



# AAQHC Newsletter

A Voice For Safety and Quality

APRIL 12, 2019

*"Quality in a service or product is not what you put into it. It is what the client or customer gets out of it."  
~Peter Drucker*

## President's Message

Dear Members

The first of the free webinars was held on Friday 12<sup>th</sup> April. This webinar focused on the NSQHSS Standard 3 Updates on Edition 2 and from feedback received, was very successful. For those who could not attend the slides will be available on the Shared Learning tab of the aaqhc website. Members log on using your email address.

Our next free webinar will be held on June 7 and will cover the most important topic of Understanding Comprehensive Care. A promotional flyer will be sent shortly with registration details. To ensure you secure a place (as they are very limited) register early.

To meet your needs, we welcome ideas for future topics. Just email [aaqhc@aaqhc.org.au](mailto:aaqhc@aaqhc.org.au) with your suggestions.

As you have already read the Fellowship Credentialing Programme has been reviewed and refined to make it more accessible for our members. We will again offer 3 scholarships to members which waives the application fee. Please apply to [aaqhc@aaqhc.org.au](mailto:aaqhc@aaqhc.org.au) by the 31<sup>st</sup> May 2019.

Our Mentoring Program continues, and this program is a great way of establishing a network of people working in the quality management area. Even if you have been in the quality arena for an extended time, being mentored is one of the most valuable and effective development opportunities.

Having the guidance, encouragement and support of a trusted and experienced mentor can provide you with a broad range of personal and professional benefits, including:

- Exposure to new ideas and ways of thinking;
- Advice on developing strengths and overcoming weaknesses;
- Guidance on professional development and advancement; and
- The opportunity to develop new skills and knowledge

We are also offering one free registration to the Australian College of Nursing (ACN) National Nursing Forum to be held in Hobart in August. If you interested please send an email to AAQHC. The Forum is the ACN's

signature annual leadership and educational event bring together nurses, students and other health professionals from around the country and across the globe. This is a great opportunity for networking.

Regards

Robyn Quinn  
President

**AAQHC**

Contact us at

[aaqhc@aaqhc.org.au](mailto:aaqhc@aaqhc.org.au)

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## **New Serious Incident Management Legislation in NSW**

### Background

In 2005 New South Wales was recognised nationally and internationally as leading improvement in the quality and safety of services provided to patients, families and carers. In the NSW public health system, the incident management system has been in place under the NSW Health Patient Safety and Clinical Quality Program since 2005. At the time, the NSW Government invested \$55 million in the Program to ensure patient safety and excellence in healthcare through systematic management of incidents and risks, via the new Incident Information Management System, Clinical Governance Units in each local health district/network, a quality assessment program and the establishment of the Clinical Excellence Commission.

The framework for responding to serious clinical incidents is currently outlined in the NSW Health policy directive Incident Management (PD2014\_004). The policy provides direction for a standardised approach to managing clinical and corporate incidents using Root Cause Analysis (RCA) methodology by privileged investigation teams for the most serious clinical incidents.

Currently, a privileged RCA team investigates and produces a report with findings, root causes/contributory factors and recommendations for improvement in 70 days. However, a review of the RCA methodology identified clinicians and families felt disengaged as they struggled with the outcome of RCA investigations that did not always answer some of the more difficult questions, and the and the lack of consistent and clear communication with health services following investigation into a serious incident.

Following the review, the Health Administration Act 1982 (NSW) was amended in 2018 to support a new policy to implement new practices to benefit patients, families and clinicians, and to research different investigation methodologies to redesign the NSW Health clinical incident management system.

In 2019, the NSW Clinical Excellence Commission is leading the change in consultation with the NSW Ministry of Health.

The key changes are:

- conducting an immediate preliminary risk assessment following a serious incident;
- using alternate, approved incident investigation methodologies;
- strengthening ongoing and compassionate disclosure and engagement with patients, carers and families; and
- further support for clinicians who identify as "second victims" or care for the care giver as they feel they are not always adequately supported by the system following the incident.

It is also proposed the timeframe for the findings report would be reduced to 45 days from 70 days enabling earlier disclosure of investigation findings to patients, carers and families, who will also be invited to contribute to the investigation process at their discretion.

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### **Changes to labelling and regulation of hard surface disinfectants**

(commencing 1 April 2019) and outcomes of the review of products containing chlorhexidine.

The labelling and regulation of hard surface disinfectants is changing as a result of consultation by the Therapeutic Goods Administration (TGA) on the regulation of low-risk products. These changes take effect on 1 April 2019 and will have an impact on healthcare facilities.

These changes are part of reforms by the TGA to the regulation of low risk products, to reduce regulatory burden for industry and allow sponsors and the TGA to focus on areas of risk with these products and higher-risk products.

Key points

Healthcare facilities are advised that:

- Some hard-surface disinfectants will no longer need an Australian Register of Therapeutic

Goods (ARTG) entry, simplifying supply and procurement.

However, please note that:

- Chlorhexidine labelling has been updated to minimise the risk that these solutions are accidentally misused as skin antiseptics.

- In light of reported injuries, health professionals are reminded to ensure they are using the correct disinfectant product for the intended purpose.

The TGA undertook consultation on the regulation of low-risk products, including hard surface disinfectants in 2017, and published outcomes of that consultation on the

TGA website. Changes to the regulatory requirements for hard surface disinfectants took effect on 16 October 2018 in the Therapeutic Goods Regulations 1990. The changes included:

- Household/Commercial Grade and Hospital Grade hard-surface disinfectants with specific claims are now Listed Therapeutic Goods (which means they continue to be listed on the ARTG).
- Hospital Grade hard-surface disinfectants with no specific claims are now exempt from requiring an ARTG entry.

The TGA would recommend healthcare facilities review their procurement processes so that an ARTG entry is no longer required for Hospital Grade hard-surface disinfectants with no specific claims. Further information on the regulation and specific claims can be found on TGA's website.

Therapeutic Goods Order 54 – Standard for Disinfectants and Sterilants (TGO 54) sunset on 1 April 2019 and has been replaced by Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019. Sponsors of all hard surface disinfectants must comply with TGO 104. Please contact [LowRiskDevices@health.gov.au](mailto:LowRiskDevices@health.gov.au) for any queries regarding this downregulation.

**Review of products containing chlorhexidine**

The TGA reviewed chlorhexidine products registered in the ARTG after health professionals raised concerns with the unsafe use of such products. The TGA has worked with sponsors to strengthen labelling requirements to minimise the risk that these solutions will be accidentally misused as skin antiseptics. These labelling requirements take effect on 1 April 2019 (Noting a transition period to 1 April 2020). Concerns have been raised with the TGA about the risk of accidental injection, related to the indistinct colouration, specifically of pink chlorhexidine. The TGA has received two adverse event reports related to this type of misuse of chlorhexidine; one event caused catastrophic injury when chlorhexidine was unintentionally injected in the patient's spine. The reasons advised for the cause of the events was that the tinting could not be distinguished clearly enough when placed in the procedural site or surgical field. Chlorhexidine products are also supplied as a skin antibacterial or

antiseptic and these are regulated differently to hard-surface disinfectants:

- Skin antiseptic products are regulated as over-the-counter medicines. They are required to be entered in the ARTG and have been assessed by the TGA to ensure the manufacturer has tested that they are appropriate for use on the skin.
  - Hard-surface disinfectant products are regulated as Other Therapeutic Goods and depending on the claims may be exempt from entry on the ARTG. They have not been assessed by the TGA for use on the skin.
  - Disinfectants that clean or disinfectant medical devices are regulated as medical devices and are required to be included on the ARTG. They are not assessed for use on skin.
  - Antibacterial skin care products where claims are limited to general low level activity against bacteria (for example, “Kill 99.9% of bacteria”) are exempt from entry in the ARTG. These products must not contain substances that are included in Schedule 2, 3, 4 or 8 of the Poisons Standard
- Presentations of chlorhexidine may be tinted a range of colours including pink, red, blue and yellow in various degrees of shades. The TGA sought advice from its Advisory Committee on Medical Devices (ACMD) who noted that it is likely that hard-surface disinfectant chlorhexidine products are being misused in clinical settings as skin antiseptics.
- Advice for health professionals and healthcare facilities
- The TGA encourages health professionals and healthcare facilities to:
- Check the label on the solutions used for hard-surface disinfection and skin antiseptics to ensure that you are using the correct product and the correct solution for your intended purpose.
  - Check that when these solutions are purchased that the sponsor supplies solutions that are correctly listed in the ARTG according to the intended purpose.
  - Use hard-surface disinfectants and skin antiseptics according to the intended purpose.

#### Reporting problems

Consumers and health professionals are encouraged to report any problems with hard surface disinfectants. Your report will contribute to the TGA’s monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme

(IRIS).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Please contact [IRIS@health.gov.au](mailto:IRIS@health.gov.au) for any queries regarding chlorhexidine.

### **Australian College of Nursing Affiliation**

AAQHC has established an affiliation with the Australian College of Nursing. The benefits to members of AAQHC include:

#### **ACN Bronze Affiliates receive the following:**

- Discounted Affiliate Membership rates for all nurse employees / members (a saving of \$78 per *general* membership)
- 5% discount on all CPD courses

Visit the website [acn.edu.au](http://acn.edu.au) for details on all the courses offered by the college. Remember to state your membership of the AAQHC.

### **Promoting Your Quality Initiatives - Publish in the AAQHC Newsletter**

Publication of articles in the AAQHC Newsletter is a great way to promote quality initiatives that have made a difference to the patient/consumer and/or family and promote your/your team's great work to a wider audience.

The Newsletter is a mechanism to share ideas between AAQHC members across Australasia, however it needs your input to be successful.

If you have a great idea, thoughts on patient safety/quality and or an example of a quality initiative, put pen to paper and send it through to [aaqhc@aaqhc.org.au](mailto:aaqhc@aaqhc.org.au)