Single use items

Purpose

This Position statement gives direction and guides practice in relation to the use of single use items in the perioperative environment.

Background

Single use devices are medical devices that are labelled by the original manufacturer as 'single use' or 'a single patient use'. They are intended to be used once only, or used on a single patient only, and then discarded. The re-use of any medical device potentially increases the risk of cross-infection or contamination.

Single use devices are classified according to their potential risk to a human body. Therapeutic Goods Administration (TGA) classifications can be found on the TGA website[15].

Results from studies investigating the efficacy and safety of re-using single use devices are mixed. Adverse outcomes such as patient-to-patient disease transmission, physical trauma, device breakage and toxic reactions associated with the re-use of single use devices have been reported[5–8].

Some studies have reported effective decontamination, re-sterilisation and re-use of particular single use devices after proper procedures are followed[1–4]. However, it is clearly articulated in guidelines from organisations such as Standards Australia, ACORN, Federation of Sterilising Research and Advisory Councils of Australia (FSRACA), and Medical Technology Association of Australia (MTAA), that devices labelled for single use should not be re-used. Most Australian states and territories strongly oppose the re-use of single use devices[9,10].

The Australian Health Ministers' Advisory Council (AHMAC) decided that any reprocessing of single use devices for the purposes of re-use is to be regarded as a manufacturing activity and would require regulation by the TGA[11]. An opportunity exists for a remanufacturing facility under new regulations. At present, Australia does not have a licensed remanufacturer for single use devices[15].

The re-use of single use devices within the perioperative environment has major safety implications for patient outcomes and accountability for nursing practice.

Principle

Items labelled 'single use' shall not be re-used.

Explanatory statement

Nurses have a duty to consider federal, state and territory policies, guidelines, standards and legislation, which may include, but not be limited to:

- Standards Australia
- *Health Services Act 1997*
- Codes of conduct
- Codes of health rights and responsibilities
- *Trade Practices Act 1974*
- *Therapeutic Goods Act 1989*
- Code of good manufacturing practice
- Relevant Australian and New Zealand Standards
- Relevant National Health and Medical Research Council guidelines.

Breaches of the aforementioned standards and accompanying legislation may have ethical and legal implications, such as legal proceedings relating to:

- negligence
- failure to disclose
- breach of duty of care.

Recommendation

In keeping with TGA regulations, class three single use devices (high-risk medical devices) should no longer be re-used in any public health system facility.

Re-use of other single use devices ceased by 1 July 2007[15]. Single use devices are not designed or validated for re-use.

ACORN maintains the position that: single use items shall not be re-used.

Approval statement

This Position statement was authorised by the ACORN Board on 18 February 2010.

Revised 2009.