



NZSSA Guidelines: *Management of Instrumentation and Creutzfeldt-Jakob Disease*

Overview

This document

This document outlines the guidelines for the management of instrumentation which has been used in the care of a patient with or suspected of having Creutzfeldt-Jakob Disease [CJD] for Sterile Services Departments / Units within New Zealand which are endorsed by the New Zealand Sterile Services Association [NZSSA].

These guidelines may be used to develop policies and procedures to prevent events which could lead to transmission of CJD through a surgical procedure and provide guidance to assist health care professionals improve the quality of patient care.

In recognition of the need to systematically manage instrumentation used during patient care on a patient with or suspected of having CJD, the NZSSA has adopted the following position:

- A partnership must be developed between Sterile Services, Operating Theatres and Loan instrumentation Suppliers
- There should be policies and procedures, created in collaboration with Sterile Services and Operating Theatres to address the systematic management of surgical instrumentation.
- There should be policies and procedures, created in collaboration with Sterile Services, Operating Theatres and Suppliers, to address the systematic management of loan equipment used in patient care.
- Staff responsible for the decontamination, sterilization and use of surgical instrumentation must be trained and knowledgeable of all aspects of this process.
- Endorses the World Health Organization Infection Control Guidelines for Transmissible Spongiform Encephalopathies, from which these guidelines have been formed.
- Surgical instrumentation used on a confirmed CJD or vCJD patient must be incinerated [preferred option] or decontaminated via the guidelines outlined in this document.

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Overview, Continued

This document continued

- Surgical instrumentation used on a suspected CJD or vCJD patient must not be re-used, but quarantined by securely storing in a rigid, sealed container after use, until the diagnosis is confirmed.
 - If CJD or vCJD or diagnosis is inconclusive, the instruments should be disposed of by incineration.
 - Only if a definitive alternative diagnosis is confirmed may the instruments be decontaminated following the usual routine procedures and returned to use.
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Introduction

Purpose

To establish a standardized format that can be used as a guideline to develop policies and procedures to systematically manage surgical instrumentation use in the care of a patient with or suspected of having CJD.

Surgical instrumentation includes instrumentation loaned from other healthcare facilities and Suppliers for specific procedures.

Scope

For use by Sterile Services, Operating Theatres and Loan Instrument Suppliers throughout New Zealand.

Associated documents

The table below identifies associated documents.

Type	Title/Description
Standard	<ul style="list-style-type: none">AS/NZS 4187:2003 – Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.
Guidelines	<ul style="list-style-type: none">WHO/CDS/CSR/APH2000.3 – WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. Report of a WHO Consultation – Geneva, Switzerland, 23 – 26 March 1999.
Other	<ul style="list-style-type: none">Health Canada: Infection Control Guidelines: Classic Creutzfeldt-Jakob Disease in Canada. Canada Communicable Disease Report November 2002. Volume 28S5.NSH Health Service Circular: Variant Creutzfeldt-Jakob Disease: Minimising the risk of transmission. Series Number: HSC 1999/178; 13th August.Scottish Executive Health Department: Variant Creutzfeldt-Jakob Disease: Minimising the risk of transmission. NHS HSC 1999/65; 31st August.UK Department of Health – Advisory Committee for Dangerous Organisms CJD Guidelines 2003.AORN – Standards, Recommended Practices and Guidelines – 2006 Edition with Official AORN Statements.



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Background

Transmissible spongiform encephalopathies [TSEs]

TSEs are also known as prion diseases and are fatal, degenerative brain diseases. The TSE agents are hardy, remain infectious for years in a dried state, and represent a unique infection control problem because prions exhibit an unusual resistance to conventional chemical and physical decontamination methods.

One TSE of particular interest to Sterile Services is Creutzfeldt-Jakob Disease [CJD].

Modes of transmission

Modes of transmission of CJD that have been identified are:

- Through the use of peripheral injection of human gonadotropin and growth hormone
 - Transplanted tissues
 - Contaminated surgical instruments
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Decontamination

The abnormal protein associated with CJD is very resistant to all common methods of inactivation used in current decontamination practices.

Prions exhibit an unusual resistance to conventional chemical and physical decontamination methods. These include both gaseous [i.e. ethylene oxide and formaldehyde] and physical processes [e.g. dry heat, boiling and autoclaving at conventional exposure conditions]. Recent research has shown that prions bind tightly to steel.

A common consensus concludes that effective cleaning of surgical instruments prior to sterilization is of the utmost importance in reducing the risk of transmission of CJD via surgical procedures. Therefore, it is essential that all existing cleaning and sterilization procedures operate to the highest standards.

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Background, Continued

Surgical instruments

To further reduce the risk of transmission of CJD via surgical procedures, consideration should be given to the condition of the surgical instrumentation in use, as instrumentation which is difficult to clean and / or in poor condition makes decontamination less efficient.

Instrumentation that cannot be easily cleaned should be identified and where practicable and in a planned programme, be replaced with versions that are easier to decontaminate.

International recommendations

Australia, Health Canada, World Health Organization and the United Kingdom have the most stringent recommendations, where incineration is recommended for instruments exposed to high infectivity tissue.

Incineration or the CJD decontamination process [as recommended by WHO and adopted by these countries] must be followed without exception when instruments are exposed to high or low infectivity tissues of a high risk patient or high infectivity tissues and CSF of an at risk patient. This recommendation includes endoscopy equipment such as bronchoscopes.

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Recommendations

Preamble

The following are the recommendations from WHO regarding the decontamination and sterilization of surgical instruments to prevent iatrogenic and nosocomial transmission of Transmissible Spongiform Encephalopathies of which CJD is one. These recommendations are endorsed by the NZSSA.

Surgical procedures

- Before admission to a hospital or healthcare facility, the infection control team should be informed of the intention to perform a surgical procedure on any person with confirmed or suspected TSE.
 - Every effort should be made to plan carefully not only the procedure, but also the practicalities surrounding the procedure, e.g. instrument handling, storage, cleaning and decontamination or disposal.
 - Written protocols are essential.
 - All staff involved in procedures on patients with or suspected of having CJD and subsequent re-processing or disposal of potentially contaminated items, should be aware of the recommended precautions, and be adequately trained.
 - Staff should be made aware of any such procedures in sufficient time to allow them to plan and to obtain suitable instruments and equipment [such as single use items].
 - Schedule the patient at the end of the day's operating list.
 - Staff must adhere to protocols that identify specifics regarding pre-operative, peri-operative and post-operative management of the patient, disposable materials, including bandages and sponges, and re-usable materials.
 - Ancillary staff, such as laboratory and Sterile Services personnel, must be informed and appropriate training provided.
 - Microbiologist to be involved in the decision as to whether to incinerate or decontaminate contaminated instrumentation.
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Recommendations, Continued

Handling of surgical instruments

Determination of which method to use for decontamination of surgical instruments is based upon the infectivity level of the tissue and the way in which instruments will subsequently be re-used.

For example:

- Where surgical instruments contact high infectivity tissues, single-use surgical instruments are strongly recommended.
- If single-use instruments are not available, maximum safety is attained by destruction of re-usable instruments.
- Where destruction is not practical, re-usable instruments must be handled and decontaminated as outlined towards the end of this section.
- Although CSF is classified as a low infectivity tissue and is less infectious than high infectivity tissues it recommended that instruments contaminated by CSF should be handled in the same manner as those contacting high infectivity tissues.

General measures for cleaning instruments and environment

- Instruments should be kept moist until cleaned and decontaminated.
- Instruments should be cleaned as soon as possible after use to minimize drying of tissues, blood and body fluids onto the item.
- Avoid mixing instruments used on no detectable infectivity tissues with those used on high and low infectivity tissues.
- Recycle durable items for re-use only after TSE decontamination by methods outlined in this document.
- Instruments to be cleaned in automated mechanical processors must be decontaminated by methods outlined towards the end of this section before processing through these machines, and the washers (or other equipment) should be run through an empty cycle before any further routine use.
- Cover work surfaces with disposable material, which can then be removed and incinerated; otherwise clean and decontaminate underlying surfaces thoroughly using recommended decontamination procedures outlined towards the end of this section.

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Recommendations, Continued

General measures for cleaning instruments and environment *continued*

- Be familiar with and observe safety guidelines when working with hazardous chemicals such as sodium hydroxide (NaOH, 'soda lye') and sodium hypochlorite (NaOCl, 'bleach').
- Observe manufacturers' recommendations regarding care and maintenance of equipment.

Transportation of contamination instrumentation

- Those instruments used for invasive procedures on TSE patients [i.e. used on high or low infectivity tissues] should be securely contained in a robust, leak-proof container labelled "Biohazard".
- They should be transferred to the sterilization department as soon as possible after use, and treated by a method outlined towards the end of this section, or transferred to the incinerator.
- A designated person who is familiar with the WHO guideline should be responsible for the transfer and subsequent management.

Destruction of surgical instruments

Items for disposal by incineration should be isolated in a rigid clinical waste container labeled 'Hazardous' and transported to the incinerator as soon as practicable.

Quarantine

- All instrumentation for quarantine is required to have gross bio-burden removed prior to transportation to the Sterile Services Unit, where they shall be pre-clean prior to quarantine.
- If a facility can safely quarantine instruments until a diagnosis is confirmed, quarantine can be used to avoid needless destruction of instruments when suspect cases are later found not to have a TSE.
- Items for quarantine should be cleaned by the best non-destructive method as outlined in the 'Decontamination Procedures' section, sterilized, packed, date and labeled 'Hazard', and stored in specially marked rigid sealed containers in a dedicated area within the decontamination area..

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Recommendations, Continued

Quarantine *continued*

- Monitoring and ensuring maintenance of quarantine is essential to avoid accidental re-introduction of these instruments into the circulating instrument pool.
 - If TSE is excluded as a diagnosis, the instruments may be returned to circulation after appropriate sterilization.
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Anaesthesia

- TSEs are not transmissible by the respiratory route; however, it is prudent to treat any instruments in direct contact with mouth, pharynx, tonsils and respiratory tract by a method outlined in this document.
 - Destruction by incineration of non re-usable equipment is recommended.
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Decontamination Procedures

General considerations

TSE agents are unusually resistant to disinfection and sterilization by most of the physical and chemical methods in common use for decontamination of infectious pathogens.

Variability in the effectiveness appears to be highly influenced by the nature and physical state of the infected tissues. For example, infectivity is strongly stabilized by drying or fixation with alcohol, formalin or glutaraldehyde. As a consequence, contaminated materials should not be exposed to fixation reagents, and should be kept wet between the time of use and disinfection by immersion in chemical disinfectants.

Disinfectants

The following table outlines ineffective or sub-optimal disinfectants:

Chemical disinfectants	Gaseous disinfectants	Physical processes
<u>Ineffective:</u> <ul style="list-style-type: none"> • alcohol • ammonia • β-propiolactone • formalin • hydrochloric acid • hydrogen peroxide • peracetic acid • phenolics • sodium dodecyl sulfate (SDS) (5%) 	<u>Ineffective:</u> <ul style="list-style-type: none"> • ethylene oxide • formaldehyde 	<u>Ineffective:</u> <ul style="list-style-type: none"> • boiling • dry heat (<300°C) • ionising, UV or microwave radiation
<u>Variably or partially effective:</u> <ul style="list-style-type: none"> • chlorine dioxide • glutaraldehyde • guanidinium thiocyanate (4 M) • iodophores • sodium dichloro-isocyanurate • sodium metaperiodate • urea (6 M) 		<u>Variably or partially effective:</u> <ul style="list-style-type: none"> • autoclaving at 121°C for 15 minutes • boiling in 3% sodium dodecyl sulfate (SDS)

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Decontamination Procedures, Continued

Decontamination of instruments

The most stringent recommendations are applied to instruments contacting high infectivity tissues of a person with a known TSE, which will also subsequently be re-used in the CNS or spinal column. Policy makers are encouraged to adopt the highest decontamination methods feasible until studies are published which clarify the risk of re-using decontaminated instruments.

It was emphasized that the safest and most unambiguous method for ensuring that there is no risk of residual infectivity on surgical instruments is to discard and destroy them by incineration.

Those surgical instruments that are going to be re-used may be mechanically cleaned in advance of subjecting them to decontamination.

- Mechanical cleaning will reduce the bio-load and protect the instrument from damage caused by adherent tissues.
- If instruments are cleaned before decontamination, the cleaning materials must be treated as infectious waste, and the cleaning station must be decontaminated by one of the methods outlined towards the end of this section.
- The instruments are then treated by one of the decontamination methods recommended in this document before reintroduction into the general instrument sterilization processes.

It is recommended that, where possible, two or more different methods of inactivation be combined in any sterilization procedure for these agents. Procedures that employ heat and NaOH [either consecutively or simultaneously] appear to be sterilizing under worst-case conditions [e.g., infected brain tissue partly dried on to surfaces]. Moreover, hot alkaline hydrolysis reduces biological macromolecules to their constituent sub-units, thereby cleaning as well as inactivating.

Complex and expensive instruments such as intracardiac monitoring devices, fiberoptic endoscopes, and microscopes cannot be decontaminated by the harsh procedures specified in this document.

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Decontamination Procedures, Continued

Decontamination of instruments *continued*

- Instead, to the extent possible, such instruments should be protected from surface contamination by wrapping or bagging with disposable materials.
- Those parts of the device that come into contact with internal tissues of patients should be subjected to the most effective decontaminating procedure that can be tolerated by the instrument.

Some instruments can be partly disassembled [e.g. drills and drill bits]. Removable parts that would not be damaged by autoclaving, NaOH, or bleach should be disassembled and treated with these agents.

These cleaning procedures should be applied even if the instrument has been re-used before discovery of its potential contamination.

Contaminated instruments or other contaminated materials should not be cleaned in automated washers without first having been decontaminated using a method recommended towards the end of this section.

Decontamination of work surfaces

Because TSE infectivity persists for long periods on work surfaces, it is important to use disposable cover sheets whenever possible to avoid environmental contamination, even though transmission to humans has never been recognized to have occurred from environmental exposure.

It is important to mechanically clean and disinfect equipment and surfaces that are subject to potential contamination, to prevent environment build-ups.

Surfaces contaminated by TSE agents can be disinfected by flooding, for one hour, with NaOH or sodium hypochlorite, followed by water rinses.

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Decontamination Procedures, Continued

Decontamination of wastes and waste-contaminated materials

Liquids used for cleaning should be decontaminated in situ by addition of NaOH or hypochlorite or any of the procedures listed towards the end of this section, and may then be disposed of as routine hospital waste.

Cleaning tools and methods should be selected to minimize dispersal of the contamination by splashing, splatters and aerosols.

Where possible, cleaning tools such as brushes, towelling and scouring pads, as well as tools used for disassembling contaminated apparatus, should either be disposable or selected for their ability to withstand the disinfection procedures outlined towards the end of this section.

Upon completion of the cleaning procedure, all solid wastes including disposable cleaning materials should be collected and decontaminated. Incineration is highly recommended.

Automated cleaning equipment must not be used for any surgical instrument, equipment or material that has not previously been thoroughly decontaminated following the recommendations outlined in the '*decontamination of instruments*' section above. Cleaning of the automated cleaning equipment post processing instruments used during a CJD or suspected CJD surgical cases should be done according to manufacturer's instructions.

Personal protection during decontamination procedures

Persons involved in the disinfection and decontamination of instruments or surfaces exposed to the tissues of persons with TSE should wear single-use protective clothing, gloves, mask and visor or goggles.

Handling of contaminated instruments during transfers and cleaning should be kept to a minimum.

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Decontamination Procedures, Continued

Decontamination risk categories The following table outlines the recommended level of decontamination for different risk categories:

Patient category	Tissue category	Decontamination options
Confirmed or suspect cases of TSE	High infectivity	See decontamination methods for TSEs listed after this table.
	Low infectivity	See decontamination methods for TSEs listed after this table [but note that CSF, and peripheral organs and tissues are regarded as less infectious than the CNS]
Persons with known prior exposure to human pituitary derived hormones, cornea or dura mater grafts	High infectivity	See decontamination methods for TSEs listed after this table.
	Low infectivity	Routine cleaning and disinfection procedures
Members of families with heritable forms of TSE	High Infectivity	No consensus was reached. The majority felt that TSE decontamination method should be used, but a minority felt this was unwarranted.
	Low Infectivity	Routine cleaning and disinfection procedures.
All of the above categories	No detectable infectivity	Routine cleaning and disinfection procedures.
Confirmed or suspect cases of CJD	All tissue categories	See decontamination methods for TSEs listed after this table.



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Decontamination Methods

General

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration.

Wherever possible, instruments and other materials subject to re-use should be kept moist between the time of exposure to infectious materials and subsequent decontamination and cleaning.

Incineration

- Use for all disposable instruments, materials, and wastes.
 - Preferred method for all instruments exposed to high infectivity tissues.
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Autoclave / chemical methods for heat-resistant instruments

- Immerse in NaOH and boil for 10 min at atmospheric pressure; clean, rinse in water and subject to routine sterilization.
 - Immerse in sodium hypochlorite (preferred) or NaOH (alternative) at ambient temperature for 1 hr; clean; rinse in water and subject to routine sterilization.
 - Autoclave at 134°C for 18 minutes [pre-vacuum].
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Flash Sterilization

Flash sterilization is ineffective in destroying the CJD agent and **MUST NEVER** be considered as a processing method for reusable instruments exposed to the CJD agent.

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Decontamination Methods, Continued

Chemical methods for surfaces and heat sensitive instruments

- Flood with NaOH or undiluted sodium hypochlorite; let stand for 1 hr.; mop up and rinse with water.
 - Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefit may be derived from the use of one or another of the partially effective methods listed in table above titled: Ineffective or sub-optimal disinfectants.
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Autoclave / chemical methods for dry goods

- Immersible goods that can withstand either NaOH or sodium hypochlorite should first be immersed in one or the other solution (as described above) and then heated in a pre-vacuum autoclave at 121°C for 1 hr.
 - Bulky immersible goods of any size that cannot withstand exposure to NaOH or sodium hypochlorite should be heated in a pre-vacuum autoclave at 134°C for 1 hr.
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Notes about autoclaving and chemicals

Pre-vacuum autoclaves:

- Air is exhausted by vacuum and replaced by steam.
- Porous load autoclaves are optimized for sterilization of clean instruments, gowns, drapes, towelling, and other dry materials required for surgery.
- They are not suitable for liquid sterilization.

Sodium Hydroxide (NaOH, or soda lye):

- Be familiar with and observe safety guidelines for working with NaOH.
 - 1N NaOH is a solution of 40 g NaOH in 1 litre of water.
 - 1N NaOH readily reacts with CO₂ in air to form carbonates that neutralize NaOH and diminish its disinfective properties.
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Decontamination Methods, Continued

Notes about autoclaving and chemicals *continued*

- 10 N NaOH solutions do not absorb CO₂, therefore, 1N NaOH working solutions should be prepared fresh for each use either from solid NaOH pellets, or by dilution of 10 N NaOH stock solutions.

Sodium hypochlorite (NaOCl solution, or bleach):

- Be familiar with and observe safety guidelines for working with sodium hypochlorite.
 - Household or industrial strength bleach is sold at different concentrations in different countries, so that a standard dilution cannot be specified.
 - Efficacy depends upon the concentration of available chlorine and should be 20,000 ppm available chlorine. One common commercial formulation is 5.25% bleach, which contains 25,000 ppm chlorine. Therefore, undiluted commercial bleach can be safely used.
 - If solid precursors of hypochloric acid are available, than stock solution and working solutions can be prepared fresh for each use.
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