrieving items from clean areas is expected.

**Q: Is it acceptable for dental practitioners and dental assistants who perform clinical procedures to have any type of artificial fingernails or fingernail polish (i.e., Shellac or Gel nails)?**

**A:** It is not acceptable for dental practitioners, assistants or team members performing clinical procedures to have any type of artificial nails or polish. If any dental team member performing clinical procedures is wearing artificial nails or polish, they should be instructed to remove these, as these items harbour microorganisms and significantly inhibit the ability to perform effective hand hygiene. 'Hand hygiene is the most important measure to avoid the transmission of harmful germs and prevent health care-associated infections' (World Health Organization).





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