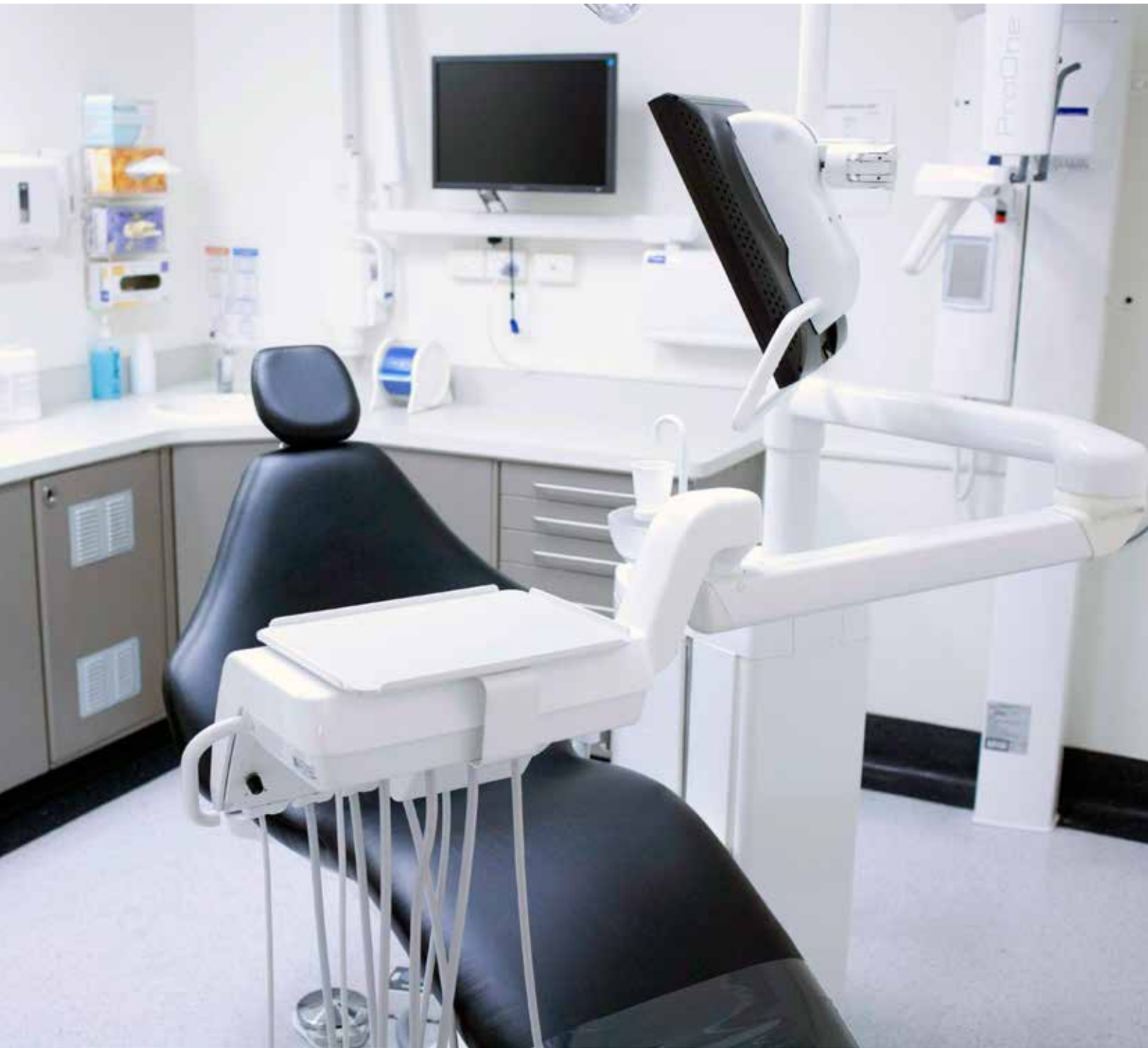


Guidelines for Infection Control

Third Edition



ADA's Guidelines for Infection Control

Third Edition

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Disclaimer: The routine work practises 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 third edition of the *ADA's Guidelines for Infection Control* incorporates a number of changes that have arisen since the publication of the second edition in 2012, including the release in December 2014 of the revised *AS/NZS 4187*. It is the intention of the Australian Dental Association (ADA) that these infection control guidelines will continue to be updated every three years to ensure they remain aligned to the evidence base of infection control.

This current edition of the *ADA's Guidelines for Infection Control* is the result of over 25 years dedicated work by the members of the ADA's Infection Control Committee. During that time the Committee has assisted external expert bodies such as the National Health and Medical Research Council (NHMRC) and the Communicable Diseases Network of Australia (CDNA) to help define safe practise. Quite fittingly, the *ADA's Guidelines for Infection Control* are now recognised as a key source of information for the NHMRC Guidelines, and have been identified by the Dental Board of Australia as a mandatory resource for dental practitioners.

The production of this document has required a considerable effort over a long period. Special thanks and acknowledgment are due to the Editor of the second and third edition of the Guidelines (Professor Laurence Walsh) and to current and former members of the ADA's Infection Control Committee (currently chaired by Dr Sharon Liberali), for their generous donation of time and their technical advice and expertise in preparing this document.

The ADA declares that no conflict of interest existed in the development of these guidelines, and that they have been developed independently without any corporate interest or sponsorship.

Rick Olive

President
Australian Dental Association

What's new

This third edition of the *ADA's Guidelines for Infection Control* contains a significant number of additions to the second edition published in 2012.

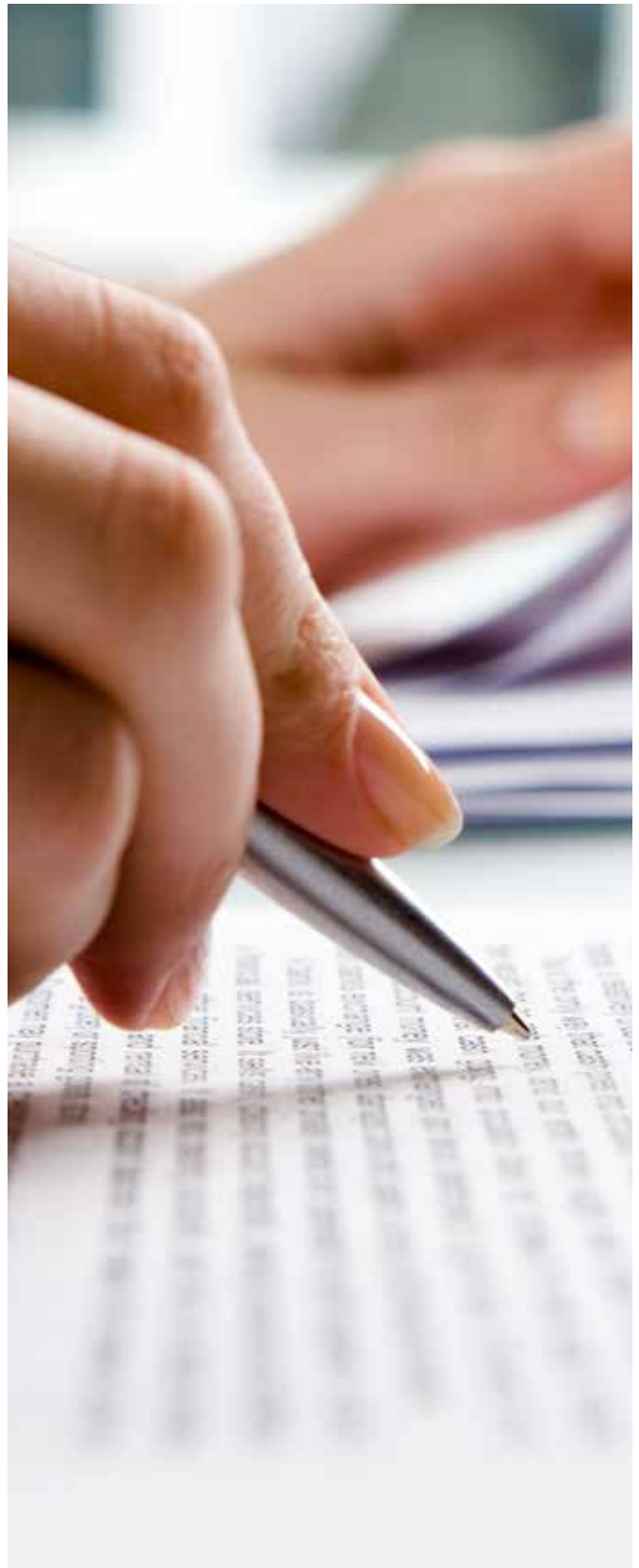
These changes are a direct result of the ADA's commitment to remaining aligned with current international best practice in evidence-based infection control.

They are also a consequence of revisions to the two main standards relevant to instrument processing in Australian dental practices, *AS/NZS 4815* and *AS/ANZ 4187*, both of which are considered key resources in the formulation of the Dental Board of Australia *Guidelines on Infection Control*, and hence in the creation of this document.

Registered dental practitioners are legally required to comply with all of the Dental Board of Australia's policies and guidelines, which includes ensuring that mandatory infection control guidelines are instituted in full in their practices.

This is an obligation that cannot be delegated.

It's important that every registered dental practitioner familiarise themselves with every new element of infection control practice included in this document and incorporate them into their practice's infection control manual.



Introduction

The *ADA's Guidelines for Infection Control* describes the infection control procedures dental practitioners and their clinical support staff are expected to follow in a dental practice. It outlines the primary responsibilities of dental practitioners in relation to infection control, and provides the rationale for those obligations. Greater details on key aspects are provided in the companion resource, the *ADA's Practical Guide to Infection Control*.

The routine work practises outlined in the *ADA's Guidelines for Infection Control* 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. It is important to acknowledge that professional judgement is essential in determining the application of these guidelines to the situation of the individual dental practice environment. Individual dental practices must have their own infection control procedures in place, which are tailored to their particular daily routines. Professional judgement is critical when applying these guidelines to the particular circumstances of each individual dental practice.

Each dental practitioner is responsible for implementing these guidelines in their clinical practice and for ensuring their clinical support staff are familiar with and able to apply them. Therefore, each dental practitioner must ensure that they and their staff fulfil their obligations to practise in a safe and hygienic manner. The individual practitioner is responsible for ensuring compliance with infection control requirements throughout the practice. This cannot be delegated.

The Dental Board of Australia's *Guidelines on Infection Control* address how dental practitioners can prevent or minimise the risk of the spread of infection in the dental setting. There are two critical parts to these guidelines – documentation and behaviours.

All dental practitioners when they apply for or renew their registration undertake to comply with all relevant legislation, and the Dental Board of Australia registration standards, codes and guidelines – this includes the Board's *Guidelines on Infection Control*. These requirements apply to all dental practitioners, be they an employee or employer. Failure to comply with these guidelines may lead to a practitioner's conduct being investigated by the Board.

All clinical support staff require appropriate training in the infection control measures they are expected to undertake everyday. Compliance with procedures is more likely if those involved in carrying them out understand the rationale behind the requirements. This includes knowing how infections are transmitted; what personal protection is needed and when and how to use it correctly;

what vaccinations are needed and why; details of how to keep the practice clean and hygienic and what to do in the event of an exposure incident such as a skin penetrating injury with a sharp instrument. Effective infection control involves not only maintaining documentation about the various procedures and processes in a specific manual, but reviewing protocols, training and documentation on a regular basis, and ensuring staff members undertake the procedures in a consistent and uniform manner.

Supporting and reference documents

These guidelines are mainly evidence-based or otherwise based on current international best practice, and have been drawn from current expert knowledge and advice in infection control. These guidelines will be regularly reviewed and updated in light of changes in the knowledge base. References used to prepare these guidelines are listed at the footer of each page in which they are cited and can be sourced for further information. Practitioners should also refer to the NHMRC *Australian Guidelines for the Prevention and Control of Infection in Healthcare*. The NHMRC Guidelines should be regarded as a companion document to the *ADA's Guidelines for Infection Control* as it addresses the foundations of infection control across all healthcare settings, including dental practice, and provides specific advice on situations where additional risk-based precautions are warranted.

Two standards from Standards Australia are relevant to instrument reprocessing in dental practice, namely *AS/NZS 4815* and *AS/NZS 4187*. Both documents are identified as key resources in the Dental Board of Australia's *Guidelines on Infection Control*.

The Australian and New Zealand Standard *AS/NZS 4815 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* is relevant to office-based dental practice. Public dental clinics and large facilities would generally operate under *AS/NZS 4187 Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*.

AS/NZS 4187 was updated in 2014, while the former document remains current, and is subject to a proposal for revision to maintain it as a contemporary and relevant document into the future. The 2014 update of *AS/NZS 4187* and future revision of *AS/NZS 4815* take into account international standards and global guidelines, such as those from the International Organization for Standardization (ISO). As a result the newly revised *AS/NZS 4187* is written in a different format from the previous 2003 version. Future editions of the *ADA's Guidelines for Infection Control* will take into account points raised following the revision of *AS/NZS 4815*.

Definitions

AS or AS/NZS refers to the Australian and New Zealand standards, authored by SAI Global. These are referred to as either AS or AS/NZS followed by the relevant standard number.

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

Clinical support staff members are those staff other than registered dental practitioners who assist in the provision of dental services – namely dental chairside assistants, dental laboratory assistants and dental technicians.

Contaminated zone is that area of work in which contamination by patient fluids (blood and saliva) may occur by transfer, splashing or splatter of material. It includes the operating field in the dental operator, as well as the instrument cleaning area within the sterilising room. Contamination must be confined and contained to this area.

Dental Board refers to the Dental Board of Australia.

Dental practitioners is an inclusive term that refers to those registered by the Dental Board to provide clinical dental care to patients, and comprises 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.

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. These procedures include those where the dental staff's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. Three different types of EPPs are described in the CDNA *Australian National Guidelines for the Management of Health Care Workers known to be Infected with Blood-Borne Viruses*.

Category 1

The majority of procedures in dentistry are Category 1 EPPs because they are undertaken with the hands and fingertips of the dental practitioner visible and outside the mouth.

The possibility of injury to the practitioner's gloved hands from sharp instruments and/or tissues is slight, and the risk is remote of the practitioner bleeding into a patient's open tissues. The possibility of injury to the practitioner's gloved hands from sharp instruments and/or tissues is slight, and the risk of the practitioner bleeding into a patient's open tissues is remote.

Category 2

In a smaller group of procedures, designated as Category 2 EPPs, the fingertips may not be visible at all times; however, injury is unlikely to occur to the practitioner's gloved hands from sharp instruments and/or tissues. If injury occurs it is likely to be noticed and acted upon quickly to avoid the dental practitioner's blood contaminating a patient's open tissues.

Category 3

Category 3 EPPs in dentistry are surgical procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages in which there is a distinct risk of injury to the dental practitioner's gloved hands from sharp instruments and/or tissues. In such circumstances, it is possible exposure of the patient's open tissues to the practitioner's blood may go unnoticed or would not be noticed immediately. Such procedures include: maxillofacial surgery; oral surgical procedures including surgical removal of teeth and dento-alveolar surgery; periodontal surgical procedures; endodontic surgical procedures; and implant surgical procedures (such as implant placement and recovery). The definition of Category 3 EPPs excludes forceps extraction of highly mobile or exfoliating teeth.

Invasive procedure is any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs, or repair of traumatic injuries to the soft tissues.

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.

Surgical procedure is one where there is a planned breach of a patient's skin or mucosa and penetration into deeper layers of tissue which have a different immune response.¹

Traceability is a protocol that requires a record of the distribution and location of each individual instrument during use and after each sterilisation cycle and during storage, e.g. using laser engraving of individual instruments.

Note: this is different from batch control identification (previously termed tracking) which links a sterilising cycle to a package of instruments used on a patient.

¹ From section B5.3 of the NHMRC 2010 *Australian Guidelines for the Prevention and Control of Infection in Healthcare* and Appendix 1 of the CDNA *Australian National Guidelines for the Management of Health Care Workers known to be infected with Blood-Borne Viruses*.

A. Infection control

1. What is infection control?

The purpose of infection control in dental practice is to prevent the transmission of disease-producing agents such as bacteria, viruses and fungi from one patient to another, from dental practitioner and dental staff to patients, and from patients to dental practitioner or other dental staff. In addition, it is necessary that endogenous spread of infection is also prevented by limiting the spread of infectious agents.

Successful infection control involves:

- understanding the basic principles of infection control;
- creating systems that allow infection control procedures to be implemented effectively and make compliance with them easy (this includes having clear procedural documentation, and comprehensive training of dental staff together with a process of regular monitoring of the application of these systems and procedures);
- keeping up-to-date regarding specific infectious diseases, particularly newly-evolving infection challenges such as avian (H5N1 or H7N9) influenza, emerging human influenza viruses, and multiple resistant organisms, and how to take precautions against them; and
- identifying settings that need modified procedures (e.g. nursing homes).

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, when the dental staff member's hands or clothing become contaminated, where patient-care devices are shared between patients, when infectious patients have contact with other patients, or where 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 viral influenza, can be transmitted through respiratory droplets (i.e. large-particle droplets > 5 microns in size) generated by a patient 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.

Droplet transmission can occur when a staff member's hands become contaminated with respiratory droplets and transferred to susceptible mucosal surfaces such as the eyes, 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 into or via contaminated hands.

There is good evidence viral influenza and certain other respiratory infections can spread via aerosols as well as by droplets. This has implications in terms of how close items, such as open boxes of gloves, are positioned in relation to possible sources of contamination, such as the patient's mouth or the instrument washing sink of the sterilising room. Since concentrations of pathogens in aerosols decrease with increasing distance from the patient's mouth,² a distance of 1.829 m (6 feet) has been recommended for medical staff examining patients with suspected influenza. This distance serves as a useful evidence-based measure in terms of how far open glove boxes should be from the patient's mouth to minimise the likelihood of aerosol contamination.

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. For instance, 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 person is approximately one in three (depending on the infective status of the source of injury). In comparison, the chance of transmission of the hepatitis C virus (HCV) by similar means is one in 30; and for HIV/AIDS, one 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 control focuses on limiting or controlling factors influencing 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 efficient hand hygiene;
- using personal protective equipment;
- using disposable products where appropriate (e.g. paper towels); and
- following risk minimisation techniques such as using rubber dam and pre-procedural mouthrinsing.

² Bischoff WE, Swett K, Leng I, Peters TR. Exposure to influenza virus aerosols during routine patient care. *J Infect Dis*, 2013;207:1037-1046.

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

- undertaking regular hand hygiene before gloving and after glove removal;
- 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;
- respiratory hygiene and cough etiquette;
- using aseptic non-touch techniques where indicated;
- appropriately handling used linen and clinical gowns; and
- using, where appropriate, environmental barriers such as plastic coverings on surfaces and items that may become contaminated and are difficult to clean.

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. radiographs, 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.

There are a number of situations where patients have a specific highly infectious condition that necessitates the use of transmission-based precautions in addition to standard precautions, to address the increased risk of transmission.

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

The requirements for transmission-based precautions are listed in the NHMRC Guidelines. In brief, contact precautions are used when there is a risk of direct or indirect contact transmission of infectious agents (e.g. MRSA, *Clostridium difficile*, or highly contagious skin infections/infestations) that are not effectively contained by standard precautions.

Droplet precautions are intended to prevent transmission of infectious agents spread through respiratory or mucous membrane contact with respiratory secretions. Positive pressure ventilation is not required as these microorganisms do not travel over long distances in droplets or aerosols.

Airborne precautions, such as wearing P2 (N95) surgical respirators, are designed to reduce the likelihood of transmission of microorganisms that remain infectious over time and distance when suspended in the air. 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*. At present there is a lack of evidence from clinical trials regarding the additional benefit of P2 (N95) respirators over conventional surgical masks for reducing the risk of transmission of viral influenza. A mask tightly sealed 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 mask blocks 56% and a poorly fitted respirator only 66% of infectious virus particles.³ In other words, a poorly fitted N95 surgical respirator performs no better than a loosely fitting surgical mask.

The majority of procedures undertaken in dentistry generate aerosols. Therefore, it is important to recognise that patients with active tuberculosis, measles, chickenpox or viral influenza pose a considerable risk to dental staff and patients if they undergo dental treatment. Patients for whom airborne precautions are indicated, formal risk assessment should be undertaken to determine the need for dental treatment.

Non-urgent treatment should be delayed or postponed. If patients require urgent care, transmission-based precautions must be followed.

³ 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 simulated patient examination room. *Clin Infect Dis*. 2012;54:1569-1577.

Additional measures would include patients being seen as the last patients of the day. Use of pre-procedural mouthrinses and rubber dam is essential, together with minimising the use of aerosol-generating techniques, and two cycles of cleaning for environmental surfaces. In general, there will be few situations where the use of analgesics and appropriate antimicrobial agents will not allow a delay until the patient is no longer infectious.

2. Legislative frameworks

Registered dental practitioners are legally required to comply with the Dental Board of Australia's policies and guidelines. This responsibility cannot be delegated to the dental assistants or practice manager or practice owner. Rather, each registrant must ensure they fulfil the obligations to practise in a safe and hygienic manner.

In the area of infection control, the Dental Board stipulates the expectations for infection control are based on the current edition of the *ADA's Guidelines for Infection Control* and NHMRC Guidelines, plus current versions of either *AS/NZS 4815* or *AS/NZS 4187* for instrument reprocessing.

It is essential for staff members to understand the infection 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 infection control protocols). Such directives can be shown to be reasonable by reference to the current *ADA's Guidelines for Infection Control*.

3. Duty of care

Dental practitioners have a common law legal duty of care to their patients, and must ensure that effective infection control measures are in place and are complied with in the practice.

For all staff members, there are also duties of care to the person 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 the assessment of their performance.

Staff members who repeatedly demonstrate poor compliance with infection control expectations should be given both verbal warnings in private as well as written warnings, and be reminded of the points above and their need to follow lawful safety directives, as this will be very useful in the event of a later charge of unfair dismissal. Jurisdictional work health and safety laws are framed in such a way as to empower employers in the situation where an employee has shown wilful disregard of the required safe working procedures.

The Dental Board 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.⁴ 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; and ensure that, in attending a patient, they take such steps as are practicable to prevent or minimise the spread of infectious diseases. Consequently, all dental practitioners and clinical support staff have a responsibility to follow the specific infection control policies in their place of work.

⁴ See the Dental Board of Australia *Guidelines on Infection Control*, July 2010 <http://www.dentalboard.gov.au/Codes-and-Guidelines.aspx>

Dental practitioners must:

- develop and implement work practises to ensure compliance with infection control standards;
- document their infection control protocols in an infection control manual;
- ensure that all dental staff have read the infection control manual and have been trained in the infection control protocols used in the practice;
- provide their dental staff with access to key resources such as these Guidelines, the NHMRC Guidelines, and AS/NZS 4815 or AS/NZS 4187;
- have in place a system of reporting, monitoring and rectifying breaches of infection control protocols (which would involve addressing this topic in staff meetings and recording the outcomes from such discussions);
- ensure an immunisation programme for dental staff is in place and is in accordance with the current edition of the *Australian Immunisation Handbook*;
- maintain a vaccination 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 personal protective equipment;
- implement a hand hygiene programme consistent with the national hand hygiene initiative from Hand Hygiene Australia (HHA) which promotes the use of alcohol-based hand rubs 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;
- implement systems for environmental cleaning;
- implement systems for processing of reusable instruments and devices;
- be aware of their immune status. The Dental Board stipulates that all dental practitioners must be aware of their infectious status for the blood-borne viruses HBV, HCV and HIV, seek expert medical advice from an infectious diseases specialist familiar with the requirements of dental practice or from an expert advisory panel if diagnosed with a blood-borne virus. Such advice could include a prohibition on undertaking exposure prone procedures (EPPs) if viraemic; and
- follow through after potential exposures to blood-borne viruses, including reporting the incident if it was an occupational exposure, undergoing testing, and if necessary, seek specialist medical management.

Note: it is not necessary for practitioners to stop performing EPPs after the exposure, unless they are found to have become infected with the blood-borne virus.

Under work health and safety legislation, practice owners have an obligation to provide and maintain a safe working environment for employees and for members of the public. This means 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 control in their workplace.

The law demands that dental practitioners take reasonable steps to accommodate a patient's disability. It is a breach of anti-discrimination laws for dental practitioners to refuse to treat or impose extra conditions on a patient who has a disability such as being infected with or being a carrier of a blood-borne virus.⁵

4. Treating patients with blood-borne viral infections

Patients with hepatitis B, C or HIV are treated using standard precautions and the same cleaning and sterilisation techniques as for other patients. It is important for dental practitioners and their staff to feel assured that their infection control procedures are adequate for all patients – whether patients carry blood-borne viral infections or not. Patients should not want to hide their infectious status because of the way the staff act in their presence – and those providing their care want to know about these conditions for other reasons, so that care can be provided safely and effectively.

5. Infected dental practitioners

All dental practitioners when applying for or renewing their registration undertake to comply with all relevant legislation, Dental Board registration standards, codes and guidelines – this includes the Dental Board of Australia's *Guidelines on Infection Control*.

They also declare that they are aware of their infection status for blood-borne viruses and will comply with the Communicable Diseases Network Australia's (CDNA) *Australian National Guidelines for the Management of Health Care Workers known to be Infected with Blood-Borne Viruses* and with the requirements of the Dental Board's *Guidelines on Infection Control* in relation to blood-borne viruses.

The Dental Board requires registered dental practitioners to comply with the CDNA *Australian National Guidelines for the Management of Health Care Workers known to be Infected with a Blood-borne Viruses* (CDNA National Guidelines), irrespective of what local 'workplace' guidelines are in place.

They must follow the advice of their treating medical practitioner and any additional stipulations of jurisdictional public health authorities. If a dental practitioner knows or suspects they have been infected with a blood-borne virus, they should consult an appropriately experienced medical practitioner or infectious disease specialist familiar with the requirements of dental practice. This includes seeking treatment, modifying their clinical practice where appropriate, which may include not performing EPPs, in accordance with the relevant policies and guidelines of the Dental Board and the current CDNA National Guidelines. It is not appropriate for a practitioner to rely on their own assessment of the risk that they pose to patients.

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.

The Dental Board's *Guidelines on Infection Control* state that practitioners are required to make a declaration that they are aware of their blood-borne virus status and that they will comply with the CDNA National Guidelines as well the requirements of the Dental Board's *Guidelines on Infection Control*. This policy also applies to registered dental students.

The CDNA National Guidelines set the requirements in relation to the management of healthcare workers including dental practitioners with blood-borne viruses and any restrictions in the performance of exposure-prone procedures. It is essential that dental practitioners be aware of and comply with the most current version of these guidelines which may change as new evidence in the management of healthcare workers with blood-borne viruses emerges.

Risks of transmission from an infected clinician to a patient are 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 operator skill and experience. Effective anti-viral drug treatment protocols reduce the infectivity of individuals, and persistent negative results may result in a review of the infectious status of the practitioner. This may influence whether or not the practitioner may perform EPPs. The CDNA National Guidelines recommend regular testing for blood-borne viruses for the duration of the practitioner's career, to ensure virus levels remain undetectable.

⁵ Anti-discrimination, privacy, industrial relations and equal opportunity laws apply. Relevant state, territory and commonwealth legislation is listed in the References and Additional Reading.

B. Standard precautions of infection control

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

1. Hand hygiene

Hand hygiene is a general term applying to processes aiming to reduce the number of microorganisms on hands. This includes either the application of a waterless antimicrobial agent, e.g. alcohol-based hand rub (ABHR), to the surface of the hands, or the use of soap/solution (plain or antimicrobial) and water, followed by patting dry with single-use towels.

Comprehensive information on contemporary hand hygiene measures is found on the Hand Hygiene Australia (HHA) website www.hha.org.au.

The HHA protocol is to use an ABHR for all clinical situations where hands are visibly clean. The normal routine in dental practice should be for dental staff to use ABHR between patient appointments and during interruptions within the one appointment. ABHR is applied onto dry hands and rubbed on for 15-20 seconds, after which time the hands will be dry.

Hand hygiene is required after removal of gloves. This must be done before the dental practitioner writes or types up patient notes. Hand gel is used again immediately before gloving for the next patient.

If handshaking occurs, either at the start or end of an appointment, it may increase the risk of transmission of skin-borne pathogens.⁶ This risk can be mitigated by undertaking additional hand hygiene after shaking hands. Practitioners should not shake a patient's hand when greeting them in the reception without having first completed hand hygiene.

ABHR can be used as often as is required. However, a compatible moisturiser should be applied up to four times per day. ABHR must only be used on dry skin; wet hands dilutes the product thus decreasing its effectiveness. Unlike detergents, ABHRs do not remove skin lipids and they do not require paper towel for drying.

A range of ABHR products are registered with Therapeutic Goods Administration (TGA). These contain a sufficiently high level of alcohol (ethanol or isopropanol) to achieve the desired level of decontamination. Practitioners must not use ABHR products that do not carry TGA approval. Typically, suitable ABHR will contain a skin emollient to minimise the risk of skin irritation and drying, have minimal colour and fragrance, and will leave the hands in a dry state after being rubbed in for 15-20 seconds.

Bottles of ABHR should not be 'topped up' because the outside of the dispenser may become contaminated. Empty dispensers should be discarded and not reused. To date, attempts to recycle/reuse ABHR dispensers have proven not to be cost effective in Australia.

Staff with an existing skin irritation may experience a stinging sensation when first using ABHR. This usually subsides over several weeks with the ongoing use of an emollient-containing ABHR. However, medical advice should be sought if symptoms persist.

Both alcohol-based gels and solutions are available with proven efficacy designed for use in healthcare settings. ABHR products designed for domestic use lack TGA registration. As a result, domestic products must not be used in clinical settings. Only a limited number of alcohol-containing foams are certified for use for hand hygiene in healthcare settings. Particular attention to handwashing 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 inactivate norovirus, hepatitis B and certain other enteric viruses which spread readily from contact with contaminated surfaces.

Dental staff must be educated on the correct use of ABHR and handwashing products, and caring for their hands. Regular use of skin moisturisers both at work and at home should be promoted. Moisturising skin care products used in the dental practice must be compatible with the ABHR.

For further information on hand decontamination with ABHR, see www.hha.org.au. This site also has posters on 'How to Hand Rub' and 'How to Handwash' which can be downloaded for use in dental practice.

Hands must always be washed at the start of a working session, after toilet breaks, and when leaving the surgery. They must be washed with soap and water when visibly dirty or contaminated with proteinaceous material, or visibly soiled with blood or other body fluids. Washing hands with soap and water is preferred in these situations as it guarantees a mechanical removal effect.

Washing hands with soap and water immediately before or after using an ABHR is not only unnecessary, but may lead to dermatitis. For this reason, it is both desirable and convenient to position ABHR dispensers close to the clinical working area (but away from contamination by splash and aerosols), rather than at an existing handwashing sink.

Handwashing should be undertaken in dedicated (clean) sinks preferably fitted with non-touch taps (or carried out using a non-touch technique) and not in the (contaminated) sinks used for instrument cleaning.

⁶ http://apps.who.int/iris/bitstream/10665/78060/1/9789241503372_eng.pdf and http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf

If touch taps are used, the taps may be turned on and off with a paper towel.

Hand hygiene must be undertaken before and after contact with every patient, before gloves are put on and after they are removed. If hands are washed, wet hands must be dried with single-use linen or disposable paper towels.

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 as well as 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 from irritant contact dermatitis, primarily caused by frequent and repeated use of handwashing products – especially soaps, other detergents, and paper towel use, resulting in drying skin. Other factors that may contribute to dermatitis include fragrances and preservatives in hand care products (which can cause contact allergies), donning gloves while hands are still wet, using hot water for handwashing, failing to use moisturisers and using poor quality paper towels.

Lacerated, chafed or cracked skin can allow entry of microorganisms, any cuts or open wounds need to be covered with a waterproof dressing. All hand, wrist or nail jewellery, (e.g. rings, wrist watches and bracelets) must be removed prior to putting on gloves as their presence compromises the fit and integrity of gloves and promotes significant growth of skin microorganisms.

A plain band ring such as a wedding ring may be left on for non-surgical procedures but may cause irritation of the underlying skin, in which case it should be removed.

Artificial fingernails must not be worn as they can harbour microorganisms. Nail polish should be clear, but preferably dental staff should not wear nail polish. All fingernails must be kept short to prevent glove tears and to allow thorough hand cleaning. The hands of dental staff should be free of jewellery and false nails, with any cuts or abrasions covered with waterproof dressings. Wrist watches are also discouraged as they impair correct handwashing.

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

2. Personal protective equipment

Wearing personal protective clothing and equipment where 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, including gloves, mask, eyewear and gown must be removed before leaving the work area (e.g. dental surgery, instrument processing or laboratory areas).

Gloves

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

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 occur to the gloves during use.

Disposable gloves used in patient care must not be washed before or after use nor should they be reused. A new pair of gloves must be used for each patient and changed as soon as they are cut, torn or punctured. Gloves must be removed or overgloves worn before touching any environmental surface without a barrier or before accessing clean areas. Gloves must be removed as soon as clinical treatment is complete and hand hygiene undertaken immediately to avoid the transfer of microorganisms to other patients or environments.

Non-sterile examination gloves may be worn for non-surgical general dental procedures. Gloves supplied for use in dental practice are required to conform to **AS/NZS 4011**. Sterile gloves must be worn when a sterile field is necessary for procedures such as oral, periodontal or endodontic surgery.

Both opened and unopened boxes of gloves must be stored away from aerosol contamination where they will not be exposed to droplets generated by patient care. Gloves must be worn when cleaning instruments and environmental surfaces. The type of glove worn must be appropriate to the task. For instance, 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 instrument cleaning, rather than disposable latex gloves. These utility gloves can be reused, but must be washed in detergent after each use, stored dry and replaced if torn, cracked, peeling or showing signs of deterioration.

It is strongly recommended to use powder-free gloves for patient care because this reduces exposure of staff to latex proteins via both respiratory and contact routes, thereby minimising the risk of developing latex allergy. If the dental practitioner, clinical support staff member or patient has a proven or suspected allergy to latex, alternatives must be used such as neoprene or nitrile gloves. A latex-free protocol must also be followed including use of non-latex rubber dam, and use of non-latex materials such as prophylaxis cups.

Note: patients with multiple food allergies 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 *ADA's Practical Guide to Infection Control*.

Masks

Dental procedures can generate large quantities of aerosols of three microns or less in size and a number of diseases may be transmitted via the airborne (inhalational) route. In the dental surgery environment, the most common causes of airborne aerosols are the high-speed air rotor handpiece, the ultrasonic scaler and the triplex syringe. The aerosols produced may be contaminated with bacteria and fungi from the oral cavity (from saliva and dental biofilms), as well as viruses from the patient's blood.

Therefore, dental practitioners and clinical support staff must wear suitable fluid-resistant surgical masks that block particles of three microns or less in size. Masks protect the mucous membranes of the nose and mouth and must be worn wherever there is a potential for splashing, splattering or spraying of blood, saliva or body substances, or where there is a probability of the inhalation of aerosols with a potential for transmission of airborne pathogens. However, it is suggested that masks be worn at all times when treating patients to prevent contamination of the working area with the operator's respiratory or nasal secretions/organisms.

Surgical masks for dental use are fluid-repellent paper filter masks and are suitable for both surgical and non-surgical dental procedures that generate aerosols. The filtration abilities of a mask begin to decline with moisture on the inner and outer surfaces of the mask after approximately 20 minutes.

It is difficult to change masks during long procedures (such as surgical procedures), and is not necessary unless the mask becomes completely wet from within or without.

Masks supplied for use in dental practice are required to conform to **AS/NZS 4381**. They are required to be adapted to the user's face. Compared to a surgical mask with two ties, eddy currents are more of an issue with ear loop masks because of their poor fit, since they gape at the sides and often around the chin.

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

Masks must:

- be put on before performing hand hygiene and donning gloves;
- be fitted and worn according to the manufacturer's instructions – this means using both tie strings where the mask has two ties, and adapting the mask to the bridge of the nose;
- cover both the nose and mouth, and where possible be folded out fully to cover the chin and upper neck; and
- be removed by touching the strings and loops only.

Masks must not:

- be touched by the hands while being worn; or
- be worn loosely around the neck while the dental practitioner or clinical support staff member walks around the premises, but be removed and discarded as soon as practical after use.

Eye protection

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. Reusable or disposable eyewear supplied for use in dental practice is required to conform to **AS/NZS 1337**. An alternative to protective eyewear is a face shield. However, this does not protect from inhaled microorganisms and must be worn in conjunction with a surgical mask.

Eyewear protects the eye 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), cutting wires and cleaning instruments and equipment.

Eyewear must be optically clear, anti-fog, distortion-free, close-fitting and should be shielded at the sides. Prescription lenses are not a substitute for protective eyewear unless they are inserted in frames designed to provide a suitable level of protection to the orbital region.

Patients must be provided with protective eyewear to minimise the risk of possible injury from materials or chemicals used during treatment. Tinted lenses may protect patients from the glare of the operating light. Spectacles for vision do not 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 single-use or can be reused after cleaning with detergent and water. Reuseable protective eyewear for patients touches intact skin which is a non-critical site. In cases where the patient has sustained facial trauma and it is likely blood contamination of the patient's protective eyewear occurs, use of disposable eyewear would be prudent as it removes the need for complex decontamination.

Protective clothing

Protective clothing (e.g. disposable gown), should be worn while treating patients when it is possible aerosols or splatter are likely to be generated or when contaminated with blood or saliva. The most suitable type of protective clothing and equipment used varies according to the nature of the procedure and is a matter of professional judgement. Where there is a risk of large splashes with blood or body substances, impermeable protective clothing must be worn. Disposable protective clothing items should be placed in general waste after use, or if visibly contaminated with blood these must be disposed of according to local waste management regulations.

Items of protective clothing must be changed as soon as possible when they become visibly soiled or after repeated exposure to contaminated aerosols. The protective gown worn in the clinical area must be removed before eating, drinking, taking a break or leaving the practice premises.

Uniforms worn by dental practitioners and clinical support staff must be clean and in good condition. Reusable cloth gowns and coats can be washed in a separate washing cycle.

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).

3. Surgical procedures and aseptic technique

The requirements for oral surgical procedures include using sterile gloves, appropriate sterile drapes, sterile instruments, and surgical handwashing (using an anti-microbial handwashing solution). Long hair must be tied back and covered and beards must also be covered.

It is important to wear sterile gloves for surgical dental procedures (including placing dental implants), as stipulated in the NHMRC Guidelines. Entry into sterile tissue for removal of fully unerupted teeth, enucleation of radicular cysts and endodontic surgery require sterile gloves.

The principles of sterile aseptic technique must be applied to all surgical procedures undertaken in the dental practice setting. Sterile gloves must be used when EPPs are undertaken such as incision into mucosal soft tissues, surgical penetration of bone or elevation of a muco-periosteal flap. Sterile gloves are required for the surgical removal of teeth, for minor oral surgery procedures, for periodontal surgery, surgical endodontics and for dental implant placement.

In addition, these procedures include specific requirements for surgical handwashing (using an anti-microbial handwashing solution), gowning and gloving. Sterile gloves supplied for use in dental practice are required to conform to *AS/NZS 4179*.

Supplies for use during oral surgery, such as sterile cotton pellets and gauze can be sterilised in the dental practice using a cycle for porous loads, or purchased already sterile. It will be uncommon for office based dental practice to require large volumes of porous items such as dressings and bandages. In line with *AS/NZS 4815* and *AS/NZS 4187* it is recommended that goods such as dressings and bandages be obtained sterile from commercial sources, ready for use.

4. Management of sharps

Frequently, the practice of dentistry involves the use of sharp instruments. Occasionally, conditions of limited access and poor visibility will increase the risk of a penetrating injury to dental staff and expose 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 to blood-borne diseases in the dental surgery.

Consequently, it is essential all sharp instruments must be handled and used with care, and the techniques 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 and must be placed in a puncture-resistant tray or bowl after each use. Instruments and sharp items must be carried from the surgery to the sterilising area in a lidded puncture-resistant sharps transport container.

Needles must not be re-sheathed unless using an approved recapping device or single-handed technique. 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 staff members are not injured during patient changeover.

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.

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

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

Disposal of sharps

The clinician using a disposable sharp item must be responsible for its immediate safe management or disposal after use. This must be at the point of use (i.e. the operatory or treatment room) unless transferred in an appropriate container.

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

Appropriate sharps containers are those conforming to *AS 4031* or *AS/NZS 4261* as applicable.

A separate sharps container should be located in each operatory, close to the point of use of any disposable sharp. Disposable sharps should be placed directly into an approved sharps container, while reusable sharps such as burs are placed into a stand. This should be the first step in the changeover process between patients. 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.

Burs should be removed from handpieces before removing the handpiece from the dental unit, to reduce the risk of sharps injury.

Disposable sharps, if not placed by the operator into a sharps bin located at the chairside, could alternatively be placed after use in a specific puncture-proof dish to minimise risk. In this situation, the operating clinician has a responsibility to minimise the risk of sharps injury when finished with the disposable item.

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. Sharps containers must be sealed when they have been filled to the line marked on the container or when three-quarters full, and then collected by licensed waste contractors for disposal according to local waste management regulations.

5. Management of clinical waste

Management of medical and related waste (also referred to as contaminated waste) must conform to local state or territory regulations. Jurisdictional Environmental Protection Agency (EPA) regulations should be consulted for accepted waste management protocols. In general, contaminated waste should be held in leak-proof thick yellow bags labelled with the biohazard symbol, and removed by a licensed contractor. These clinical waste bags must conform to *AS/NZS 3816*.

Waste in the dental practice should be separated according to its category (medical or non-medical) at the point of generation. Bags and containers for medical waste should be appropriately colour coded and labelled as biohazard or medical waste. Medical waste includes recognisable human tissues (excluding teeth) and material or solutions containing free-flowing blood.

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 mercury used in dental practise) must never be disposed of at local refuse tips that use compaction of an open landfill. Medical waste and sharps containers must be stored securely before collection by licensed waste contractors for final disposal using approved technologies by licensed/accredited contractors.

Extracted teeth once cleaned of visible blood, debris, adherent soft tissues and saliva may be given to the patient.

Alternatively they can be wrapped in paper towel or placed in a disposable cup and covered with setting plaster before disposal in the general waste. In some states and territories it is illegal to incinerate teeth restored with amalgam because of issues with mercury vapour emissions, therefore these teeth must not be placed in medical waste or into sharps containers. Local regulations may apply on waste management and disposal of teeth.

Information on chemical waste management for radiography is provided in the *ADA's Practical Guide to Infection Control*.

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.

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 control. Work areas should be well lit and ventilated with sufficient uncluttered and easily cleaned bench space to accommodate necessary equipment. This is important when planning new premises or renovating existing premises.

The dental operator and instrument reprocessing rooms must have clearly defined clean and contaminated zones. The contaminated zone is the area which becomes contaminated by splashes and droplets originating from the patient's mouth (typically within a distance of one metre). Aerosols generated from patient care may extend further than splashed material (up to approximately 1.8 metres).

The clean zones of the dental practice include office areas, staff room, 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 contaminated with material from patient care, as well as the instrument cleaning area. After gloving, staff may move from the clean zone to the contaminated zone but never the reverse direction. In the dental operator, 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 working surfaces during the changeover between patients, rather than using contaminated gloves from assisting with the previous patient.

Floor coverings in the dental operator 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 of the flooring with the walls are preferred for ease of cleaning.

Carpet is acceptable in the waiting room but must not be used in clinical, laboratory and instrument reprocessing areas as it is not impervious.

Computer keyboards in the dental operator may harbour microorganisms such as *Staphylococcus aureus* (MRSA) and should be covered where possible in treatment areas, and regularly cleaned in non-treatment areas. A number of keyboards are available with flat surfaces which can be wiped over with detergent or with alcohol-impregnated wipes between patient appointments. 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.

Eating and common room areas for dental staff must be separate from patient treatment areas and the dental laboratory and conform to work health and safety regulations.

Lunchroom crockery must not be washed in the handwash sinks or in instrument wash basins. Food must not be stored in a refrigerator with dental materials, sealed clinical specimens or medical products such as drugs or blood because of the risks of cross-contamination.

Cleaning the environment

Floors, walls and curtains pose minimal risk of disease transmission in a dental practice; nevertheless, these surfaces must be maintained in a clean and hygienic condition.

State and territory public health regulations require that premises be kept clean and hygienic.

Inanimate objects such as toys act as fomites and can spread infections through indirect contact. For this reason, it is prudent to wipe down the hard surfaces of toys in reception and waiting areas on a periodic basis using detergent impregnated wipes designed for use on clinical hard surfaces, to reduce the levels of transient microorganisms.

Environmental surfaces such as bench tops outside the contaminated zone must be cleaned weekly using detergent and water. The practice should develop a schedule to ensure areas including floors, window sills, door handles, and telephone handsets are cleaned weekly. Likewise, a schedule should also be developed for cleaning solid surfaces in the waiting room. Walls, blinds and window curtains in patient care areas must be cleaned when they are visibly dusty or soiled.

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 bench tops 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 neutral detergent. Standard precautions (including wearing of personal protective equipment as applicable) must be implemented when cleaning these surfaces.

A neutral detergent and warm water solution or commercially packaged pre-moistened, neutral detergent wipes should be used for all routine and general cleaning. Neutral pH detergents are best for environmental cleaning because they are less likely than acid or alkaline detergents to damage metals such as stainless steel or to cause skin irritation.

Neutral detergents also leave little residue on surfaces. Fresh cleaning solutions of detergent should be prepared daily as instructed by the manufacturer. Containers for these fresh solutions should be emptied, washed and dried overnight prior to refilling for subsequent use.

Written protocols for cleaning the practice must be prepared, including methods and frequency.

General work surfaces in the dental operatory outside the contaminated zone must be cleaned after each session or when they become visibly soiled. Sinks and wash basins must be cleaned at least daily, or more frequently as appropriate.

Usually, spittoons cannot be removed for cleaning or sterilising. They are not classified as instruments as they do not contact any part of the body. The spittoon should be cleaned after each patient by wiping with neutral detergent using disposable paper towels.



C. Infection control strategies within the contaminated zone

The contaminated zone boundaries should be clearly defined, because this has implications for surface management and for the placement of equipment. The goal during dental treatment is to contain contamination within this zone, both by 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 use of rubber dam, pre-procedural antiseptic mouthrinses, high volume evacuation and correct patient positioning. Rubber dam minimises the spread of blood or saliva. When rubber dam is not applied, high volume aspiration becomes essential.

All surfaces and items within the contaminated zone must be deemed contaminated by the treatment in progress. These surfaces must be cleaned and the items in the zone disposed of, decontaminated, or cleaned and sterilised before commencing treatment of the next patient. Clinical contact surfaces in the contaminated zone not barrier protected 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 and aerosols.

For equipment that is difficult to clean, a protective covering such as a plastic wrap may be necessary. Items where barrier protection may be required include:

- the operating light handle and its hand operated switch, the X-ray head, tubing for suction, triplex syringe, and instrument cradles;
- the polymerising light, intraoral camera and fibre-optic illuminator; and
- the bracket table and handle.

Any surface barriers used on such surfaces should be disposed of after each patient treatment, and a new barrier placed in general waste.

In an operatory utilised by multiple dental practitioners, and where dental assistants are not routinely assigned to the same operatory, use of barriers may be preferable. However, if barriers are not used, a documented cleaning protocol should be followed.

1. Clean and contaminated zones

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

Dental practitioners and clinical support staff should not bring personal effects, changes of clothing or bags into clinical (patient treatment) areas where cross-contamination is likely to occur.

It is recommended, where possible, that materials such as cotton rolls, dental floss, gingival retraction cord and restorative materials should be pre-dispensed from bulk supplies that are kept in drawers or containers which keep these bulk supplies free of contamination from splashes or aerosols.

However, if additional instruments and materials have to be retrieved from outside the contaminated zone during a patient treatment, it must be by a method that does not contaminate other instruments or materials in the drawers.

The options include:

- open drawers by elbow touch; retrieve instruments and materials with a no-touch technique such as transfer tweezers; use over-gloves or single-use barriers on drawer handles. If transfer tweezers are used, these must be kept separate from other instruments;
- gloves must be removed and hands decontaminated with ABHR before dispensing additional materials.

When moving from the contaminated zone to a clean zone to touch non-clinical items without a barrier, gloves must be removed and hands washed or decontaminated with ABHR before touching the item. The individual must then perform hand hygiene (e.g. with ABHR) and re-glove before re-entering the contaminated zone.

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 by dust, aerosols, and droplets. They must never be stored loose out of their blister packaging in cardboard containers as these absorb water and cannot be cleaned.

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 sharps and must be disposed as sharps waste. If they are polymer, they 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.

2. Waterlines and water quality

The organisms which 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 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.

Most dental unit waterlines contain biofilm, which acts as a reservoir of microbial contamination. Biofilm in dental unit waterlines may be a source of known pathogens (e.g. *Pseudomonas aeruginosa*, non-tuberculous mycobacteria, and *Legionella* spp). Waterlines must be cleaned and disinfected in accordance with the manufacturer's instructions. 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.

An independent water supply can help to reduce the accumulation of biofilm. The manufacturer's directions should be followed for appropriate methods to maintain the recommended quality of dental water and for monitoring water quality. Biofilm levels in dental equipment can be minimised by using a range of measures, including water treatments using ozonation or electrochemical activation, chemical dosing of water (e.g. with hydrogen peroxide, peroxygen compounds, silver ions, or nanoparticle silver), flushing lines (e.g. triple syringe and handpieces) after each patient use, and flushing waterlines at the start of the day to reduce overnight or weekend biofilm accumulation. This is particularly important after periods of non-use (such as vacations and long weekends). Flushing each day has been shown to reduce levels of bacteria in dental unit waterlines.^{7,8}

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

Water quality

Sterile irrigants such as sterile water or sterile saline as a coolant are 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 NHMRC *Australian Drinking Water Guidelines*. The number of bacteria in water used as a coolant/irrigant for non-surgical dental procedures should be less than 500 CFU/mL, since this is a widely used international limit for safe drinking water.⁹ When treating immunocompromised patients, it is recommended that water from dental unit waterlines contain less than 200 CFU/mL. Bacterial levels can be tested using commercially available test strips or through commercial microbiology laboratories.

Levels of microorganisms in dental unit waterlines can be assessed using commercial test kits. Typically, these are a growth medium which is inoculated with a water sample and then incubated at room temperature for up to seven days, after which time colony counts are made.

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

3. Single-use items

Single 'one patient' use non-sterile items, including disposable triple syringe tips, plastic low and high velocity evacuator tips, prophylaxis cups, micro-brushes, plastic Dappen dishes, and disposable impression trays must not be reprocessed and reused on another patient, but must be discarded after use. For common simple triple syringe designs (DCI or A-dec type), disposable triple syringe tips are preferred due to efficiency reasons (difficulty of cleaning and challenge to air removal and steam penetration).

Ultrasonic cleaning does not remove all bioburden from within the lumen of metal triple syringe tips, so accumulation of internal bioburden over time could potentially occur.

⁷ Cobb CM, Martel CR, McKnight SA3rd, Pasley-Mowry C, Ferguson BL, Williams K. How does time-dependent dental unit waterline flushing affect planktonic bacteria levels? *J Dent Educ.* 2002;66(4):549-55.

⁸ Watanabe E, Agostinho AM, Matsumoto W, Ito I. Dental unit water: bacterial decontamination of old and new dental units by flushing water. *Int J Dent Hyg.* 2008;6(1):56-62.

⁹ CDC (2003) Guidelines for Infection Control in Dental Health-Care Settings, page 29

Moreover, metal triple syringes need to be sterilised in a pre-vacuum cycle to ensure air removal and steam penetration. Many practices find disposable plastic tips for DCI/A-dec triple syringes easier to use and more convenient than metal syringe tips thus enhancing infection control.

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 very relevant to matrix bands, stainless steel endodontic files, reamers and broaches. These items are to be considered single-use items as there is currently no cleaning method validated as being effective in removing organic material from these 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, 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.

4. Matrix bands

Matrix bands contacting 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 before use to sterilise plain stainless steel matrix bands. A wide range of matrix bands are now available including some combined with wedges for interdental protection which are not suitable for steam sterilising because of heat sensitive components (e.g. combination of a steel plate and a plastic wedge).

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 *AS/NZS 4815*, 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 multiple uses must be discarded into the sharps waste. They are also difficult to clean. Therefore, staff must look for the tell-tale signs of wear and corrosion as these burs are reprocessed.

Typically, this is seen after the third or fourth cycle of use, particularly when a corrosion inhibitor is not used during reprocessing. Dental practices may use lower cost stainless steel burs as single-use items to eliminate the need to clean and inspect them. This ensures burs when used are always sharp. Without special lighting and magnification, it is not possible to properly clean and inspect burs with small cutting heads.

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

Most surgical burs for dento-alveolar surgery are designed for reprocessing, and are made of materials such as tungsten carbide that do not degrade under steam sterilising. Likewise, silicon nitride burs are also designed for reprocessing.

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

6. Implant drills

The manufacturer's advice is important, as the materials used in implant drills vary, with some being made from stainless steel and intended for reuse, and others for single-use only. For stainless steel burs, reuse may be possible if appropriately cared for, undamaged and correctly reprocessed to be free of contamination.

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

D. Instrument reprocessing

Contaminated instruments can transmit infections between patients and 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 and, as a general rule, if an instrument cannot be cleaned it cannot be safely reprocessed. Reprocessing instruments must be in accordance with *AS/NZS 4815* and/or *AS/NZS 4187*.

1. Categories of instruments: infection risk relative to instrument use¹⁰

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.

Equipment and instruments used in the treatment of mucosal lesions or diseased soft tissue and that 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 electrosurgery, cryotherapy and related devices and tips.

Critical Item: 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 used immediately after sterilisation or bagged prior to sterilisation and kept stored in bags until used. Instruments stored in bags found to be damaged must be re-sterilised before use.
3. It is recommended to use batch control identification for these surgical instruments.

Semi-critical Item: 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; and other noncritical items when used occasionally in the mouth (e.g. Le Cron carver).

1. Instruments must be sterilised where possible and when not possible a barrier must be placed (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 in a way to prevent contamination prior to use by being kept bagged in closed drawers or in dedicated containers such as instrument cassettes.
4. Instruments used in semi-critical procedures should, where possible, be sterilised between patients but do not need batch control identification and are not required to be sterile at the point of use.
5. In some rare instances thermal disinfection using heat and water is acceptable and professional judgement needs to be exercised (e.g. thermal disinfection of denture polishing buffs may be appropriate as these are unlikely to be contaminated with blood).

Non-critical Item: Where there is contact with intact skin (lowest risk).

Examples: prosthetic gauges and measuring devices; face bows; protective eyewear; bib chain and Dappens dishes; 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 instruments should be stored in the same way as semi-critical instruments to prevent environmental contamination prior to use.

¹⁰ Based on the Spaulding classification system as described in section B4.1.1 of the 2010 NHMRC Guidelines.

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, functional testing, packaging, labelling, disinfection and sterilisation.

Part of the dental premises must be designated as the reprocessing area for reusable instruments (including cleaning, packaging and sterilising) and not used for any other purpose. Ideally, this should be a dedicated room separate from the treatment room(s) but if not possible because of limited space, instrument reprocessing should occur well clear of the contaminated zone with good workflow processes established and where there is minimal risk of aerosol contamination of the reprocessing area.

The cleaning process should flow in one direction, from contaminated to clean. If instrument washing must take place in the clinical or laboratory area due to limitations of space, then contaminated areas and instrument washing sinks must be clearly designated. Instrument flow must be in one direction: from contaminated through to clean. The instrument reprocessing area must be appropriate in layout and size for the volume of instruments being reprocessed.

To minimise particulate contamination and bio-burden (pathogenic bacteria, fungi and viruses), the principles of environmental control need to be observed. The reprocessing area must be divided into distinct areas for:

- receiving, cleaning and decontamination;
- preparation and packaging;
- sterilisation; and
- storage.

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

Following are design features for the reprocessing area which will facilitate successful infection control:

- instrument flow in one direction – from dirty to clean;
- good lighting to minimise the risk of sharps injury and enable inspection of cleaned instruments;
- 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 and taps provided with anti-splash devices. Ideally there should be several sinks – one for handwashing and one for manually washing contaminated instruments;
- both hot and cold water taps should ideally be non-touch or electronic in operation and liquid handwash dispensers should be operated by 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 area for sterile items awaiting storage; essential to prevent damage to packs.

Trays of instruments, when removed from the steam steriliser, should be placed on racks and not directly on the bench to prevent damage from water condensation under the cooling packages.

3. Transfer of contaminated instruments and sharps

Instruments should be carried to the sterilising area in a cassette or in a container that is preferably lidded and puncture-proof, to minimise handling and prevent the potential for a penetrating injury if the container is dropped.

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 sterilising room. Gloves must then be taken off and hands washed. Once the cleaning process commences, heavy-duty utility gloves must be worn.

Remember: instruments must pass in one direction only, from contaminated to clean.

4. Cleaning

Used dental instruments are often heavily contaminated with blood and saliva unless pre-cleaned by wiping at the chairside. Pre-cleaning is strongly recommended to improve the safety and effectiveness of instrument reprocessing. Dental instruments and devices contaminated with blood, saliva, cements and other contaminants must be treated to prevent substances drying on them. This will reduce the need for intensive cleaning by hand at a later stage. It is recommended that gross soil be removed from instruments by wiping them at the chairside onto an adhesive-backed sponge or dampened gauze on the bracket table using a one-handed method to prevent the risk of sharps injury during the wiping action. Alternatively, if they are unable to be cleaned immediately, the instruments may be soaked in detergent or an enzymatic agent to prevent hardening of residue.

For pre-cleaning, use a mildly alkaline detergent solution. Mildly alkaline detergents are more suitable for dissolving proteinaceous materials than neutral detergents, but are more irritating to skin should accidental splashing occur.

Under *AS/NZS 4815*, using enzymatic agents as a routine measure in instrument reprocessing is discouraged because of skin irritancy and other workplace health and safety issues. In dental practice, such agents are used in approved and validated protocols reprocessing rotary nickel-titanium for endodontic files. The use of these agents on an occasional basis for soaking surgical instruments before mechanical cleaning is acceptable.

The use of manual cleaning is discouraged where mechanical cleaning can be used for items, i.e. no hand scrubbing before instruments are placed into an ultrasonic cleaner or instrument washer/thermal disinfectant.

Instruments must be completely cleaned before being disinfected or sterilised as the presence of organic material left on instruments/equipment may prevent steam penetration during sterilisation.

Cleaning significantly reduces the number of microorganisms that need to be killed during sterilisation or disinfection. In addition, removing organic material lessens the chance of microorganisms multiplying on the instruments before reprocessing commences. If saliva dries and coagulates – particularly if blood is present or if hot water is used for cleaning – it can entrap the organisms inside the mass formed and inhibit penetration of the sterilising/disinfecting agent. When potential disease-producing organisms are killed, released endotoxins may remain, causing fevers in patients if introduced into cuts or wounds. Similarly, dislodged soil and foreign particles, even if sterile, can produce severe complications such as granulomas if they enter a cut in the skin or ulcer in a breach of the oral epithelium.

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

These staff must use heavy-duty utility (puncture and chemical-resistant) gloves, and wear eye protection/face shield and a mask. A waterproof/fluid-resistant gown/apron is also recommended. Cleaning techniques should aim to avoid spraying liquids into the air. Likewise, the lid should be kept on the ultrasonic cleaner when in use to prevent dispersion of aerosols and droplets of fluids.

Splashes of cleaning agents on a person's skin must be washed quickly with clean water and then treated in accordance with the manufacturer's instructions.

Instruments can be cleaned either by hand or mechanically (in either an ultrasonic bath or instrument washer/disinfectant).

Automated mechanical cleaning is preferred to manual cleaning as it is more efficient, reduces the risk of exposure to blood and reduces the risk of penetrating skin injuries from sharp or pointed instruments.¹¹

Following either manual or mechanical cleaning, instruments should be checked visually under good lighting to ensure all soil/contaminants are 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.

¹¹ Miller 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):39-43.

Manual cleaning

Lukewarm tap water is suitable for the manual cleaning of instruments.

Hot water should not be used at this stage as it coagulates protein which increases the difficulty of cleaning. Similarly, cold water solidifies lipids and should not be used.

Cleaning dental instruments by hand is the least efficient method, but if used, the instruments should be fully immersed in a dedicated instrument cleaning sink that is pre-filled with lukewarm water and instrument-grade detergent (not domestic detergents). A long-handled instrument brush should be used to remove debris until the item is visibly clean. A wire bur brush maintained in good condition may be used for cleaning tungsten carbide and diamond burs.

Common household detergents must not be used for manual instrument cleaning in dental practice as they are high foaming which impairs the visibility of instruments and increases risk of a penetrating injury during cleaning. Cleaning agents must not leave any residue after rinsing. This is difficult to achieve if household products are used.

The greater the pH of a detergent, the better it works but the more corrosion and skin irritation are likely to occur. This explains why neutral or mildly alkaline detergents are used for manual cleaning of instruments as well as hard surfaces such as benchtops. In contrast, moderately alkaline detergents are used in ultrasonic cleaners, and strongly alkaline detergents in thermal disinfectors and clothes washing machines. Low foaming detergents are a special requirement for ultrasonic cleaners.

Abrasive cleaners such as steel wool and abrasive cleaning powders should not be used as they can damage instruments and may leave residue.

Following manual cleaning, instruments should be thoroughly rinsed with warm to hot running water to remove all traces of detergent, and then inspected visually under good light to ensure all surfaces of all instruments are clean. Cleaning brushes used for manual cleaning must be washed, rinsed and stored dry.

Mechanical cleaning

Mechanical cleaning of instruments can be carried out in instrument washers or ultrasonic cleaners. Instrument washers/disinfectors are more efficient at pre-sterilisation cleaning than either ultrasonic cleaners or manual cleaning. Also, instrument washers are more efficient than a domestic dishwasher. The use of domestic dishwashers to process dental instruments is not permitted. In addition, instrument washers must not be used as a substitute for sterilisation.

There are both bench top and floor-mounted models of instrument washers for use in dental practice.

These connect into the water supply and drainage systems and must be serviced according to the manufacturer's instructions. These systems must comply with **AS 2945** or **AS 3836**. Washer/disinfectors must be well maintained and cleaned regularly to prevent formation of biofilms that could contaminate the instruments being processed.

Ultrasonic cleaners complying with **AS 2773** 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 are particularly useful for cleaning jointed instruments such as scissors, 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, tank, 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 heavily contaminated);
- an aluminium foil test (or another approved performance test) must be performed daily and the result recorded;
- lids must be closed during operation (to avoid dispersal of aerosols);
- instruments must be completely submerged in fluid; and
- no part of the operator's fingers or hands are permitted to be immersed in the fluid during operation of the cleaner.

At the end of each day, the ultrasonic cleaner tank must be emptied, cleaned and left dry.

For further information see the *ADA's Practical Guide to Infection Control*.

Drying instruments

Instruments to be sterilised by steam should be dried as residual moisture on instruments following cleaning may impede the sterilisation process. Suitable methods include using a drying cabinet, lint-free cloth or wipe, and a short rinse in very hot water.

Instrument washers have a drying cycle which eliminates the need for a separate drying step.

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 to be presented sterile at the point of use may be zero.

In a specialist periodontal or oral surgery practice instruments should be routinely sterilised in wraps so they can be used in surgical procedures as well as in non-surgical procedures. General dental practice sits between these two extremes.

In practices where considerable amounts of periodontal closed debridement as well as periodontal surgery or implant placement occur, having the inventory of scalers and cassettes packaged allows versatility for use in both surgical and non-surgical patient appointments.

Some practices may choose to delineate instruments for semi-critical (routine non-surgical) dentistry from those used in surgical procedures or at critical purposes sites. Only the latter need to be packaged in a wrapped bag, while semi-critical instruments can be kept in cassettes or trays.

A high level of staff training is essential for this segregated approach to be used, as accidents can easily occur when two different systems are being used in parallel. Instrument processing mistakes are often the result of poor training and inadequate supervision. In a multi-operator dental facility, it is prudent to assign one individual the supervision and oversight of instrument reprocessing. Wrapping all instruments reduces one important variable from the equation.

Note: instruments in cassettes can be easily wrapped and provides a suitable approach for gaining the benefits of cassette use.

Instruments that must be sterile at 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 then stored appropriately until used. In an emergency situation, a critical instrument may be steam sterilised unbagged and then transported to the operator in a sterile container for immediate use.

Where possible, non-critical instruments should be stored in cassettes or bagged, since these methods facilitate storage and protect against contamination from aerosols.

Paper bags/wraps conforming to **AS 1079.2** and textile linen wraps conforming to **AS 3789.2** are suitable for steam sterilisation.

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 by using a heat sealing machine, applying steam steriliser tape, or by using self-sealing bags. String, domestic adhesive tape, staples and elastic bands are not suitable for sealing packs.

Identification colour-coded tapes on instruments 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. Further, silicone rubber rings used to identify instruments may impede sterilisation and if used, microorganisms may be present under the rubber ring after sterilisation, thus compromising the sterility of the instrument. Therefore, etching of instruments as a method of identification is preferred for critical instruments.

Adhesive stickers, felt tipped non-toxic marking pens, and rubber stamps using water-resistant ink may be used for the labelling of packs and bags on the laminated side of packs prior to sterilisation. The labels placed on wrapped items must state the date of processing. It is not valid to state an expiry date, since the effective storage life is event related and does not have a fixed time. The date of processing information is useful for stock rotation of stored instruments or instrument sets.

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

6. Batch Control Identification (BCI)

As a quality assurance or risk reduction measure, dental practices should use a system for critical packages of equipment, i.e. critical instruments used in surgical procedures.

This requirement arises from **AS/NZS 4815** which states batch control numbers should be in place to link steriliser cycle batch information of a critical item that has been sterilised to the patient.

Batch Control Identification (BCI) links a pack of surgical instruments used on a patient to a particular sterilising cycle and thereby allowing dental practitioners to demonstrate critical dental instruments used on the patient have been through a particular steriliser cycle with verifiable performance data. This does not apply to semi-critical items used in routine dentistry. Thus, in office-based general dental practice the use of BCI would be limited.

A batch code comprises a simple sequence of numbers, such as those produced from a labelling gun, or can be combinations of a number sequence with codes for the date and the steam steriliser number (if the practice has several steam sterilisers).

As described in *AS 4815*, the BCI includes the steriliser identification number or code (if there is more than one steriliser within the facility), the date of sterilisation, and the cycle or load number.

Batch information can be recorded on packs prior to steam sterilising using non-soluble permanent marker ink, or by using adhesive labels applied with a labelling gun, provided the inks and adhesives used can 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. Systems exist which include batch identification printed in barcodes which can be scanned for entry into electronic patient records.

At the time of the critical procedure, as instruments are removed from their packages, the empty packages should not be immediately placed into the waste, but rather put to one side in a clean zone of the operatory. Batch number information can later be recorded into the patient's treatment records by the clinician responsible, as part of writing up the procedure notes.

The ADA supports BCI for instruments that enter, or are capable of entering, tissue that is normally sterile. This protocol uses batch control numbers to link an item's steriliser cycle batch information to the patient record entry for a specific procedure. The Spaulding instrument classification BCI aligns with the possibility that instruments, if incorrectly sterilised, may introduce pathogens into critical sites. BCI links the surgical instruments used on a patient to a particular sterilising cycle and thereby allows dental practitioners to demonstrate that critical dental instruments used on a patient have been through a particular steriliser cycle with verifiable performance data.

It allows proper examination of instances where instrument sterilising processes and practices are in question and is worthwhile in terms of public good. BCI has been widely used in the dental profession for some years and is a well-established protocol.

BCI is clearly designated as a mandatory requirement in *AS/NZS 4815* and *AS/NZS 4187*. Both require pouches or packages with individual instruments or instrument sets to have BCI recording:

- a. Steriliser identification number or code (if there is more than one steriliser within the office-based health care facility);
- b. Date of sterilisation; and
- c. Cycle or load number.
- d. The manufacturer's batch/lot number of any commercially prepared implantable items.

As stipulated in *AS/NZS 4815*, batch numbers link the steriliser cycle batch information for a critical item that has been sterilised back to the appointment the patient attended. In addition to surgical instruments, batch numbers should be used for sterile surgical drapes.

BCI assists in the risk management of items that have been used on patients, primarily critical items used on patients during surgical dental procedures.

Some dental practices will not need this type of system because they do not perform surgical procedures where reusable critically sterilised instruments and equipment are used, or only use single-use or disposable instruments and equipment for surgical procedures.

Batch numbers and date information can be placed on packages by hand using an indelible pen, using a self-inking stamp, or by using adhesive labels from a labelling gun.

It is important the inks used do not run or become unreadable during steam sterilisation. If a stamp is being used, the same stamp used to mark the date and steriliser cycle information can also be used to make a stamped entry into the steam steriliser record book for the relevant load.

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 sterilising practices.

This is used together with the signed printouts to record the key characteristics of each cycle. This record book must be filled in when the cycle is loaded, with the date, cycle number, load type and cycle programme. It is also recommended that the identification of the loading operator be included (e.g. their full name, initials or operator code). This task should be completed before the cycle start button is pushed. At the end of the cycle, the unloading operator fills in the information for physical parameters (e.g. based on the printout), and the status of the chemical indicators are okay, before signing off the load is suitable for use.

It is important the loading operator does not fill in the record book while still wearing contaminated gloves and should not push the start button until the loading entry is complete. This sequence is designed to eliminate the situation of a load being returned to use which has not been entered or sterilised.

By completing the record, the unloading operator is stating 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 like an incorrect cycle, an overloaded chamber or wrongly positioned items when they open the chamber, the record book identifies who should be followed up about these problems.

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

7. Steam sterilisation

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 right temperature and pressure for the right length of time to kill microorganisms. The sterilisation process requires all air in the chamber be replaced by steam.

Dry heat sterilisation and chemiclaves are not recommended for routine sterilising of dental instruments and equipment.

Ultraviolet light and boiling water do not sterilise instruments and must not be used for sterilisation. Boiling water may be suitable for disinfection of certain prosthetic items such as polishing buffs.

Bench top steam sterilisers (also called autoclaves) are the most reliable and efficient sterilising units for use in office-based practice. Such sterilisers must be TGA approved and operated according to *AS/NZS 4187* and/or *AS/NZS 4815* and the manufacturer's instructions.

Types of sterilisation cycles:

- **N class cycles** – used for unwrapped, solid items. Steam pushes the air downwards using gravity and forces it out a port in the bottom of the chamber;
- **S class cycles** – specified by the manufacturer and used with multi-pulse vacuum steam sterilisers to suit loads of certain types and configurations; and
- **B class cycles** – for hollow objects where the ratio of the length of the hollow portion to its diameter is more than 1:5. In these cycles there is a greater challenge for air removal. Air is exhausted by a mechanical pump to create a vacuum before steam is introduced into the chamber.

Some steam sterilisers are capable of being operated through more than one kind of cycle, depending on the circumstances and the type of instruments. Steam sterilisers running S class cycles can be used as long as their chambers are loaded properly and any wrapped items come out dry. Many practices prefer pre-vacuum steam sterilisers as these can be run with S cycles or with B cycles. The latter is designed for hollow items. S class cycles must only be used for those types of instruments and load configurations specified by the manufacturer in the operator's instruction manual.

8. Maintenance and testing

All steam sterilisers must be commissioned on installation.

Validation of the sterilisation process

In order to ensure appropriate sterilisation of items in the surgery, a concept known as validation of the sterilisation process is undertaken. In order to ensure the items are sterilised, the function of the steriliser must be checked.

The validation process involves the following steps:

- Commissioning (installation qualification and operational qualification)
- A commissioning report includes installation documents and operation verification. This is performed by the service technician when new or repaired sterilisers are installed in the practice.

Performance qualification

- a. Physical qualification (by a qualified instrument technician or manufacturer's technician):
 - Calibration report (annually); and
 - Penetration report which checks the physical attributes of the steriliser. This record is obtained after major repairs or when pack contents or packaging changes significantly.

- b. Microbiological report to confirm functioning of the steriliser using a biological indicator (spore test).
- c. The Validation report summarises satisfactory completion of commissioning, operational and performance qualification.

It is validation of the total process.

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

Monitoring of cycles

It cannot be assumed sterilisation has been achieved without appropriate testing and load checking. Time, temperature and, where applicable, pressure must be measured with continuous, automatic, permanent monitoring (e.g. process recorder, printer or data logger). Where these parameters are displayed on the devices/gauges of steam sterilisers which have no recording device, readings of the sterilising process should be 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 recorded.

The steam steriliser's performance must also be monitored by periodic testing (including daily and weekly tests as described in *AS/NZS 4815* or *AS/NZS 4187*).

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

Operating the steam steriliser

As with all infection control procedures, clinical support staff must be trained in the correct operation of the steam steriliser.

An operator's manual for each type of steam steriliser must be available, 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 (some instruments made of plastic cannot withstand the process).

Steam sterilisers incorporating a drying cycle in their design can be used to process both wrapped and bagged items. Steam sterilisers without a drying cycle are only suitable for sterilising unwrapped items which must be used immediately after sterilisation if they are critical items.

9. Steam steriliser performance tests

Steam sterilisers, particularly those capable of running a B class cycle, are complex machines. It is necessary to regularly monitor the sterilisation process to ensure the process has met all parameters and that consequently the reprocessed instruments can be assumed to be sterile.

A range of tests must be carried out prior to commencing the first sterilising cycle for sterilisers with a B class cycle. In summary these include:

- **Leak rate test** – a simple push-button operation that is built into steam sterilisers with a B class cycle.

It tests the security of seals on the machine. Most modern pre-vacuum steam sterilisers incorporate automatic air leak detection. A leak rate test is only performed weekly. In the absence of automatic air leak detection, this test should be run every working day.

- **Air removal and steam penetration test** (Class 2 chemical indicator) – Bowie-Dick type test for use when processing porous loads, or a process challenge device (PCD) – also known as a Helix test – for non-porous loads. For porous loads, a Bowie-Dick type test must be performed before the first sterilising cycle of the day in order to determine whether the steam steriliser is operating correctly in terms of its air removal capabilities. When pre-vacuum sterilisers are used to process solid or cannulated (hollow) loads using B class cycle, a daily Helix test is to be conducted.

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

Loading

The 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 and items must not be packed one on top of the other. There are several stacking devices that enable correct loading of the steam steriliser. Correct loading also reduces damage to packs and their contents, and maximises the efficient use of the steam steriliser.

To ensure air removal, hollow items should be loaded according to the manufacturer's instructions.

Items awaiting sterilisation must be stored in a dedicated 'pre-sterilisation' area, not in the steam steriliser. This will minimise the risk these items will be recirculated as already sterilised instruments.

A Class 1 chemical indicator must be placed in each loading tray being processed if non-bagged items are loaded. For wrapped items, a Class 1 chemical indicator must be included on the outside of each package as a visual check the item has been through the process.

Drying

Steam sterilisers used to process packaged items must have a dedicated drying cycle to produce a dry load.

External fans or boosted air conditioning must not be used to force cool items.

To avoid contamination and thermal injury in units without a drying cycle, allow unwrapped instruments to dry and cool in the steam steriliser before they are handled. Cooling items must not be placed on solid surfaces since condensation of vapour inside the pack may result. Packaged or unpackaged items must never be dried by opening the door of the steam steriliser before the drying cycle is completed.

Use sterile unwrapped critical instruments immediately after completion of the sterilising process.

Checking the completed load

A number of variables influence the process of sterilisation: quality of cleaning (residual bio-burden); choice of packaging materials; packaging technique; steriliser loading technique; sterilant quality (levels of ions and lubricants); and cycle parameters (time, temperature, saturated steam). With regard to the latter, once the sterilising process (including the drying cycle) is complete, a number of checks need to be made and the results recorded.

Check the readings – pressure, temperature, time – on the steam steriliser's instruments and compare them to the recommended values. For readings outside its specified limits, the sterilisation cycle must be regarded as unsatisfactory (regardless of results obtained from chemical indicators) and the sterilising cycle repeated. If the second cycle is unsatisfactory, the steam steriliser must not be used until the problem has been rectified by an instrument technician.

Logs and printouts must be retained for inspection and monitoring. Modern steam sterilisers have an integral printer or data logger to allow the parameters reached during the sterilisation cycle to be recorded for routine monitoring. For unwrapped loads of dental instruments and equipment, steam sterilisers must reach a holding temperature of 134°C –137°C for three minutes. Existing older type bench top steam sterilisers must, where possible, be fitted with mechanisms to electronically record these sterilising parameters.

If no such mechanism is available, parameters must be monitored and recorded manually or use process indicators for each cycle.

Visually check that bags and their contents are dry

Check that the external (Class 1) chemical indicator on the bag and any internal (Class 4, 5 or 6) chemical indicators have made the required colour change. If one pack has not changed colour the whole load must be regarded as suspect.

Check each bag to ensure it is undamaged and sealed properly.

Instrument packs must not be used if mechanical or chemical indicators indicate any flaws in the sterilising process.

If the bag/packaging is compressed, torn, unsealed or wet or if items have been dropped on the floor or placed on contaminated surfaces, the affected instruments must be considered contaminated and must be repackaged and reprocessed.

Retention of hard copy printouts from steam sterilisers

Practices must retain printouts from steam sterilisers for a minimum of seven years. Thermal printouts tend to fade with time and become illegible, effective solutions are to either photocopy them to give a stable hard copy, or scan them for digital storage. Ink printouts do not fade. Some modern steam sterilisers offer data capture which is a suitable alternative provided the data is periodically downloaded from flash memory cards and regularly backed up.

A requirement of *AS/NZS 4815* is that records are maintained of instrument reprocessing and steriliser cycles. This cannot be for less than the period of time defined by regulatory authorities.

In addition to steriliser cycle records, other records to be retained include:

- a. Results of performance tests of equipment;
- 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.

10. Steam steriliser monitoring tests

Regular monitoring of the sterilisation cycle is necessary to ensure the sterility of reprocessed instruments.

Chemical indicators

Chemical indicators show that certain temperatures, times and pressures have been reached during the sterilising process.

Instruments are assumed to have been sterilised when the correct sterilisation parameters have been achieved.

Chemical indicators provide information about conditions in the steam steriliser at the specific locations where they are placed, whether in the chamber, in packs of a steam steriliser load or in a process challenge device. Some indicators such as Class 1 types are only sensitive to changes of 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 – these are intended for use on individual packs of wrapped instruments to indicate the unit has been exposed to the sterilisation process (e.g. steam steriliser indicating tape, indicating labels). Place a Class 1 indicator in each load if un-bagged, semi-critical or non-critical instruments are processed. For wrapped loads, the Class 1 indicator on each pack must be examined after the sterilising cycle to ensure the pack has been exposed to a sterilising process. These indicators usually fail only when there is gross malfunction of the steam steriliser. External indicators are Class 1 chemical indicators, which provide visual confirmation a pouch has been in a steam or heat sterilising process. These indicators do not provide insight into the conditions inside the pouch. Internal indicators, by contrast, are Class 4, 5 or 6 chemical indicators.

Class 2 – a specific test – either a Bowie-Dick type test for use when processing porous loads or a Helix process challenge device (PCD) for solid or hollow instruments – which measures the effectiveness of air removal and even penetration of steam in a pre-vacuum steriliser. Cool air pockets (which may be caused by an overcrowded chamber), incorrect wrapping, positioning, or use of packaging materials are very common causes of failed sterilisation in downwards displacement steam sterilisers. Air pockets occur less often in pre-vacuum steam sterilisers.

Helix tests, which create an air removal challenge in a hollow item, can be used with a regular load as well as in an empty chamber.

Bowie-Dick type tests can only be used in an empty chamber, ideally at the start of each day once the chamber is warm. With a pre-vacuum steam steriliser, an air removal test such as a Helix test or Bowie-Dick type test must be run daily.

When using a B Class cycle to sterilise porous loads of cotton rolls, gauze post-extraction packs, cotton wool, etc. a Bowie-Dick type test is recommended. If hollow loads such as handpieces are to be sterilised in a B Class cycle the appropriate test is the Helix type PCD.

Class 3 – indicators respond to only one critical variable (e.g. temperature). These indicators have poor accuracy and are only used with dry heat sterilisers. They have limited value in general dentistry.

Class 4 – are designed to react to two or more of the critical sterilising variables (e.g. time and pressure) and indicate exposure to a sterilisation cycle at the values of the variable as stated by the manufacturer. These show a gradual colour change during sterilising. Their accuracy is $\pm 2^{\circ}\text{C}$ and $\pm 25\%$ on time. Using a Class 4 chemical indicator is regarded in *AS/NZS 4815* as the lowest level of internal indicator (i.e. Classes 5 and 6 perform better). Inclusion of indicators inside every pouch is essential for 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.

Class 5 – an integrating indicator indicating time, temperature and moisture sometimes called a biological emulater because it is timed to change colour at a temperature of 134°C . It is at this point the probability of residual viable organisms remaining is less than one in a million (the sterility assurance level). Their accuracy is $\pm 1^{\circ}\text{C}$ and $\pm 15\%$ on time.

Class 6 – Class 6 indicators have the highest precision – their accuracy is $\pm 1^{\circ}\text{C}$ and $\pm 5\%$ on time. A correct colour change indicates the sterilising parameters of temperature, pressure and time have been achieved. A Class 6 indicator must be used in each load when using an 'on-loan' steam steriliser or when waiting on a technician to carry out IQ and PQ on a newly purchased or majorly-repaired steam steriliser or when using a steam steriliser without a printer.

Where instruments are intended to be sterile at point of use, and full validation of the cycle parameters has not yet been undertaken, an internal multi-parameter time and temperature chemical indicator should be used within each package.

While *AS/NZS 4815* permits chemical indicators between Classes 4 and 6 to be used for such a purpose, a Class 6 indicator is preferable because of its ability to provide additional information on steam quality that is not provided by Class 4 and 5 indicators.

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

Storage of chemical indicators

Chemical indicators are designed to be read at the end of a cycle, but the colour change chemistry is not intended to provide results of archival quality if these indicators are stored for several years.

This is particularly the case with Class 5 and 6 indicators, which use sophisticated multi-step chemical reactions. Indicators should not be stored. When kept in record books, acid released from the paper of the record book can permeate into the indicator and cause colour changes.

Biological indicators

Only biological indicators that use highly heat-resistant spores actually show that sterility has been achieved. Steam sterilisers that have not been calibrated or validated should be monitored by a weekly test using a biological indicator or alternatively each load must be processed with a biological emulator. The preferred test organism for steam sterilisation is *Geobacillus stearothermophilus*.

For further information see the *ADA's Practical Guide to Infection Control*.

11. Disinfection

Disinfection does not ensure the degree of safety associated with sterilisation because it does not always destroy all microbial forms (e.g. bacterial spores). It is not a sterilising process and must not be used where reusable instruments can withstand steam sterilisation. It may be used for non-critical instruments and some semi-critical (e.g. prosthetic instruments) which cannot be steam sterilised.

Thermal disinfection using washer-disinfectors

Thermal disinfection uses heat and water at temperatures which destroy pathogenic non-spore-forming vegetative organisms.

A common use for thermal disinfection in dentistry is for some prosthetic instruments, polishing buffs and brushes. Most instruments used in dental prosthetics are semi-critical or non-critical items and many can be disinfected by heat and water in a thermal disinfectant. However, as single-use disposable instruments are now available, the use of a thermal disinfectant should be minimised. If a high temperature thermal disinfectant is used the proper temperature and time parameters must be ensured.

The process

The item to be thermally disinfected must be cleaned prior to disinfection. If an item is not clean it cannot be disinfected.

Wet instruments can be placed into the thermal disinfectant/instrument washer.

The chamber of the thermal disinfectant must be cleaned regularly. Most units connect directly to mains water and drain directly into the normal waste plumbing.

Small electric ovens and microwaves must not be used as a means of thermal disinfection in dental practice.

Chemical disinfection using instrument disinfectants – high level

For practical purposes there is no place for cold high level chemical disinfection (e.g. glutaraldehyde) in dentistry.

Chemical disinfectants should only be used when thermal disinfection is unsuitable (e.g. some prosthetic or laboratory items). Instrument disinfectants must be TGA-registered, and used according to manufacturer's directions.

Different types of disinfectants must not be mixed or combined and must be used before expiry dates. Products must be used at the recommended concentration for soaking and exposure time. Unused product must be discarded each day – 'topping up' is not acceptable.

Instruments must not be stored in disinfectant solutions either before or after thermal disinfection or sterilising. Likewise, instruments must not be left overnight in solutions inside the chamber of an ultrasonic cleaner. Rather, the chamber should be emptied and the instruments rinsed thoroughly at the end of the day.

Ultraviolet cabinets must not be used for instrument disinfection.

12. Storage of processed instruments

The correct storage of processed instruments is important to protect them from environmental contamination. In the dental surgery the major source of environmental contamination is splashes of fluids that strike items and surfaces, and aerosols of airborne bacteria and viruses which settle over time on instruments and equipment.

Instrument cassettes and instrument packs must be kept in such a way that contamination from splashes and aerosols does not occur.

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

Wrapped packages of sterilised instruments must be examined before opening to ensure the barrier wrap has not been compromised during storage. If there is any doubt that sterility was achieved during processing or the instrument pack has been compromised, re-clean, repack and re-sterilise.

Storage areas for sterilised instruments in packs must be dedicated for that purpose only and be free of dust, insects and vermin. For open shelving, all items must be stored above floor level by at least 250 mm, from ceiling fixtures by at least 400 mm, and protected from direct sunlight, and from winds from open windows.

Semi-critical instruments

Storage of unwrapped semi-critical instruments and non-critical items must be in clean, dry, dust-free, dedicated containers or drawers to protect them from environmental contamination. Semi-critical instruments must be stored away from the contaminated zone, and in an area protected from splashing and aerosols produced during equipment washing, ultrasonic cleaning and reprocessing, or from clinical procedures and handwashing. Keeping trays and cassettes of semi-critical instruments in closed drawers, cupboards or lidded containers will help to protect them from contamination by aerosols and splashes. Storage containers used for semi-critical instruments must be kept clean, dry, dust-free and in good condition, and be cleaned periodically. Cardboard boxes must not be used as storage containers for instruments as these are porous, cannot be adequately cleaned and may harbour organisms.

Critical instruments

Critical instruments/items must be stored in a way that maintains the integrity of packs and prevents contamination from any source. This is necessary so instruments are sterile at the time of use. Items required to remain sterile must not be stored in ultra-violet cabinets or disinfectant solutions as these processes will compromise sterility.

It is important that critical wrapped instruments are stored in a clean dry area, and before use are subjected to minimal handling. During storage, packs can be contaminated by:

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

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 or placed on a contaminated surface.

This will facilitate environmental cleaning, allow unrestricted airflow and prevent heating and degradation of the packaging material.

Drawers or sealed containers are preferred for the storage of sterile wrapped items because the drawers or containers can be located at a height allowing the contents to be easily seen and the most recently processed items are placed towards the back of the drawer. If the area used for storage is too small, too high, crowded or awkward it makes access difficult, which in turn increases the likelihood of compromising the packaging.

User checks to be made before using instruments

The integrity of bagged/wrapped packs must be checked before using the instruments. Packages showing evidence of damage must not be used.

Care should be taken when moving packages of instruments within drawers to reduce the chance of a surface breach through instruments perforating the paper or textile of the package.

Unwrapped semi-critical and non-critical items

As mentioned above, instruments must be stored dry, and in a way that will prevent contamination prior to use.

This can be achieved by storing in:

- instrument cassettes in drawers, cupboards or the like;
- trays in closed drawers lined with plastic sheeting; or
- trays or cassettes in sealable plastic containers with lids.

The drawers or containers must be cleaned with detergent and water periodically and all instruments in the drawers must be reprocessed before replacement in drawers.

Care must be taken to ensure storage areas in the dental operatory do not become contaminated. As described earlier, during patient treatment, de-gloving, over-gloving or using a suitable no-touch technique (transfer tweezers) must be used to access items.

E. Documentation and practice protocols for infection control

1. Maintaining sterilisation records

Dental practitioners must maintain records relating to the sterilisation process.

These sterilisation records include maintenance records, performance tests on the sterilising equipment (such as spore tests, air leakage and air removal tests), records of validation, and daily steriliser cycle records. The latter must incorporate batch information where BCI is used for packages of critical instruments. It is also necessary that records are maintained for daily tests on ultrasonic cleaners (such as the foil test).

Maintenance of these records provides evidence of quality management processes and allows for BCI of critical instruments. How long documentation needs to be kept varies depending on the states or territories, but is typically seven years. If the steriliser data is not scanned or in electronic form, it is important that printer readouts remain legible for at least seven years.

For this reason, ink-based printouts are preferred as thermal printouts may need to be photocopied to ensure they remain readable when archived. As an alternative, they may be scanned and the images kept on the practice's computerised file and records system.

For each sterilising cycle (even those that do not include any packs of critical instruments) the results of the cycle must be recorded as follows:

- steam steriliser number or code (to identify the machine the item was sterilised in);
- date;
- cycle or load number;
- contents of load – e.g. wrapped or unwrapped items;
- cycle parameters 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);
- result of the steam steriliser physical readouts or printout for the cycle;
- result of the chemical indicators used in the cycle. This checking should include all external and internal chemical indicators; and
- identification (signature or initials) of the person who has checked the steam steriliser readouts and chemical indicator result, and who authorises release of the load for use.

Data showing that the steam steriliser met performance data must be recorded. The cycle record should be initialled by the dental staff member reviewing them.

Keeping chemical indicators is not required as these are not a substitute for a permanent record of a sterilising process and because exposed chemical indicators may change with time and are therefore not a reliable record.

Routine recording of cycle data from sterilisers enables identification of items should the question arise as to whether sterility problems or another failure occurred with the load.

The results of any performance qualification tests for sterilisers must also be recorded, including:

- date of the test;
- brand and type of packaging system tested;
- type of biological indicator used and the batch number. It is important to check that the biological indicators to be used have not expired;
- location and number of the steam steriliser (if there are multiple steam sterilisers in the practice);
- name of the operator running the performance qualification; and
- exact parameters which have been tested.

A certificate of calibration and operational qualification should be issued by the technician carrying out the process and also must be kept as part of the documentation for the dental practice.

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 be repeated annually, even when there has been no change in the type or method of instrument packaging.

Validation of cycle parameters involves using multiple biological (spore) tests. 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 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. After the three cycles have been completed, the ten biological indicators comprising the nine which have been processed, and the tenth (as a control) are then developed and the results recorded.

Where the parameters are appropriate for the removal of air and the penetration of steam, then all nine steam steriliser indicators should show no colour change; in other words, they should indicate complete killing of the spores or deactivation of the spore enzymes as appropriate. If there is a colour change, which signifies a failed test result, the holding time for the steam steriliser should be increased in increments of one or two minutes, and the entire validation procedure repeated, in order to establish the minimum time required. The results of the validation process must be recorded.

The information should include:

- date of the test;
- brand and type of packaging system tested;
- type of biological indicator used and the batch number. It is important to ensure prior to the validation process that the biological indicators to be used have not expired;
- location and number of the steam steriliser (if there are multiple steam sterilisers in the practice);
- name of the operator running the validation tests; and
- exact parameters which have been validated.

With instruments for routine dentistry that are handled in trays and do not require packaging, problems of air removal are minimal. For such loads, validation is not necessary. Rather, validation is directed to items required to be sterile at point of use (critical items).

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

2. Infection control for dental practitioners and clinical support staff

Immunisation

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 advised to have immunisations and are to be offered relevant vaccinations consistent with the current edition of *The Australian Immunisation Handbook*.¹²

The expectations for all healthcare workers – and thus for dental practitioners and clinical support staff – is immunisation against the Hepatitis B Virus (HBV); varicella (if seronegative); measles, mumps, rubella (if non-immune); pertussis (whooping cough); and annual immunisation for viral influenza.

Those working with remote Indigenous communities are advised to also receive immunisation for hepatitis A, while those at high risk of exposure to drug-resistant cases of tuberculosis should also undergo vaccination with Bacille Calmette-Guerin (BCG).

All dental practitioners and clinical support staff should be vaccinated against HBV if they have no documented evidence of pre-existing immunity (from natural infection or prior vaccination) and ensure they are assessed for immunity post-vaccination. After a full course of HBV immunisation or rubella vaccination, testing for antibody levels should be carried out to identify poor responders.

Dental practices should have education programmes to support their immunisation strategy, and all dental staff should be advised of the potential consequences of non-immunisation. Any staff member has the right to refuse vaccination; however, 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/health records for dental staff. It is recommended that dental staff also maintain their own 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.

The rationale for asking for vaccination status for hepatitis B is that successful vaccination confers lifelong immunity – even if and when serum antibody level wanes, since there is lifelong immunological memory in lymphocytes, something not easily tested for using commercial tests. *The Australian Immunisation Handbook* does not ask for immunisation status to be known when healthcare workers apply for a job.

Their vaccination status is required, but not their immune status.

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

¹² The Australian Immunisation Handbook, 10th Edition (2015) www.health.gov.au

Education

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

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

This induction programme should comprise the following:

- general orientation to the physical environment of the practice;
- practice expectations in terms of infection control and safe working procedures;
- recommendations for vaccination prior to commencing work;
- reporting requirements for sharps injuries and workplace incidents;
- policy on wearing and cleaning of uniforms;
- emergency procedures for fire and medical emergencies;
- first aid procedures;
- management of waste streams and hazardous substances;
- confidentiality of patient information;
- identification of clean and contaminated zones;
- use of personal protective equipment;
- safety rules in terms of hair, footwear and jewellery;
- procedures for changeover between patients; and
- instrument cleaning and sterilisation.

To supplement and update the information provided from the initial induction, regular staff meetings should be held to discuss infection control matters.

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 sharps (e.g. a sharps injury caused by dental instruments, burs, needles 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 with blood or body fluids with the mucous membrane of the mouth, nose or eyes.

While the site where a penetrating injury has been sustained can become infected with microorganisms, the major area of concern to dental practitioners and clinical support staff is the risk of the transmission of HIV, HBV and HCV by contaminated blood.

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 the relevant skin area is intact.

To comply with work health and safety legislation, all exposure incidents must be recorded and followed up. The required post-injury counselling 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 obtained from the source (i.e. the patient) wherever practicable. These tests include HBV, HCV and HIV. Where the source is positive, follow-up tests will need to be repeated at intervals for the injured person, to assess the status of seroconversion. Post-exposure prophylaxis may be available from public hospitals. This process would normally be overseen by specialists in infectious diseases.

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

4. Infection control manual and other practice management issues

Each practice owner has a duty to:

- take a detailed medical history to establish if a patient may be more susceptible to infection and therefore may require transmission-based precautions to prevent infection (e.g. patients with leukaemia or neutropenia may require antibiotic prophylaxis);

- ensure adequate physical facilities are maintained and all equipment is always in sound working order by regular quality checks; and
- provide infection control education and training in hygiene and management of infectious hazards.

This information should be provided to employees at the time of appointment.

Dental practices should:

- maintain awareness of new vaccine-preventable diseases (such as H1N1 and other forms of viral influenza), and ensure dental staff at risk are 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 their right to refuse to give information on their infection status or to refuse to be tested for a blood-borne virus;
- develop a plan for infection control within the practice;
- provide dental staff infection control measures including personal protective equipment and immunisation, effective reporting systems for breaches of protocols and safe work practices;
- inform dental staff at the time of their employment of the health screening policies of the practice;
- inform patients of the risks associated with their dental care and the protocols in place for protecting their privacy and confidentiality;
- inform patients of the practice's infection control strategies and provide information about procedures for dealing with concerns about infection control procedures; and
- provide all dental staff with a specific programme of education and training in infection control principles, policies and procedures.

Infection control manual

Each practice must develop a comprehensive infection control manual pertinent to the daily routines of the practice. It must describe the infection control procedures for the practice as a whole and be used as the foundation for training dental staff.

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

Information and specifications in the manual must include:

- methods of hand hygiene (both routine and surgical);
- personal protective equipment requirements;
- setting up the treatment area between patients;
- environmental cleaning protocol;
- defined zones that require barrier protection and cleaning between patients;
- protocol following an exposure incident, e.g. 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 to avoid cross-contamination;
- quality control mechanisms including documentation for the maintenance and monitoring of equipment;
- immunisation requirements;
- single-use items;
- recording of information during patient treatment in a manner to avoid cross-contamination;
- use of computers and computer-run equipment during patient treatment in a manner to avoid cross-contamination;
- management of waterlines used in direct patient contact; and
- handling latex allergy in dental patients and dental staff.

Practice infection control manuals must be regularly updated if and when new guidelines are produced by the Dental Board, the ADA or the NHMRC.

F. Special areas and their particular dental infection control requirements

Some 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 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 personal protective equipment (e.g. masks, protective eyewear) must be used in case of spattering of blood or other body fluids.

It is recommended to use heat-tolerant or disposable intraoral radiograph devices (unless using digital radiography) wherever possible and 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 in a container (such as a disposable cup) for transport to the developing area.

Use protective barriers where possible on developing equipment and when surfaces become contaminated they must be cleaned.

Contaminated radiography equipment (e.g. radiograph tube head and control panel) must be cleaned after each patient use. Alternatively, barrier protection can be applied and must be changed after each patient use.

Digital radiography sensors come into contact with mucous membranes and are considered semi-critical devices. They must be cleaned and covered with a barrier before use on subsequent patients.

Most state regulations accept film packets and barrier envelopes contaminated with saliva or blood as being able to be disposed of as general waste. However, some regional authorities require these to be treated as contaminated medical waste. 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 operator.

2. Specialised intraoral equipment and devices

Specialised intraoral equipment and devices include:

- handle and tip of the curing light;
- CAD/CAM;
- computer components associated with CAD/CAM and other electronic devices;
- air abrasion;
- intraoral cameras and image capture devices;
- lasers;
- apex locators;
- electronic periodontal probe;
- occlusal analysers; and
- electrosurgery units.

Several factors need to be considered as to whether a barrier is needed on a piece of dental equipment. The first relates to responsibilities of importers/suppliers and the second to responsibilities of registered dental practitioners.

Importers/sponsors of therapeutic goods must comply with the legislation covering their sale, including providing accurate, evidence-based advice on reprocessing as per the *Essential Principles under the Medical Devices Regulations* (Commonwealth). Under the TGA approach, suitable reprocessing protocols for the piece of equipment should be covered under the TGA registration including mandatory compliance with the essential principles. These reprocessing considerations will form a central part of the directions for use as will any advice to clinicians specifically with regards to the Spaulding classification (Sterile – then sterilise; Mucosal – 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 second aspect relates to the responsibility of registered dental practitioners to correctly apply the *ADA's Guidelines for Infection Control*. Professional judgement is needed by the dental professional – who must consider the situation at hand with the device, and any suggested barrier and its adequacy. 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 will have parts that can be steam sterilised and other parts need to be covered (e.g. sheaths for intraoral cameras and digital imaging sensors). If the manufacturer recommends and supplies a dedicated barrier which covers the parts of the device which could come into contact with saliva, then failure of that barrier during operation is unlikely to occur. In contrast, if a staff member at the clinical level improvised a barrier using cling film, aluminium foil or a sandwich bag, then depending on the device this may work, or its integrity may be compromised because of poor fit or limited adaptation – in other words it depends on whether or not the barrier can do and has done its job.

Some lasers have touch panels for operation, for which there are adhesive stick-on covers to cover the panel fully so no wiping is required afterwards as these simply pull-off. Using a wipe may damage the combined touch panel display so it should be avoided. Thus there are situations where wiping would not be appropriate.

Older dental equipment may need barriers as the surfaces to be protected are very hard to clean. In contrast, most modern equipment has been designed to be cleaned, with minimal use of barriers. Very smooth suction tubing has been designed for wiping (as per the manufacturer's instructions) and should be undertaken as the means of surface management.

A range of options exist for surface management of specialised devices such as intraoral cameras used in patient examination and intraoral scanners used to record digital impressions. A disposable shroud or sheath is most widely used. 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. Manufacturer recommendations provided with the device should be followed carefully regarding appropriate surface management. It is preferable to limit the use of agents such as glutaraldehyde due to workplace health issues arising from skin contact with glutaraldehyde or inhalation of its vapours.

AS/NZS 4815 discusses medical diagnostic instruments and points out that instruments used in semi-critical sites require cleaning in accordance with manufacturer's instructions and then either sterilise (if possible) or high level disinfection. Because intraoral cameras and scanners will be exposed to saliva and potentially blood, and cannot tolerate heat sterilisation, protection with a single-use barrier is the preferred approach.

Dental practitioners and clinical support staff should consult the manufacturers as to the appropriate barrier and cleaning/sterilisation procedures required for these devices.

Use of disinfectants

A different approach is taken in Australia compared to Europe and the USA with less use of disinfectants here, because:

- a. steam sterilisation is more efficient and safer;
- b. thermal disinfection can be used for many items which cannot withstand steam sterilisation;
- c. some disinfectants pose workplace health and safety issues if skin contact or inhalation occurs; and
- d. incorrect techniques used with disinfectant compromises their efficacy.

If the item is exposed to mucous membrane or body fluids and cannot tolerate heat sterilisation then, at a minimum, it must be cleaned first then protected with a single-use barrier before patient use.

When replacing barriers:

- remove the contaminated barrier/covering while gloves are still on;
- remove gloves and decontaminate/wash hands;
- if there is any chance of saliva or blood contamination of the item it should be cleaned by wiping with a neutral detergent before the next barrier is put in place; and
- it is not always essential (but it is highly recommended) to clean items between change of barriers.

Items with barriers must be cleaned each day.

Curing light

Curing light tips are semi-critical pieces of equipment. They should be heat sterilised or have an appropriate barrier placed over the tip for each patient. Although some curing light tips may be heat sterilised this is not necessary if an appropriate barrier has been applied to the tip during treatment of the patient. Another advantage of a barrier is that the sensitive light-conducting rods are protected from accidental damage or material contamination. Barrier protection is an appropriate level of infection control for all curing light tips, as the equipment is not intended to contact mucosa.

The handle of the curing light and the tips must always be cleaned prior to having the barriers placed and a new barrier 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 devices as they create particular bio-aerosol hazards. Air abrasion devices create alumina dust, which can be a respiratory irritant for dental practitioners, clinical support staff as well as patients.

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 soft tissue vaporisation. Most bacteria and viruses are rendered non-viable by laser or electrosurgery, even though fragments may be present in the plume. The presence of an infectious agent in plume might not be sufficient to cause disease from airborne exposure, especially if the agent's normal mode of transmission is not airborne. There is no evidence that blood-borne viral diseases such as HIV or HBV can be transmitted through aerosolisation and inhalation of plume or other dental aerosols. High filtration surgical masks combined with high volume suction can prevent inhalation of particles in plume by dental practitioners, clinical support staff and patients. As well as particles of tissue and fragments of microorganisms, plume also contains gases (e.g. hydrogen cyanide, benzene and formaldehyde) which are irritant and noxious. Evacuation systems which remove plume vapour and particles must be used when using electrosurgery units, dental lasers and air abrasion/particle beam units.

3. Implants

For surgical procedures involving placement of implants both the instruments and the implants used must be sterile at the time of use. Full aseptic procedures with sterile fields must be employed. Explanted devices must not be reprocessed and reused.

4. Impressions

Thorough rinsing with cold running water is designed to remove saliva and traces of blood. This is followed by the application of a diluted detergent using immersion or spraying. This detergent has a surfactant action which removes remaining microorganisms from the impression. Further 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 decontaminated and should be marked as such if being transported to an off-site laboratory.

Following detergent treatment, the use of additional chemical agents on the impression is optional. Of the available agents, immersion in a weak (0.5% hypochlorite solution for up to 15 minutes) does not cause deterioration. However, higher concentrations or longer exposure times will degrade the quality of the impression and resulting cast.

5. Dental laboratory and dental prosthetics

Standard precautions and safe work practices must be used in the dental laboratory. The most important phase is the thorough cleaning of material that has contacted oral tissue (e.g. impressions). Thorough rinsing with cold running water, followed by the application of a diluted detergent and further rinsing must continue until all visible contamination is removed.

Manufacturers' instructions for disinfectants must be followed carefully when cleaning and disinfecting prosthetic items and materials. At all stages of handling of the prosthetic item standard precautions must be applied as even after cleaning, biological contamination may still be present.

Standard precautions include:

- all materials, impressions, dental prostheses, intra and extra-oral appliances must be cleaned thoroughly before insertion and adjustment;
- areas for grinding or cutting plaster, making models and for instrument management and sterilisation must be well separated and not used at the same time, if both procedures use the same room;
- implantable items must be sterile at the time of implantation. Surgical guides for implant surgery can be decontaminated using suitable aldehyde-based or other chemical agents. However, care must be taken to rinse these thoroughly to remove all traces of disinfectant prior to their use;
- any instruments, equipment, attachments and materials used in the operatory on contaminated prostheses or stages of prosthetic work should be either single-use or cleaned and preferably heat sterilised after each patient use. If unsuitable for heat sterilisation these items should be thermally disinfected (e.g. polishing mops); and
- when polishing appliances which have been worn in the mouth, repaired appliances or relined appliances, polishing pumice should be dispensed for individual use and the pumice tray cleaned after each use.

All materials transported to and from dental laboratories must first be cleaned and placed in a sealed bag or container.¹³

¹³ Some states/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 manufacturer's instructions and must be sterilised after each patient. Similarly, ultrasonic scaler handpieces must be sterilised between patients. Both dental handpieces and ultrasonic scaler handpieces must not be fully immersed in water at any stage of cleaning.

The exterior surfaces of dental handpieces must be cleaned thoroughly, and then their internal aspects cleaned and lubricated prior to sterilising, according to the manufacturer's instructions (e.g. using an aerosol / pressure pack spray can or an automated lubricating and cleaning device).

Care should be taken to ensure lubricants used do not compromise the sterilisation process. This can be achieved by replacing weekly the deionised water in steam sterilisers which recycle water from one cycle to the next. It is strongly recommended automatic lubricate and flush-through systems be used for cleaning and lubricating dental handpieces because of their lower oil dosing rates.

Following sterilisation, handpieces must be stored in a way to prevent contamination. Handpieces should not be fitted to the dental unit until required for use on a patient. Once fitted to the dental unit and exposed to contamination during treatment they must be reprocessed even if not used on the patient.

Debate continues about the effective decontamination of handpieces. In theory, a pre-vacuum steam steriliser will remove the air from the lumen of a dental handpiece, allowing steam to penetrate more quickly. Current opinion is that effective pre-sterilisation cleaning of conventional high and low speed dental handpieces and subsequent processing in a downward displacement steam steriliser is acceptable for general dental treatment. Although using a pre-vacuum cycle is preferred. Surgical handpieces must be sterilised using a pre-vacuum (B type) cycle in a pre-vacuum steriliser.

If a dedicated handpiece cleaning system is not used, the following protocol should be adopted for the pre-sterilisation cleaning of handpieces:

- if instructed by the manufacturer, place a blank bur in the chuck during cleaning to prevent water contamination and damage to the handpiece bearings;
- clean the outside of the handpiece with detergent and water – never clean or immerse the handpiece in disinfectant solutions or the ultrasonic cleaner;
- lubricate the handpiece with pressurised oil for the recommended period;

- clean off excess oil;
- sterilise in a steam steriliser; and
- run the handpiece briefly before use to clear excess lubricant. This step is not needed if an air purge has been run at the end of the lubricating process prior to sterilisation.

For further information on handpiece management see the *ADA's The Practical Guide to Infection Control*.

7. Specimens

Each biopsy specimen must be placed in a sturdy, leak-proof container labelled with the biohazard symbol to protect those handling and transporting specimens. Gloves must be worn when handling pathology specimens and specimen containers. Once the specimen has been placed in the container it must be packaged appropriately in a sealed container to prevent leakage during transport.

Appropriate biohazard labelling must be placed on pathology specimen containers before dispatch. It is preferable to use plastic zipper bags carrying the appropriate designation provided by the pathology laboratory. If a biopsy specimen container is visibly contaminated, clean and disinfect the outside of the container before placing it into the transport bag or container.

8. Endodontic irrigants

Practitioners should ensure products used are certified for the TGA for clinical use in dentistry. This has been an issue with preparations of sodium hypochlorite, since these have been used in the past for decontamination of plastic-enveloped radiographic films, as well as 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 Australian Register for Therapeutic Goods (ARTG). This register lists specific solutions of sodium hypochlorite at concentrations of 1% and 4% for use in endodontics, as Class IIA Medical Devices.

These solutions are registered with the intended function of assisting debridement, cleaning and chemical breakdown of pulpal soft tissues of the root canal.

9. Gutta percha points

Immediately prior to use, gutta percha points can be disinfected by a one-minute immersion in 5.25% sodium hypochlorite solution. Further information on disinfection of gutta percha points can be found in the *ADA's Practical Guide to Infection Control*.

10. Hand operated endodontic files

Reprocessing hand files is not practicable as they are typically labelled as single-use items. It is both ineffective and unsafe, and likely to result in a sharps injury.

Protocols with proven effectiveness for cleaning rotary nickel titanium files have limited effectiveness in removing bioburden from hand files made from either stainless steel or nickel-titanium alloy and cannot be used. In addition there are concerns regarding staff safety.

Potential transmission of pathogens from one patient to another via contaminated endodontic files and other dental instruments has led to single-use devices and more stringent assessment of re-sterilisation of instruments.

In 2006, *AS/NZS 4815* indicates that regardless of whether endodontic files were for single patient use or not, endodontic reamers and files are extremely difficult and hazardous to clean.

Stainless steel endodontic hand files used to commence most endodontic procedures are difficult to clean using either hand or mechanical cleaning methods due to their small size and complex shape. Attempts to clean stainless steel or nickel titanium endodontic files by manual scrubbing, plunging them into sponge, or placing them into an ultrasonic cleaner without pre-treatment using enzymatic agents are equally ineffective. These items are single-use.

11. Nickel-titanium (NiTi) endodontic files

For nickel-titanium (NiTi) files, a protocol combining a specific enzymatic agent with ultrasonic cleaning has been developed.

This protocol has been shown to be effective for all types of rotary NiTi endodontic files.

It uses a combination of mechanical and chemical removal of debris from the files, followed by pre-soaking in an enzymatic agent, and ultrasonic cleaning.

This aligns with the requirements of *AS/NZS 4815* which indicates that a validated cleaning method is used, which is safe for staff.

When NiTi endodontic rotary files are reprocessed, the pre-sterilising cleaning process must be validated as being effective. A verifiable process is described below.¹⁴

Cleaning rotary nickel-titanium endodontic files:

- immediately after use remove stoppers and insert the files into a scouring sponge soaked with chlorhexidine gluconate aqueous solution;
- clean the files by using 10 vigorous in-and-out strokes in the sponge;
- place the files in a wire mesh basket and immerse in a suitable enzymatic cleaning solution for 30 minutes;
- follow this by 15 minutes ultrasonification in the enzymatic cleaning solution;
- drain and rinse in running water for 20 seconds;
- proceed to steam sterilisation.

A dental practice intending to reprocess rotary NiTi endodontic files should closely follow the above protocol. If a dental practice quarantines rotary files for a single patient for a course of treatment for the one tooth, they should follow this validated protocol. Moreover, reprocessing of root canal files is for NiTi files only, not for stainless steel files which must be single-use.

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

12. Relative analgesia equipment

Most componentry of relative analgesia equipment can be sterilised. Usually the exceptions are the scavenger control valve, (the vacuum control block) and depending on the model the fresh gas hose. Reusable masks must be cleaned and sterilised. Cleaning can be done manually or by thermal disinfectant. All sterilisable components can be processed in a steam steriliser at 134°C. Some nasal hoods (masks) are disposable and these must be discarded, not reused.

13. Nursing home visits

There are many dental patients whose dental treatment must be provided in a nursing home, and occasionally bedridden patients at a private home or hospital need dental care.

The facilities are often inadequate and can make it difficult to provide treatment.

¹⁴ Taken from: Parashos P, Linsuwanont P, Messer HH. 'A cleaning protocol for rotary nickel-titanium endodontic instruments' Aust Dent J 2004; 49 (1):20-27.

Standard precautions apply when providing dental care in these settings. These include wearing gloves and other protective clothing and proper hand decontamination. Dental practitioners and clinical support staff may need to carry all necessary personal protective equipment.

During transport, all instruments and materials must be carried in lidded metal or rigid plastic clean containers to prevent damage or spillage. After use, the instruments must be placed in a 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 or sprayed with a cleaner to prevent hardening of debris before transport back to the dental practice or laboratory.

Items such as impressions, try-ins and articulators must be transported in sealed plastic containers. Impressions should be rinsed of blood and saliva prior to transporting to the laboratory.

Waste should be separated at the point of generation. General waste should be disposed of in the general waste of the nursing/private home or hospital. Sharps and medical waste must be dealt with according to state regulations (a designated sharps container as indicated in *AS/NZS 3816* must be transported with other instruments and equipment for this purpose).



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

Some situations require additional infection control measures from the standard precautions already outlined.

Additional measures are now referred to as transmission-based precautions. Transmission-based precautions must be applied for patients with known or suspected infectious diseases not managed by standard precautions alone, for example, tuberculosis, measles, H5N1 avian influenza and SARS. Transmission-based precautions are tailored to the specific infectious agent concerned and may include measures to prevent airborne, droplet or contact transmission.

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

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

Instruments used in routine dental and endodontic procedures which come into contact with lower infectivity tissues can be routinely reprocessed for all patients with potential Creutzfeldt-Jakob disease (CJD) infection, including those in both high and low risk categories.¹⁵ Nearly all patients and office-based dental procedures fall in this category.

Prions are not found in oral tissues or in saliva, allowing patients with suspected or confirmed prion diseases to undergo normal dental treatment including dento-alveolar surgery without additional measures. This applies for those with classical or iatrogenic CJD as well as other prion diseases such as fatal familial insomnia (FFI). No special precautions are needed for routine dentistry. Only oral and maxillofacial surgery involving the central nervous system needs additional measures, including instrument tracing that relates a patient to an instrument rather than just an instrument to a sterilisation cycle.

Other than this unique situation in specialist practice, the ADA does not support traceability, a protocol which also requires a record of the distribution and location of each instrument after each sterilisation, delivery and clinical use. Transmission of prion diseases in office-based dental practice is not a concern because of the lack of prions in peripheral tissue and the proven non-infectivity of saliva, and dental and oral soft tissues. There are no benefits to public health or to the operation of a dental practice by having traceability of dental instruments. The ADA regards it as an unnecessary impost for office-based practice.

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.

A dental practice considering treating these patients should only do so after having conducted a written risk assessment. Most patients for whom transmission-based precautions are required would normally be quarantined to their home or too ill to consider any treatment other than relief of the most 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. The patient should be seen as the last patient of the day, appropriate barrier precautions must be used and staff assisting in the dental treatment must be aware of their immune status for the relevant infectious disease of the patient. The use of rubber dam, where possible, for restorative work is recommended to reduce exposure of dental practitioners and clinical support staff to potentially infected aerosols. When treating these patients it would also be prudent for clinical staff to wear well-adapted close fitting masks with high filtration capabilities (such as P2/N95 surgical respirators). It would also be prudent to use additional cycles of surface cleaning at the end of the appointment.

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

2. *Staphylococcus aureus* (MRSA)

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, and abnormal skin (such as wounds, ulcers and eczematous skin). Normally, it is not found in the oral cavity but may occasionally be isolated from oral infections.

No special infection control precautions are necessary for the dental treatment of patients colonised with MRSA but care should be taken to prevent colonisation of the operator. Care should also be taken to limit the zone of contamination and in disposal of waste.

¹⁵ See section B5.2 of the 2010 NHMRC Guidelines

MRSA can survive on surfaces such as computer keyboards for days and for weeks under acrylic nails.¹⁶ Dental staff known to be colonised with MRSA must not undertake or assist with major surgical procedures in hospitals.

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. The other group of vulnerable patients for MRSA are those in long-term care facilities, who will not comprise a significant part of office-based practice for most dental practices.

Where a patient is known to be a carrier of MRSA, contact precautions apply, and care should be taken to prevent colonisation of the dental surgery environment from the patient. Double wiping of all surfaces touched by the patient, and ensuring minimal contamination of surfaces during treatment of the patient will guard against contamination of the operatory.

Dental practitioners known to be carriers of MRSA 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, peri-oral skin. Organisms may be distributed by air coming from the nose and particularly by nose blowing. They should avoid wearing jewellery and artificial nails, as these harbour MRSA.

3. H5N1 avian influenza

H5N1 avian influenza is a highly pathogenic and contagious influenza virus normally only infecting birds and occasionally pigs. Transmission-based precautions will be essential should this disease enter Australia as a human-to-human transmission of the virus.

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

4. Human infections with avian influenza A (H7N9) viruses

Avian influenza can occur in several forms, including H5N1 and more recently H7N9. Most human infections with these strains have resulted in severe respiratory illness and a much higher morbidity and mortality than most other human influenza strains. To date, most H7N9 cases have occurred in mainland China and Taiwan. Most patients had contact with poultry or wild birds, or animal settings, such as live poultry markets, prior to the onset of their illness.¹⁷ To date, there is no evidence to suggest person-to-person transmission. Practitioners should be aware of this respiratory illness in patients who have travelled to China within the timeframe of ten days of onset of illness. Patients with H7N9 should not undergo any elective dental treatment. Urgent dental treatment requires both contact and droplet precautions, as this places staff within the range of close contact (less than two metres).

5. Allergies to chlorhexidine

Practitioners using chlorhexidine mouthrinses, hand washes, or irrigants should be aware of the potential risks of allergic responses. Chlorhexidine's unique molecular structure has two identical epitopes, chlorhexidine 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. This is an uncommon problem with only ten well documented cases of allergy in patients during the first 20 years of its use. There are now over 60 reports of anaphylaxis to chlorhexidine in the literature, beginning from 1983.¹⁸⁻²¹ 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, for example by subgingival irrigation during periodontal debridement, or by irrigation into extraction sites.

¹⁶ Schultz, Gill, Zubairi, Huber, Gordin (2003) Bacterial contamination of computer keyboards in a teaching hospital; and Rutala, White, Gergen, Weber (2006) Bacterial contamination of keyboards: efficacy and functional impact of disinfectants.

¹⁷ Centers for Disease Control and Prevention. Emergence of Avian Influenza A(H7N9) Virus Causing Severe Human Illness - China, February-April 2013. MMWR 2013; 62(18): 366-71. Lee SS, Wong NS, Leung CC. Exposure to avian influenza H7N9 in farms and wet markets. Lancet 381(9880):1815.

¹⁸ 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.

¹⁹ 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.

²⁰ Nagendran V, Wicking J, Ekbote A, Onyekwe T, Garvey LH. IgE-mediated chlorhexidine allergy: a new occupational hazard? Occup Med. 2009;59(4):270-2.

²¹ Liippo 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. <http://www.mondaq.com/x/133104/Healthcare+Medical/Death+at+the+Dentist>

6. 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.

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, dental practitioners or clinical support staff with proven anaphylactic reactions to latex may need to wear a medical alert bracelet and carry self-injectable adrenaline.

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 from the operatory of other identifiable latex products likely to cause a reaction. Such items would include latex gloves, bungs in some local anaesthetics, latex prophylaxis cups, latex components of relative analgesia equipment, latex rubber dam, rubber bite blocks, and latex rubber alginate mixing bowls. Non-latex versions of gloves, prophylaxis cups, dental dams, bite blocks, and alginate mixing bowls are available.

Care should be taken to ensure latex and chlorhexidine compatibility when selecting hand care creams. These creams should not be petroleum-based.

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

7. Blood-borne viruses and the infected dental practitioners

Infection control against blood-borne viruses is based on the premise that for a person to be infected all of the following three conditions must be present:

- a susceptible host (i.e. anyone exposed to body fluids containing HIV, HCV or HBV or anyone not vaccinated against HBV or who does not have the HBV antibody);
- a virus with sufficient virulence (infectivity) and dose (numbers) to cause infection; and
- a portal through which the virus may enter the host, i.e. a break in the skin or sharps injury.

Although transmission of blood-borne pathogens (e.g. HBV, HCV, and HIV) in dental settings can have serious consequences, such transmission is rare. Exposure to infected blood can result in transmission from patient to practitioner, from practitioner to patient, and from one patient to another. All patients need to be treated as potentially infectious and standard precautions applied to minimise the risk of transmission of infection from person to person.

8. Exposure prevention methods and exposure prone procedures

Avoiding occupational exposure to blood is the primary way to prevent transmission of HBV, HCV, and HIV. Exposure occurs through percutaneous injury (e.g. a penetrating injury or cut with a sharp object), as well as through contact between potentially infectious blood, tissues, or other body fluids and mucous membranes of the eye, nose, mouth, or non-intact skin (e.g. exposed skin that is chapped, abraded, or shows signs of dermatitis).

The majority of exposures in dentistry are preventable.

Methods to reduce the risk of blood contacts include:

- use of standard precautions;
- use of devices with features engineered to prevent sharps injuries; and
- modifications of work practices.

Dental practitioners and students have a responsibility to know their antibody status for blood-borne viruses such as HBV, HCV and HIV. Those carrying a blood-borne virus have a legal, professional and ethical responsibility to review the way they practise dentistry in line with medical advice from their treating specialist physician and advisory panels, and the current CDNA guidelines.

Dental practitioners must avoid exposure prone procedures if they are viraemic. Current national policies for managing healthcare workers with a blood-borne viral illness should be followed.

Appendix

Blood and body fluid exposure protocol

First aid

- Stop work immediately, regardless of the situation (e.g. even if administering local anaesthetic or undertaking another type of invasive procedure).
- Allow the wound to bleed and clean it thoroughly with soap and lukewarm water. 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 and record

An assessment of the risk of transmission is an urgent priority to determine whether post-exposure prophylaxis (PEP) is necessary.

Expert medical advice from an S-100 prescriber or an infectious disease specialist is usually required to determine the need and type of PEP for the exposed person and the necessity or otherwise of testing the patient's blood after appropriate pre-testing counselling.

Each dental practice should have a clear set of written instructions on the appropriate action to take 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 the medical practitioner experienced in dealing with such cases) they must be easily accessible and understood; and all dental practitioners must follow them.

A full record of the incident should 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 or 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 blood-borne virus (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
- time which has elapsed since the exposure.

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 (known source). The staff member should be tested at the time of 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), bearing in mind the window period of the tests.

If the source patient is found to be positive for a BBV it is recommended 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 > 10 IU/mL) – 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 that enables 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 this consent, the patient should be offered pre-test counselling to provide details on the test procedure, and the long and short-term consequences to the patient of the test results.

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

The source individual should be tested for:

- HIV antibody;
- HBsAg (hepatitis B surface antigen); and
- HCV antibody (hepatitis C antibody).

If the source individual tests positive for either of these 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 for testing 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 for transmission of these viruses).

The window period causes a FALSE NEGATIVE test result. The patient may be infectious, but this is undetectable by testing. The window period for HIV is usually three months but it can, very rarely, be longer. The use of the 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 hepatitis B surface antigen (HBsAg). If the staff member is immune to HBV (anti-HBs antibodies > 10 IU/mL) they are protected. If levels of immunity are relatively low (i.e. between 10 and 100 IU/mL) a booster injection would 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 IU/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 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 6.3% if the source is 'e' antigen negative, but 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 PEP for HCV. The risks 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 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 ALT and AST (e.g. at two, three and six months) can be undertaken and possible clinical signs and symptoms monitored by an infectious diseases physician or gastroenterologist, and specific therapy considered if appropriate.

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 two or three orally administered anti-retroviral drugs and should be administered to the recipient within 24-36 hours after exposure (and preferably within two hours). This therapy should be continued for four weeks, on the advice of an infectious diseases physician.

- PEP is recommended for percutaneous (skin penetrating) exposure to potentially infectious blood or body fluids (because of the increased risk of HIV transmission).
- PEP should be offered (but not actively recommended) for exposure of ocular mucous membrane or non-intact skin to potentially infectious blood or body fluids (as there is less increased risk of HIV transmission).
- PEP should not be offered for an exposure to non-bloodstained saliva (as this is not potentially infectious for HIV).

Counselling

Some people find the experience of an occupational exposure to HCV and HIV very distressing, and they should be given the opportunity to have immediate counselling to address anxieties.

The exposed person should be advised of ways to prevent transmission of blood-borne viral diseases to others. This will include advice about safe sex, safe injecting/safe needle use, breastfeeding, blood donation and safe work practices. A staff member who has been exposed to HIV or HCV should not donate blood, semen, organs or tissue for six months, and they should not share implements that may be contaminated with even a small amount of blood (e.g. razors or toothbrushes).

Follow up

Testing for injured person

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

Additional reading

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17. **Relevant Australian Standards**

Standard number	Year	Title
1079.1 to 1079.5	1993 - 2003	Packaging of items (sterile) for patient care
2773.2	1999	Ultrasonic cleaners for health care facilities (Benchtop)
1410	2003	Sterilisers – Steam – Pre-vacuum
2182	1998	Sterilisers – Steam – Benchtop
2192	2002	Sterilisers – Steam – Downward displacement
2487	2002	Dry heat sterilisers
2514	1999	Drying cabinets for medical equipment
2773.1	1998	Ultrasonic cleaners for health care facilities - Non-portable
2945	2002	Batch-type washer/disinfectors for health care facilities
3789.2	1991	Textiles for health care facilities and institutions - Theatre linen and pre-packs
3816	1998	Rack conveyor washers for health care facilities
4011.1	2014	Single-use examination gloves – Specification
4031	1992	Non-reusable containers for the collection of sharp medical items used in health care areas
4179	2014	Single-use medical examination gloves - Specification for gloves made from rubber latex or rubber solution
4187	2014	Reprocessing of reusable medical devices in health service organizations
4381	2002	Single-use face masks for use in health care
4815	2006	Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment
4261	1994	Reusable containers for the collection of sharp items used in human and animal medical applications
1337.1	2010	Personal eye protection - Eye and face protectors for occupational applications

18. Relevant ISO International Standards

- ISO 15883-6: 2011. Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment.
 - ISO 11607-1:2013. Part 1: Requirements for materials, sterile barrier systems and packaging systems.
 - ISO 11607-1:2013. Part 2. Validation requirements for forming, sealing and assembly processes.
 - ISODTS 16775:2013. Packaging for terminally sterilised medical devices— Guidance on the application of ISO 11607-1 and ISO 11607-2.
 - ISO 15882: 2008. Sterilization of health care products —Chemical indicators— Guidance for selection, use and interpretation of results. Sterilization of health care products — Biological indicators —Guidance for the selection, use and interpretation of results.
 - ISOTS 17665-3:2013. Guidance on the designation of a medical device to a product family and processing category for steam sterilization.
 - EN 867-5:2001. Specification For Manufacturer Indicator Systems and Process Challenge Devices For Use in Performance Testing For Small Sterilisers Of Type B and Type S (Note that EN 867 and 867-5 will be superseded by ISO 11140-6.
 - ISO 11140: 2005 (series). Sterilization of health care products—Chemical indicators.
 - ISO 20857:2010. Sterilization of health care products—Dry heat— Requirements for the development, validation and routine control of a sterilization process for medical devices.
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 - Public Health Bill.,2014. Western Australia. Accessed June 2015 from http://www.public.health.wa.gov.au/2/1444/2/public_health_bill.pm

(Note: that once this Bill is passed into law (expected late 2015), Implementation will occur in a staged manner over a 3 to 5 year period, and the provisions of the Health Act 1911 will not immediately be repealed).