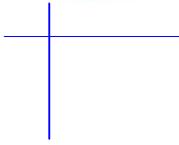




Medical Technology
Association of Australia



National Health and Medical Research Council (NHMRC)

**Consultation Paper on Australian Guidelines for the
Prevention and Control of Infection in Healthcare**

Submission by
Medical Technology Association of Australia

10 March 2010

Medical Technology for a Healthier Australia

1. Executive Summary

This submission is in response to the January 2010 consultation paper *Australian Guidelines for the Prevention and Control of Infection in Healthcare*. The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the draft Guidelines and make specific recommendations.

As a general comment MTAA would like to see adoption of best practice and where best practice is already evidenced in Australia, to incorporate those standards and practices. MTAA is concerned that the draft Guidelines have not recognized currently applied practices and in many instances the research draws on older data. In addition, MTAA has identified areas where there are gaps in the draft Guidelines and makes recommendations for the inclusion of additional areas for coverage.

MTAA recommends:

- Inclusion of guidelines mandating the use of Safety Engineered Medical Devices (SEMDs) to prevent needlestick and other sharps injuries to healthcare workers.
- Inclusion of guidelines recommending safety procedures to prevent infection from scalpel injuries.
- Inclusion of guidelines outlining the risks associated with the re-processing and re-use of single-use devices (SUDs).
- Inclusion of guidelines recommending the best procedures for avoiding cross-contamination from flexible endoscopes.
- Inclusion of guidelines to avoid infection risks associated with the maintenance and repair of devices.
- Inclusion of guidelines mandating training for all visitors to the perioperative environment.
- Inclusion of guidelines to introduce Outcome Reporting of healthcare associated infections.

2. About the Medical Technology Association of Australia and the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as bandages and syringes, to high technology items such as cochlear implants and cardiac defibrillators, in vitro diagnostic products and diagnostic imaging equipment such as ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI) machines.

Among the range of medical products are many which contribute to the management of patient and healthcare worker safety, and assist in controlling hospital-acquired infection. These include SEMDs such as safety-engineered hypodermic needles, safety syringes and infusion catheters, safety lancets and scalpels, infection control solutions and surveillance.

The medical technology industry had sales in Australia of more than \$7 billion in 2008/2009 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit and to support healthcare workers.

3. Comments on the draft Guidelines

The draft *Australian Guidelines for the Prevention and Control of Infection in Healthcare* provide recommendations that outline critical aspects of infection prevention and control. The Garling report¹ refers to 30 policies for infection control in NSW and makes 139 recommendations that aim to modernise work practices, administration and equipment.

The Guidelines should evidence best practice currently available in Australia and where current practice is not best practice, then identify the gaps and propose additional guidelines. MTAA provides comment on additional guidelines that may be included. For example, ensuring the safety of healthcare workers through a program to mandate the use of safety engineered devices, ensuring safe procedures for scalpel use, ensuring that hospitals are aware of the risks associated with re-use of SUDs, training individuals in the perioperative environment, and reporting outcomes.

4. Safety Engineered Medical Devices

The safety of healthcare employees can be improved by mandating the use of safety engineered medical devices (SEMDs) to prevent needlestick injuries. A core principle of the guidelines is *“effective work practices that minimize the risk of selection and transmission of infectious agents”*. The objective is the prevention of needlestick or sharps injuries (and associated infection) in patients, healthcare workers, pharmacists, waste handlers and laboratory/housekeeping personnel.

Sharps safety is outlined under B1 STANDARD PRECAUTIONS (B1.3 Sharps, Risks, Handling, Disposal, Safety Devices). This covers:

Section B1.3.1 Risks (Handling and Disposing of Sharps).

This section outlines the risks associated with handling sharps. Specific concern is noted regarding the use of hollow-bore needles, which are associated with increased risk for hepatitis B, hepatitis C or HIV transmission.

1.3.2 Handling. This section details standard measures to avoid sharps injuries.

1.3.3 Disposal. This section details safe ways to dispose of sharps.

1.3.4 Safety Devices. This section describes safety devices and their use; however no specific recommendation is made to actually use them. MTAA would like to see a guideline mandating the use of safety sharps.

Recommendation 8 Safe handling of Sharps should state: Safety sharps should be used wherever possible.

¹ Garling, P. Final report of the Special Commission of Inquiry: Acute Care Services in NSW Public Hospitals. Sydney: NSW Government, 27 Nov 2008.

The Guidelines note that the use of safety devices has been mandated in the UK and Europe, but not in Australia (despite being promoted by industry). As the industry association representing the manufacturers and distributors of SEMDs, MTAA points out that it is a member of a broad cross-section of interests which together are advocating the mandatory introduction of SEMDs, together with improved education and reporting of incidents. The coalition partners and objectives are set out in the Consensus Statement at Attachment A.

The Guidelines state that their introduction needs to be accompanied by “*education of healthcare workers so that they are used properly and any risk to patients is minimized*”, and that: “*In the meantime if a facility chooses to use safety-engineered devices, introduction of the devices must be supported by a comprehensive training and education program*”. MTAA agrees and would like to see more detail provided, for example specifics outlining the competency-based training needed for staff using new safety technology.

The Guidelines state that “*a range of devices has been designed with built-in safety features that reduce the risk of injury involving a sharp ... their use has recently been mandated in the UK and Europe, but not yet in Australia*”. Australia is behind the majority of international healthcare systems that have introduced safety sharps and MTAA would like to see the use of safety sharps mandated in Australia. The USA introduced safe needles into health care settings in 2000 and the use of devices with safety engineered features is thought to have reduced the rates of needlestick injuries².

The Guidelines provide the following clinical question for systemic review:

(ii). Does the use of retractable devices show a decreased rate in the incidence of sharps injuries for health care workers?

There is compelling evidence available internationally to show the scale of the problem of risk arising from the use of non-SEMD in Australia and much evidence to show that SEMDs reduce injury. MTAA does not promote the use of any specific SEMD. There is a wide variety of products available in the market. Retractable technology is only one example of the broad range of SEMDs which have been designed and produced with built-in safety features to assist in reducing the risk of occupational exposure to bloodborne pathogens in healthcare. These devices include: syringes with guards or sliding sheaths that shield the attached needles after use; needles that retract into a syringe after use; shielded, blunting or retracting needles used for intravenous cannulation; shielded needles used for phlebotomy procedures, blunt suture needles, surgical blades with protective covers etc. Evidence showing the scale of the problem is outlined below:

- In Australia at least 18,500 nurses and other healthcare employees suffer needlestick and sharp object injuries every year³.
- Approximately 50% of needlestick injuries are not reported. Therefore the actual number of injuries in Australia is likely to be in excess of 30,000 per year⁴.

² Jagger et al. (2008). The impact of U.S. policies to protect healthcare workers from bloodborne pathogens: the critical role of safety engineered devices. *Journal of Infection and Public Health*, 1(2), 52-71.

³ Murphy, C. (2008). Improved surveillance and mandated use of sharps with engineered sharp injury protections: a national call to action. *Healthcare Infection*, 13, 33–1107.

- Needlesticks and other sharps are identified as high risk occupational hazards by 43.5% of nurses⁵.
- The Needlestick Safety and Prevention Act was implemented in the USA in 2001 and safety-engineered sharps must be used where feasible⁶.
- Since mid 2000, occupational health & safety legislation/regulations have mandated the use of safety engineered medical devices in the majority of Canadian provinces⁷.
- Guidelines incorporating the use of safety-engineered sharps as a standard were incorporated into EU health and safety legislation in the week commencing 8 March 2010. The three directives (89/391/EC, 89/655/EC and 2000/54/EC) mandate the use of safety engineered devices and ban the practice of recapping⁸.
- The introduction of the Needlestick Safety and Prevention Act (USA, 2000) was associated with a 36% decrease in the rate of injury from hollow-bore needles⁹.
- A UK study found that introducing safety needles and concomitant training significantly reduced the number of reported needlestick injuries (from 16.9/100,000 to 6/100,000, $p < 0.045$)¹⁰.
- A study in an Australian teaching hospital showed that the use of safety devices such as retractable syringes and needle-free IV systems reduced needlestick injuries by almost 50%¹¹. The study reported a reduction of percutaneous injuries from 3.39 pre-implementation to 1.5 injuries per 100 staff annually.
- A recent ECRI report on the "Top 10 medical technology hazards for 2010"¹² ranked needlesticks and other sharps injuries as number 6.

The Australian Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting state that: "*Where possible, alternatives should be considered, including needleless intravenous systems, the use of blunt needles for drawing up sterile solutions from ampoules, or the use of retractable needle and syringe systems*"¹³. However, requirements differ between Australian states and there is no centralized system for monitoring and reporting sharps injuries. Chapter 23 of the Infection Control Guidelines outlines safety measures for Needlestick and other blood or body fluid incidents. Additionally, the Australian National Council for AIDS, Hepatitis C and Related Diseases (ANCAHRD) has published a comprehensive bulletin

⁴ Perry, J., & Jagger, J. (2003). Healthcare Worker Blood Exposure Risks: Correcting some outdated statistics. *Advances in Exposure Prevention*, 6(3), 28-31.

⁵ Australian Safety and Compensation Council (ASCC). Occupational Exposures in Australian Nurses, July 2008. Canberra: ASCC; 2008.

⁶ United States Department of Labor. Occupational Safety and Health Administration. Needlestick Safety and Prevention Act (H.R. 5178), November, 2000.

⁷ Canadian Occupational Health and Safety Regulations. Sharps Safety Regulations (BC, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia).

⁸ Framework Agreement on sharps safety, signed by HOSPEEM and EPSU July 17, 2009.

⁹ Jagger, J. (2007). Caring for Healthcare Workers: A Global Perspective. *Infection Control and Hospital Epidemiology*, 28, 1-4.

¹⁰ Adams, D. & Elliot, T.S. (2006). Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study. *Journal of Hospital Infection*, 64(1), 50-5.

¹¹ Whitby et al. (2008). Needlestick injuries in a major teaching hospital: The worth-while effect of hospital-wide replacement conventional hollow-bore needles. *American Journal of Infection Control*, 36, 180-186.

¹² 2010 Top 10 Technology Hazards. Health Devices, November, 2009, 38(11). www.ecri.org.

¹³ Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting. Australian Government. Department of Health and Ageing. January 2004.

which outlines the management of exposure to blood and body fluids contaminated with blood, including needlestick/sharp injuries¹⁴.

The draft Guidelines state that: *“All health care establishments must develop their own infection control protocols for communicable diseases, including clear written instructions on the appropriate action to take in the event of needlestick and other blood or body fluid incidents involving either patients or health care workers”*¹⁵. Prevention measures must include the implementation and use of safety engineered medical devices combined with relevant training and education. MTAA would like to see a national standard mandating the use of SEMDs in accordance with US, Canadian and European laws and **recommends** the following:

- Prevention and management of occupational exposure to blood-borne viruses including the implementation and use of SEMDs.
- Personal protective equipment (PPE), availability of SEMDs.
- Evidence that system for use and management of invasive devices, incorporating infection prevention and mandatory use of SEMDs, is implemented and active.
- Evidence that invasive device mandatory protocols (including the use of SEMDs) are active and complied with.

The draft Guidelines state that: *“the use of retractable safety devices on sharps has been associated with a significant reduction in needlestick injury in healthcare settings although their direct impact is difficult to determine because their introduction is often associated by other interventions (e.g. training and education, overarching hospital policies and other technologies) that in isolation could also cause a reduction in needlestick injuries”*. The question of the impact of concomitant education with safety devices cannot practically be answered. Education should be mandatory with the use of any new device. Improved safety will result from both the safety mechanics of the device and education surrounding risk and the correct use of the device. Preventing infection through the use of safety devices should include education around how to use the device as well as proper work practices (e.g. capping, sharps disposal and introducing no-hands procedures in sharps handling).

Section B1.3.5 Putting it into Practice –states that healthcare workers should *“Avoid using needles where safe and effective alternatives are available”*. MTAA **recommends** that this read *“Safe effective alternatives such as safety engineered medical devices including syringes with guards that shield the attached needle after use; needles that retract into a syringe after use and shielded or retracted needles used for intravenous cannulation should be used where possible”*.

Section B1.3.4 Needleless devices states that the *“adoption of needleless devices has contributed to a decrease in percutaneous injuries among healthcare workers. However, there may be implications for patient safety”*. *While it is difficult to assess the overall effect of needleless devices because of the wide variety of devices and systems that are*

¹⁴ Australian National Council for AIDS, Hepatitis C and Related Diseases (ANCAHRD). Bulletin No 29: Needlestick and Blood Accidents.

¹⁵ Australian Infection Control Guidelines, p23-2, Needlestick and other blood or body fluid incidents.

in use, some studies have shown an increased risk of bloodstream infections (BSI) among patients¹⁶. MTAA **recommends** that this section be expanded to include:

- Standards that address clarity and direction for healthcare providers in distinguishing the many types of needleless devices available.
- Standards that ensure that the introduction of needleless systems is supported by adequate educational programs, bundled recommendations and epidemiological surveillance.
- Inclusion of anti-reflux valves in the guidelines as an available technology and potential strategy to reduce catheter-related bloodstream infections.
- Guidelines that highlight the use of antiseptic barrier caps as a potential preventative strategy to reduce catheter-related bloodstream infections.
- Guidelines that advocate the use of brand specific data rather than general design classification data as part of a selection process for needleless systems.

5. Sharps Safety (Scalpels)

Section B1.3.2 Handling of sharps

While the Guidelines are detailed regarding needlestick injuries, less emphasis is placed on scalpel safety. Surgeons show a reluctance to use safety-engineered scalpels. Recently the term 'scalpel safety' (rather than 'safety scalpel') was coined to educate healthcare professionals about best safety practices around scalpels. The 'scalpel safety' technique involves using a single-handed scalpel blade remover and a hands-free passing technique (HFPT) (the scalpel is passed on to a tray or into a neutral zone before being picked up again)^{17, 18}.

Standard measures to avoid sharps injuries include handling sharp devices in a way that prevents injury to the user and to others who may encounter the device during or after a procedure. Examples include:

- Using instruments, rather than fingers, to grasp needles, retract tissue, and load/unload needles and scalpels.
- Giving verbal announcements when passing sharps.
- Avoiding hand-to-hand passage of sharp instruments by using a basin or neutral zone.
- Using alternative cutting methods such as blunt electrocautery and laser devices when appropriate.
- Substituting endoscopic surgery for open surgery when possible.
- Using round-tipped scalpel blades instead of pointed sharp-tipped blades.
- Double gloving.

¹⁶ Rupp et al. (2007). Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. *Clinical Infectious Diseases*, 44(11), 1408-1414.

¹⁷ Scalpel Safety (2009). Staying safe while working on the cutting edge. *Environment of Care News*, 12(3), 6-11.

¹⁸ Sinnott, M. & Shaban, R. (2010). 'Scalpel Safety', not 'Safety Scalpel': A new paradigm in staff safety. *Perioperative Nursing Clinics*, 5, 59-67.

The Australian Standard AS/NZS 3825:1998 (Procedures and devices for the removal and disposal of scalpel blades from scalpel handles) says that a used blade should not be removed with fingers or artery forceps. The standards illustrate the removal of a blade from the handle, removal by hand or artery forceps is not recommended. The standards do not recommend resheathing-type actions.

Safety devices and procedures include cut-resistant gloves and liners, hands-free passing techniques, scalpel blade removal devices and innovative safety scalpels, which may include features such as disposable scalpels that do not require blade removal, retractable blades and scalpels with round-tipped blades. There are a number of guidelines outlining the safe use of scalpels, however there is a lack of knowledge about these guidelines. A recent review on scalpel safety in the operating room setting, states that it was limited by the quantity and quality of the available evidence¹⁹. The Australian Safety and Efficacy Register of New Interventional Procedures studied the literature and found no evidence that safety scalpels were in fact safer²⁰.

The scope of the problem:

- The Centers for Disease Control and Prevention (CDC) estimates that 385,000 needlestick and other sharps-related injuries occur each year in the US²¹.
- Scalpel blade injuries account for 7-8% of these injuries²².
- The second most common injury reported in operating theatres are cuts by scalpels²³.
- Scalpel injuries are associated with a physical trauma (e.g. damage to an artery, nerve or tendon) and risk of infection (HIV/AIDS, Hepatitis B, Hepatitis C etc).
- The incidence of scalpel injury in healthcare workers who regularly use scalpels (e.g. perioperative nurses), is more than 200 times higher than the risk of needlestick injury²⁴.
- Given that scalpels are used in a contained environment, they are a good target for an injury prevention program.
- The Centers for Disease Control and Prevention (CDC) estimate that 39% of scalpel injuries are inflicted by the user on the assistant²⁵.
- Passive/automatic safety devices are generally retractable and can be operated using a single hand.
- Active/Manual safety devices require activation by the user. Activation rates vary according to the ease of use²⁶.

¹⁹ Watt, A. M., (2010). "Scalpel safety in the operative setting: A systematic review." *Surgery*, 147(1), 98-106.

²⁰ Royal Australasian College of Surgeons. Scalpel safety in the operative setting. Melbourne (stralia): Royal Australasian College of Surgeons; 2007, ASERNIP-S Report 59.

²¹ Centers for Disease Control and Prevention: Overview: Risks and Prevention of Sharps Injuries in Healthcare Personnel. www.cdc.gov/Sharpsafety/wk_overview.html.

²² Perry J. (2003). EPINet report: 2001 percutaneous injury rates. *Advances in Exposure Prevention* 6(3), 32-36.

²³ "CDC (Centre for Disease Control and Prevention) Sharps Injury Prevention Workbook." from <http://www.cdc.gov/SharpsSafety/workbook.html>

²⁴ Eienstein, H.C. et al. (1992). Epidemiology of reported sharps injuries in a tertiary care hospital. *Journal of Hospital Infection*, 20(4), 271-280.

²⁵ Center for Disease Control and Prevention. Sharps injury prevention workbook. Atlanta, GA: Center for Disease Control and Prevention; 2006.

²⁶ Alvarado-Ramy, F. (2003). A comprehensive approach to percutaneous injury prevention during phlebotomy: Results of a multicentre study, 1993-1995. *Infection Control and Epidemiology*, 24, 2, 97-104.

- Single-handed scalpel blade removers in combination with the hands-free passing technique can potentially prevent 5 times as many injuries as safety scalpels²⁷.

MTAA **recommends** that further detail and specific guidelines for scalpel safety be added. They should reference existing guidelines (e.g. Australian/New Zealand Standard 3825) and introduce new guidelines such the use of single-handed scalpel blade removers in combination with the hands-free passing technique. This would be in line with US practice. The US Joint Commission has stated that to ensure staff safety, a single-handed scalpel blade remover and a HFPT will become the norm in all operating suites in the next 5 years (the Joint Commission is responsible for inspecting hospital operating rooms for accreditation)²⁸.

6. Reprocessing of single-use devices

Section B4 APPLYING STANDARD AND TRANSMISSION BASED PRECAUTIONS TO PROCEDURES includes:

B1.5.1 PROCESSING OF INSTRUMENTS AND EQUIPMENT

The Guidelines should outline the risks associated with the reprocessing of SUDs and ensure that healthcare settings continue to ban the practice of reprocessing. Ensuring the correct use of SUDs eliminates a major potential source of healthcare associated infection. Medical devices designated by their manufacturers as single use have been increasingly developed and in use since the 1980s in response to the need to avoid cross-contamination and increase standards of care. These devices are designated single use because they are not designed and validated to be disassembled, cleaned, reassembled, repackaged and resterilised. Consequently, these devices present an increased risk to the patient or user if they are reprocessed and subsequently reused. The reprocessing of SUDs involves cleaning, sterilising, repackaging and otherwise fixing them to render them as close as possible to their original quality, performance and functionality. The risks include:

- Cross-contamination and hospital acquired infections.
- Problems decontaminating items
- Residues from chemical cleaners /disinfectants
- Breakdown/alterations in material due to corrosion by chemical agents
- Mechanical failure (stress during each cycle of reuse).
- Reactions to endotoxins (sterilisation may not deactivate toxins).
- Exposure to prion diseases (e.g. Creutzfeldt-Jacob disease).
- Difficulties monitoring reprocessing cycles.

There is no conclusive evidence to suggest that the practice of reprocessing SUDs is safe. A recent incident of an infection control breach involving the re-use of SUDs unnecessarily exposed 218 patients to increased levels of risk, while sedatives were

²⁷ Fuentes, H., et al. (2008). Scalpel Safety: Modelling the effectiveness of different safety devices' ability to reduce scalpel blade injuries. *The International Journal of Risk and Safety in Medicine*, 20(1-2), 83-89.

²⁸ Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Scalpel safety—staying safe while working on the cutting edge. *Environmental Care News* 2009;12(3):6–7.

administered during some gastroscopy and colonoscopy procedures at Inverell Hospital²⁹.

The scope of the problem:

- In most European countries the CE Mark of a reprocessed SUD becomes invalid if it is reprocessed beyond its intended use (following reprocessing the device no longer falls under the quality management system of the original manufacturer).
- The reuse of SUDs is banned in France, Spain, Italy, Portugal and Denmark³⁰.
- In Australia, a regulatory framework exists for the remanufacturing of single use medical devices.
- The more complex the device, the more difficult it is to clean.
- Examples of features of devices that are difficult to clean are acute angles, coils, long or narrow lumens, specialist surface coatings.

B1.4.2. Assessing the degree of risk

This section outlines the Risk factors for Categories of Items for Patient Care. Items such as endoscopes are 'critical' as *"these items confer a high risk for infection if they are contaminated with any microorganisms and must be sterile at the time of use. This includes any objects that enter sterile tissue or the vascular system, because any microbial contamination could cause disease"*. MTA would also include in this category any items that have been designed for single use, but reprocessed.

The top medical technology hazard for 2010 reported by ECRI in the USA³¹ is the hazard of cross-contamination from flexible endoscopes. Contamination is almost always due to failure to follow established cleaning and disinfection/sterilisation guidelines, or with the use of damaged or malfunctioning equipment. Common errors include failure to follow manufacturer's recommendations for reprocessing, failure to discard single use items, using incorrect accessories for endoscopy irrigation set-up, and improper reprocessing intervals for reusable endoscopy accessories. A Safety Communication "Preventing Cross-Contamination in Endoscope Processing" was issued by the FDA in November, 2009³². The FDA has cautioned healthcare facilities about the risks to patients if flexible endoscopes and accessories are not properly processed. They provide a number of steps to reduce these risks. The sterilisation procedures for flexible endoscopes outlined by the FDA could be included under B1.5.5 Sterilisation.

Section B4.1.2 Appropriate use of devices. This section outlines the procedures that healthcare workers must adhere to in order to reduce infection associated with single-use items, single-dose vials and multi-dose vials.

Section B1.5 Processing of instruments and equipment

1.5.1 Risks

²⁹ Reported in the *Northern Daily Leader*, Tamworth, 14 November 2009

³⁰ Eucomed white paper on the reuse of single use devices, December 15, 2009. Submitted in response to a call for information from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): http://www.eucomed.org/Home/portal/press/press_releases/2009/12/-/media.

³¹ 2010 Top 10 Technology Hazards. Health Devices, November, 2009, 38(11). www.ecri.org

³² <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm>.

- 1.5.2 Assessing risk
- 1.5.3 Cleaning
- 1.5.4 Disinfection
- 1.5.5 Sterilisation
- 1.5.6 Storage & Maintenance

B2 TRANSMISSION-BASED PRECAUTIONS

Table B4.2: Summary of processes for appropriate use of devices

Single-use items

- *Do not use the same needle, cannula or syringe for more than one patient nor to access a medication or solution that might be used for a subsequent patient*
- *Do not administer medications from a single syringe to multiple patients, even if the needle or cannula on the syringe is changed.*

The Guidelines include detailed infection control standards for the cleaning of equipment. They do not address the risks associated with the reuse of SUDs.

Table B1.4: Characteristics of aprons/gowns

MTAA **recommends** that single-use drapes and gowns in the operating theatre environment should be included. Both Australian College of Operating Room Nurses (ACORN) and the Royal Australasian College of Surgeons (RACS) (supported by the AAMI PB70 standard from the USA and EN13795 standard from the EU) make statements that single-use drapes (impervious) and gowns should be used to reduce the risk of an SSI. This is considered best practice and should be included in the draft Guidelines.

7. Additional measures to reduce infection risk

Accreditation to avoid infection risks associated with device maintenance

The Guidelines should address the risk of infection associated with the maintenance, modification and repair of medical devices. Manufacturers of medical devices, as defined under the Therapeutic Goods Act 1989, producing devices classified higher than Class I, are required to have ISO 13485 certification. Therefore companies which maintain and repair surgical or medical equipment as well as supply medical technology as a manufacturer should be accredited to ISO 13485 and companies which only repair or maintain medical devices should be accredited to ISO 9001.

Accreditation to avoid infection risks associated with visitors to the perioperative environment

The Guidelines include standards for *healthcare workers* in the perioperative environment. The standards cover attire, movement in and out of the theatre, removal of jewellery and artificial nails and nail polish. There is additional scope for the Guidelines to include mandatory safety training and education for *all* individuals in operating theatres (which may include medical company representatives who have a legitimate role in assisting the surgical team with appropriate selection of product and tools).

The Guidelines should reference current standards and training, e.g. ACORN (Australian College of Operating Room Nurses) and MTAA: Introduction to Operating Theatre Protocols. MTAA has developed training in consultation with ACORN and NSW Quality and Safety Branch. It is designed to familiarise new medical company personnel with ACORN standards and protocols for visitors to the perioperative environment and includes aseptic techniques, principles of infection control, OH&S issues and patient and confidentiality requirements. The training has been approved by the ACORN Board and is reviewed every two years in line with the review of the standards.

The Guidelines should refer to the ACORN standards for Perioperative Nursing (2006), specifically Standard 24 (S24) which provides guidance to the perioperative team regarding access and presence of visitors within the operating suite. These standards cover a wide range of visitors from multidisciplinary teams including medical company representatives to surgical assistants and media personnel.

The standards cover:

Standard Statement 1: All visitors

Standard Statement 2: Patient support person

Standard Statement 3: Students

Standard Statement 4: Surgical Assistant

Standard Statement 5: Media Personnel

Standard Statement 6: Medical Company and Commercial Representatives (MCR)

Standard Statement 7: Medical Company and Commercial Representatives (MCR) Authorisation

It should be noted that the current ACORN Standards are under review. The next edition of the Standards will be released in May 2010.

8. Infection control and Outcome reporting

C4 Healthcare-Associated Infection Surveillance

MTAA strongly **recommends** that the Guidelines address reporting standards and public disclosure of infection rates in hospitals. The Guidelines note that: *“Australia currently has no system-wide approach to measurement of patient mortality caused by or associated with HAI”*. This differs from overseas approaches. The UK’s National Health Service individually evaluates deaths caused by infection. Recent legislation in the US allows the Centers for Medicare and Medicaid to adjust reimbursement to hospitals in those cases where patient outcome has been impacted by infection (complications due to preventable infection are reimbursed at the same rate as a non-complicated treatment)³³. The US Deficit Reduction Act provides that payment can be withheld if hospitals do not comply with preventative measures. This evidence-based approach has been shown to decrease adverse outcomes by individual care providers³⁴.

³³ Barnett, T.E. (2007). The not-to-do-hidden costs of surgical site infections. *AORN Journal*, 86, 249-258.

³⁴ Dellinger, E.P. et al. (2005). Hospitals collaborate to decrease surgical site infections. *American Journal of Surgery*, 190, 9-15.

Attachment A Consensus Statement



CONSENSUS STATEMENT

Preventing needlestick injuries in the healthcare workplace

This Consensus Statement reflects the position of the Australian Infection Control Association, Medical Technology Association of Australia, the Australian Nursing Federation, the Royal College of Nursing Australia, the Royal College of Pathologists Australasia and independent experts in relation to a national call to action for the prevention of needlestick injuries in the healthcare workplace.

The provision of a safe and healthy working environment is a fundamental right of every employee in Australia. The duty of care provisions within occupational health and safety legislation aim to protect persons from all types of hazards and risks arising from work activities. Therefore it is reasonable to expect that healthcare employees in Australia should be protected from the hazard of occupational exposure to bloodborne pathogens from needlestick and sharp object injuries and the subsequent risk of acquiring a potentially life threatening bloodborne disease such as hepatitis B, hepatitis C or HIV/AIDS.

In Australia, it has been estimated that at least 18,000 nurses and other healthcare employees suffer needlestick and sharp object injuries every year¹. Numerous studies have shown that approximately 50% of needlestick injuries are not reported, with rates of underreporting ranging from 40% to 80%². *Therefore the actual number of injuries to healthcare professionals is likely to be in excess of 30,000 per year.*

A recent report published by the Office of the Australian Safety and Compensation Council found that needlesticks and other sharps are identified as high risk occupational hazards by 43.5% of nurses. The report shows that 1 in 9 nurses had at least one needlestick or other sharps injury in the past 12 months³.

Needlestick and other sharp object injuries generate significant cost for the Australian healthcare system and can result in great stress for the injured healthcare workers and their families.⁴

Independent studies show that the majority of needlestick injuries are preventable through the implementation and use of safety engineered medical devices (SEMD) combined with relevant education and training programs for healthcare employees.⁵⁻⁹

Attachment A Consensus Statement

Unlike many countries, Australia has yet to adopt a nationally consistent approach to the use of SEMD in healthcare settings either through prescriptive legislation or policy. Guidelines, awareness and education campaigns and other non-legislative initiatives alone have generally proven ineffective in preventing needlestick injuries to healthcare employees.⁹

Today, many international jurisdictions have taken steps to amend Occupational Health and Safety Legislation and include provision for mandatory use of safety engineered needles and sharps in medical workplaces.¹⁰⁻¹³

Why should healthcare employees in Australia not be afforded the same legislative protection?

The elimination of workplace hazard and risk is a fundamental principle of occupational health and safety legislation in Australia. Every needlestick or sharp object injury at work is a foreseeable hazard faced by healthcare employees in Australia.

All employees in the Australian healthcare sector have the right to work without concern of experiencing a needlestick or sharps injury. The risk of occupational exposure to bloodborne pathogens from such injuries can be and must be eliminated.

The undersigned organisations support the introduction of nationally consistent policy and/or legislation aimed at preventing needlestick injuries in healthcare. Prevention measures must include the implementation and use of safety engineered medical devices combined with relevant training and education.

Safety and quality is central to healthcare in Australia. The safety of all healthcare employees must be viewed as paramount and is everyone's responsibility. Safety for healthcare employees is as important as patient safety.

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Attachment A

Consensus Statement

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