Medical Technology
Association of Australia

Australian Commission on Quality and Safety in Healthcare

Consultation Paper on Draft National Safety and Quality Healthcare Standards

Submission by
Medical Technology Association of Australia

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1. Executive Summary

This submission is in response to the November 2009 consultation paper "Draft National Safety and Quality Healthcare Standards" released by the Australian Commission on Safety and Quality in Healthcare (ACSQHC). MTAA welcomes the opportunity to comment on the draft National Safety and Quality Healthcare (NSQH) standards and has formulated this response based on feedback from our members.

MTAA General Recommendations

- A full list of the types of healthcare facilities that should be accredited should be included.
- A greater level of detail is required before the standards can be implemented.
- Clarity is needed regarding whether the NSQH standards will replace existing standards (and/or federal/state policies) and if so, how?
- Mechanisms of data collection and measureable outcomes for each standard should be formulated.
- An outline of the 2010 pilot studies should be presented.
- A timeline for implementation should be included.

MTAA Specific Recommendations

- MTAA will provide more detailed comments on aspects of the NSQH Standards in response to the 'Australian Guidelines for the Prevention and Control of Infection in Healthcare'.
- MTAA recommends the use of Safety Engineered Medical Devices (SEMDs) to prevent needlestick injuries and the need for policy and procedures to decrease the incidences of cross-contamination from flexible endoscopes.
- The current standards should include guidelines under Medication Safety that recommend the use of smart infusion pumps and safer spinal (intrathecal), epidural and regional devices in accordance with international policy.
- The current standards should include specific detail regarding the outcome measures and the type of data that will be collected at a national level to ensure correct implementation and monitoring of the standards.

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. Examples include safety-engineered hypodermic needles, safety syringes and infusion catheters, safety lancets and scalpels, infection

control solutions and surveillance, needle-free systems and other safety engineered devices.

3. Consultation questions

In April 2008, the Australian Health Ministers endorsed a future model for safety and quality accreditation, following extensive consultation by the ACSQHC. The initial work included the development of a preliminary set of National Safety and Quality Healthcare (NSQH) Standards. In reviewing the draft standards, MTAA has considered three specific consultation questions:

2. Are there gaps in the NSQH Standards that should be addressed?
4. Is the level of detail provided adequate to implement the standards?
5. If not, what additional information is needed?

MTAA will address questions 2, 4, and 5 and provide specific comments and recommendations. We also address the need for a set of measurable outcomes to be associated with each standard.

Gaps in the NSQH Standards that should be addressed

The Commission has developed a very comprehensive set of high level standards that are essential to improving quality and safety of care for the patient. The draft NSQH Standards are written so that they can be notionally agreed by all jurisdictions and organizations. It would be helpful to include a paragraph in section *3. Context* listing those jurisdictions and healthcare organizations that the standards and accreditation process will apply to.

While the standards are inclusive, there are some gaps and a greater level of detail is required for organisations to be able to implement the standards. The standards provide a comprehensive overview but are very broad, making it difficult to give specific feedback. Current gaps in the Medication Safety standard include the use of smart infusion pumps and safer IV connectors to reduce medication error.

Clarity is needed around whether the new standards will replace existing standards (and/or federal/state policies). The Commission should explicitly state whether the current standards will replace, for example, the EQuIP standards, the Australian Guidelines for Prevention and Control of Infection in Healthcare, or the Joint Commission National Patient Safety Goals, and if not how, which set of standards has priority? MTAA recommends that each standard/element be accompanied by reference to existing policy.

Level of Detail Needed to Implement Standards

Currently each standard is associated with a list of elements and proposed solutions, however in each case a greater level of detail is needed in order to implement the standard and measure the associated outcomes. For example, the text associated with 'Solutions to preventing infection' reads: *"Just as there is no single cause of infection, there is no single solution to the problems posted by healthcare associated infections. Successful infection control requires a range of strategies across all levels of the healthcare system and a collaborative approach for successful implementation"*.

It is anticipated that a limited number of additional national standards will be developed in 2010/11 (e.g. prevention of falls, recognizing and responding to clinical deterioration and prevention and management of pressure ulcers). The need to provide greater guidance and clarity should be addressed before the additional standards are released.

More detail is required for *SQ: A1: 'Surveillance and Review of Performance data' and 'Prevention strategies based on data analysis'.* The process measures include:

1a. Evidence of a governance safety and quality management system that includes:
- *Identification of risks*
- *Surveillance and review of safety and quality data*

1b. Evidence of policies, protocols and procedures to address:
- *System for ongoing data collection, analysis, trending and evaluation of management and operational practices for review.*

Each of the above points need to contain more detail, for example, reference to existing policies, specific concerns (e.g., infection control), guidelines for data collection, monitoring and management. It would be helpful to reference existing statistics and current benchmarks, existing safety and quality surveillance systems and the impact of new or emerging technologies.

MTAA specific comments[1]

> ***2. Healthcare Associated Infection*** *which describes the standard expected to prevent infection of patients within the healthcare system and to effectively manage infections when they occur, to minimise their consequences.*
> ***3. Medication Safety*** *which describes the standard expected to ensure clinicians prescribe, dispense and administer appropriate and safe medication to informed patients.*

Some explanation is needed regarding how the solutions will complement existing policies and procedures. For example, the Garling report[2] refers to 30 policies for infection control in NSW and makes 139 recommendations that aim to modernise work practices, administration and equipment.

Needlestick Sharps Safety

The draft NSQH Standards aim to improve the safety and quality of care for patients. The standards could be expanded to include safety and quality of healthcare workers through a program to mandate the implementation and use of safety engineered devices to protect healthcare workers from the risk of preventable needlestick and sharp object injuries. This could be included under *Clinical Practice (SQ:B)* with the objective being the prevention of needlestick or sharps injuries (and associated infection) in patients, healthcare workers, pharmacists, waste handlers and laboratory/housekeeping

[1] MTAA will provide detailed comment on Healthcare Associated Infection in March 2010 in response to the 'Australian Guidelines for the Prevention and Control of Infection in Healthcare'.
[2] Garling, P. Final report of the Special Commission of Inquiry: Acute Care Services in NSW Public Hospitals. Sydney: NSW Government, 27 Nov 2008.

personnel. More detail will be provided in the March 2010 submission. Unlike other countries, Australia does not have a federal policy that mandates the use of safety engineered medical devices (SEMDs), despite a large number of international studies finding that the use of SEMDs is associated with a decrease in needlestick injuries. MTAA encourages a national standard mandating the use of SEMDs in accordance with US, Canadian and European laws.

MTAA recommends the following changes in wording:

HAI:B Process measure 1a, point 7:

- Prevention and management of occupational exposure to blood-borne viruses including the implementation and use of safety engineered medical devices.

HAI:B Process measure 4a, point 5:

- Personal protective equipment (PPE), availability of safety engineered medical devices.

HAI:B Process measure 5a:

- Evidence that system for use and management of invasive devices, incorporating infection prevention and mandatory use of safety engineered devices, is implemented and active.

HAI:B Process measure 6a:

- Evidence that invasive device mandatory protocols (including the use of safety engineered medical devices) are active and complied with.

<u>The use of Needle-free systems to prevent infection</u>

Healthcare associated infections are often associated with catheter-related bloodstream infections[3]. The insertion of an intravascular device (IVD) is associated with a number of systemic complications such as bloodstream infections (BSI)[4].

Needle-free devices have been developed to:

- Reduce the use of needles when accessing vascular devices and
- Prevent blood spillage and potential exposure to blood products used by healthcare professionals.

One way of reducing exposure to contaminated needles is to use a needle-less injection site, which can be attached, for example, to intravenous lines and catheters, and enables a method of IV line access. The current guidelines should encourage the use of Needle free devices, where possible, to protect against colonization of catheter tips[5].

[3] Sitges-Serra, A., & Girvent, M. (1999). Catheter-related Bloodstream Infections. *World Journal of Surgery, 23(6),* 589-595.
[4] Dougherty, L. & Lamb, J. (2008). Local and systemic complications of intravenous therapy *Intravenous Therapy in Nursing Practice* 2nd ed,. Blackwell Publishing, pp 167-196.
[5] Bouza, E. et al. (2003). A needleless closed system device (CLAVE) protects from intravascular catheter tip and hub colonization: a prospective randomized study. *Journal of Hospital Infection, 54,* 279–287.

4. Medication Safety – NSQH Standard 3

The most common medication errors are; using the incorrect drug, prescribing errors, administration errors and errors associated with incorrect dosage. These errors are largely preventable[6]. NSQH Standard 3 should address the following areas: the lack of specifics on the type of data required to improve medication safety and the need to utilize available health care technology systems to assist in data reporting, analysis and surveillance of clinical practice. In particular MTAA would like to see reference to the following: bar-coding technology to reduce medication errors; the use of electronic medication management systems for medication error reduction, the use of smart infusion pump technology, and the use of safe connecting devices.

SQ A: Process Measure 4a. Evidence of a risk assessment system for clinical safety and quality.

The Garling report recommends using adverse event data to inform strategies for medication safety[7]. Medical errors are the eighth leading cause of death in the United States and occur at a rate greater than motor vehicle accidents, breast cancer, or AIDS[8]. Medication Administration errors account for 38% of medication errors[9]. Errors during administration often result in an adverse drug event (ADE) that may not be detected.

Adverse drug events that are caused by intravenous (IV) medications occur more rapidly and have more severe effects and are associated with a much higher risk of patient harm than adverse drug events caused by medications administered orally[10]. It has been reported that 61% of the most serious adverse drug events in hospitals are IV-drug related[11]. An existing technology that can enhance the safe delivery of medication is smart infusion pump technology[12].

The USA has a well established practice of using smart infusion pump technology with built in dose error reduction software (DERS). Many smart infusion pumps have software that is capable of alerting the user to dose limits that are unsafe dose and programming errors (in the case where standard dose limits and concentrations are programmed into the pump's library). Additionally smart infusion pumps can be programmed so that the computer does not begin releasing the IV medication until it has confirmed a match between the barcode and the physician's orders. Approximately 60% of US hospitals use smart infusion pumps with integrated libraries and an advantage of these devices is that they can be linked to electronic prescribing software [13].

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[6] Second National report on Patient Safety. Improving Medication Safety. July, 2002. Australian Council for Safety and Quality in Health Care.
[7] Special Commission of Enquiry, Peter Garling. Acute Care Services in NSW Public Hospitals, 2008.
[8] Kohn et al. (1999). To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press.
[9] Food and Drug Administration (FDA) website: http://www.fda.org.
[10] Rothschild et al. (2005). A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Critical Care Medicine, 33(3),* 533-540.
[11] Husch et al. (2005). Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Quality and Safety in Health Care, 14(2),* 80-86.
[12] Rothschild et al. (2005). A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Critical Care Medicine, 33(3),* 533-540.
[13] Pederson et al. (2005). ASHP national survey of pharmacy practice in hospital settings: dispensing and administration. *American Journal of Health System-Pharmacy, 63,* 327-345.

UK studies have found that for each adverse drug event that is prevented by DERS, the hospital saves approximately AU$1125 plus litigation costs[14]. Based on a 350 bed hospital it has been estimated that DERS prevents about 140 serious errors each year[15]. The use of smart infusion pumps, DERS and specific recommendations for dose error reduction should be included into the draft medication standard. Many smart pump systems also collect usage data that can be analysed to track information and assess potential errors associated with patient harm. Smart pumps are already in use in a moderate number of Australian hospitals. A mandate to introduce smart pump and DERs will decrease IV administration as a medication error and capture outcome data for monitoring medication safety standards. While there is limited Australian data, data from the US show that using smart infusion pumps is associated with reduced medication errorr[16].

An additional issue to include in Standard 3 is incorrect administration of IV therapies. The significance of this problem has been recognized in recent policy introduced by the United Kingdom National Health Service (NHS). The NHS has recently mandated the use of safer spinal (intrathecal), epidural and regional devices[17]. As a result of fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route, and where epidural medicines have been administered by the intravenous (vein) route, the NHS has issued a Patient Safety Alert and asked all NHS healthcare organisations to ensure that:

- from 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with connectors that will not also connect with intravenous Luer connectors (Part A)
- from 1 April 2013 all epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes (Part B)

NHS organisations are required to review and update their purchasing policies, procedures and clinical protocols to include the use of devices with safer connectors. These devices with safer connectors are not currently available.

Other strategies that could be considered:

- The use of computerised prescribing with clinical decision-support systems.
- The development of a formal incident management system. There is currently no consistent reporting incident management systems that spans states/territories.

[14] NPSA, Safety in Doses: medication safety incidents in the NHS. 2007.
[15] Vanderveen, T. (2005). Averting High-Risk errors is first priority. Patient Safety and Quality Healthcare. www.psqh.com/mayjun05/averting.html.
[16] Adachi, W., & Lodolce, A.E. (2005). Use of failure mode and effects analysis in improving the safety of i.v. drug administration. *American Journal of Health-Systems Pharmacy, 62,* 917-20.

[17] Medication Safety: Safer Spinal, epidural and regional devices
ttp://www.nrls.npsa.nhs.uk/resources/?entryid45=65259

- Introduction of a national stepwise strategy similar to the Carefusion Medication Safety Pyramid which includes reporting and analysis in order to decrease errors[18].
    - Selecting (and Procuring, Storing, Securing) medications: aim to reduce errors due to access to high-alert drugs or look-alike packaging.
    - Ordering (and Transcribing) medications: aim to minimize errors due to transcribing, use of abbreviations and problems with the legibility and accuracy of drug orders.
    - Dispensing medications: aim to minimize compounding and calculating errors; use of ready to administer products; and ensure that medications are correctly dispensed, clearly and accurately labeled and available at the right time.
    - Administering medications: aim to ensure that the right patient receives the right dose of the right drug by the right route at the right time (the 5 Rights of Medication Safety).
    - Monitoring the effects of medications on patients: aim to reduce toxic drug concentrations and adverse drug reactions.

5. Monitoring the standards and refining existing data sources (healthcare associated infection, medication safety)

MTAA recommends adopting a broad national standard that outlines how to collect standardized baseline data and follow-up data in order to monitor the standards. The National Hospital Morbidity Database contains information on hospital admissions that are associated with adverse drug reactions that either cause the admission to hospital or occur within the hospital. The database is maintained by the Australian Institute of Health and Welfare and could be extended to monitoring ACSQHC outcomes. For example, the following statistics are currently collected[19]:

Separation Statistics by Principal Diagnosis in ICD-10-AM Australia, 1998-99, 2007-08:

- 996-999: Complications of Surgical and Medical, not elsewhere classified.
- 996: Complications peculiar to certain specified procedures (including infections due to prosthetics and grafts).
- 998.4: foreign body accidentally left during a procedure.
- 998.5: post operative infection.
- 998.7: acute reaction to foreign substance accidentally left during a procedure.
- 998.8: Other complications of Procedures, not yet classified.
- 998.9: Unspecified complication of procedure, not elsewhere.

Adverse events include: infections, medication errors and problems with medical devices. There were 382,000 separations with an ICD-10-AM code for an adverse event (4.8 per 100 separations) in Australia between the years 2007–2008.

The safety dimension of the revised National Health Performance framework includes separations with adverse events. Again, these data could be potential outcomes measures for ACSQHC standards. Data include: location, ICD-10-AM diagnoses, and

[18] Guidelines adopted from the Carefusion Medication Safety Pyramid. http://www.carefusion.com/center/medication-safety-pyramid/index.aspx

[19] Australian Government. Australian Institute of Health and Welfare. Australian Hospital Statistics 2007–08.

external causes of injury and poisoning which indicate an adverse event which occurred and was treated within a hospital setting. Some adverse events can not be identified under the ICD-10-AM codes. A consistent way of monitoring all adverse events at a national level is advised.

Adverse events are more likely to occur in the public sector. However, data for public and private hospitals are not easily comparable due to different recording standards[20]. There is a need for a set of guidelines for reporting standards that are common to both public and private health care settings. Between 2007-08 adverse effects of drugs, medicaments and biological substances (Y40–Y59) were associated with 106,000 separations. There were 238,000 separations due to procedures causing abnormal reactions/complications (Y83–Y84) and 75,000 separations due to complications of internal prosthetic devices, implants and grafts (T82–T85).

A condition onset flag will be available in the NHMD from the 2008–09 reference year. This information could be used in the future to exclude conditions that arose before the admission and to include conditions not identifiable with the codes currently used to indicate adverse events.

Data from incident monitoring systems

Many hospitals have incident reporting systems. These systems should be mandatory and should detail both why the incident occurred and the number of incidents. Currently the Advanced Incident Monitoring System (AIMS) aggregates national data on the number of incidents that occur within hospitals. AIMS is a computerized analysis system for monitoring mistakes in healthcare. The system captures details on the *how* and *why* of incidents and provides a workflow too for managing errors and responses. The software is currently used by over 400 Australian hospitals (across South Australia, Western Australia, the ACT and Northern Territory), as well as sites in New Zealand, South Africa and the United States[21]. This is an example of the type of software that could be used to monitor NSQH outcomes. Currently AIMS data are managed in stand alone hospital databases and data are not analysed at a national level.

[20] Australian Government. Australian Institute of Health and Welfare. Australian Hospital Statistics 2007–08.
[21] http://www.patientsafetyint.com/.