Short title: Medication safety BP

1. Purpose of review

PG51(A), previously titled *PS51 Guidelines for the safe administration of injectable drugs in anaesthesia,* was promulgated in 2009. PG51(A) is referenced and referred to by healthcare facility administration, fellows, and trainees. The current revision has aimed to assist administrators and practitioners in producing the safest environment for patients and staff, as well as accommodate the potentially conflicting needs for ready availability of medications and the opportunity for misuse.

2. Background

As a result of a number of lethal outcomes from the diversion and misuse of propofol, hospitals and jurisdictions have introduced different solutions to a common problem. Some solutions have included restricting access to propofol. As propofol is a drug used for the induction and maintenance of anaesthesia it must be immediately available and thus restricting access has the potential to impact on the safe conduct of anaesthesia. However, propofol should be securely stored at all times when not immediately required, for example overnight and between operating sessions.

The accompanying professional document provides guidance to the profession and hospitals to avoid the implementation of a multitude of solutions across Australian states and New Zealand. In addition, it makes recommendations aimed at reducing drug errors and risks of cross-contamination between patients.

Any change to regulatory requirements in light of recent reviews of various drugs, poisons and controlled substances legislation will also need to be taken into account.

It is recognised that there are jurisdictional differences between Australia and New Zealand, particularly with respect to purchasing authority, labelling of medications and standards pertaining to user applied labels.

3. Discussion

In reviewing the accompanying guideline, the following issues were considered:

3.1 **Title of the document -** The title was modified to reflect the broader intent of the guideline beyond simply the administration of medications and instead to include safety in management and use of medications.

3.2 **Drug errors -** In recognition of the range of reported drug errors[1, 2], which may reflect the tip of the iceberg, attempts have been made to address each potential factor. These have included:

3.2.1 Identification of vials and ampoules – with the similarity of some presentations more than just a cursory check of labels is required. Notwithstanding this, it was agreed that there should be standardisation of labelling[3] for all classes of drugs by manufacturers. There is already a standard for syringe labelling and it makes sense to apply the same system to ampoules and vials. Special attention should be directed towards standardisation of presentation of the information with regard to font, size, and colour of print.

3.2.2 Labelling of syringes by applying labels compliant with the relevant National

Standard[4]. In the specific situation where a medication is drawn up and immediately administered as a bolus, without leaving the hands of the practitioner that prepared it, labelling is not required. In all other cases labelling is required as per the National Standard for User Applied Labelling in Australia. ANZCA has released a joint statement with the ACSQHC supporting user-applied labelling standardisation for all injectable medicines and fluids[4].

In New Zealand PHARMAC is considering labelling recommendations.

3.2.3 With the increasing use of infusions for anaesthesia as well as for regional analgesia there is the potential for drug errors to occur. To minimise these errors, it is advisable to ensure that devices delivering intravenous medications are readily differentiated from those delivering local anaesthetics. Colour coding for different routes and compliance with Labelling Standards is required in Australia. With the coming introduction of the new small bore neuraxial standard the likelihood of such misconnections should be diminished. Infusion devices with Dosage Error Reduction Software may offer a safety benefit[5].

3.2.4 Patient identification and "open" versus "closed" practice environments.

Anaesthetists should be aware of the difference between an open and closed practice environment as there are implications for ensuring delivery of the correct medication to the correct patient.

In a closed-practice environment:

- the identity of the patient is beyond doubt – that is, when a single patient is receiving an injectable medicine, there is no possibility that the patient's identity is unknown, and the medicine is prepared in the presence of the patient.
- the identities of members of the patient care team are recorded.
- the medicine is administered completely within the closed-practice environment. In this case, patient identifiers are not required and a pre-printed abbreviated label may be used.

Examples of closed-practice environments are operating rooms, endoscopy rooms, catheterisation laboratories and radiology suites. Nevertheless, even in a closed-practice environment there is the risk of patient identification drug errors as exemplified by the NSW Coroner's inquest into the death of a patient from opioid overdose following an electronic prescription error[6].

In an open-practice environment there are multiple patients in the same area and full patient and user identification is required for user-applied labelling. The PACU is an open environment as there are numerous possible candidates for the drug drawn up and to be administered[7].

3.2.5 Purchasing decisions on anaesthesia drugs should be made in consultation with a designated safety officer in the department of anaesthesia or other nominated individual[8]. Purchase choices should be made in accordance with the principles articulated in PG51(A), relevant jurisdictional requirements, and with regard to local practice environments.

3.3 Infection control – the potential for cross-contamination and the need for maintaining sterility of drugs drawn up into syringes can be addressed by adherence to the principles of aseptic non touch technique[9]. The maintenance of critical micro aseptic fields is facilitated by capping of syringes.

3.4 Storage of drugs – While the storage and documentation of medications must comply with the regulations of the local jurisdictional authority, the anaesthetist should be able to directly and independently access sufficient quantities of critical drugs. Such drugs would include propofol, adrenaline, muscle relaxants, and vasopressors.

3.5 **Interruptions to supply** – Recently, availability of a number of medications has been restricted due to problems with manufacture and supply, or concerns about potential contamination. Development of an "essential medicines list" has been proposed but cannot be mandated. The existence of dual pharmaceutical suppliers of a particular medication assists in minimising disruption to availability.

3.6 **Automated medication dispensing systems** – many healthcare facilities are using medication and storage systems that allow tracking of stock levels, access identification and patient prescription. They usually require fingerprint or other identification to access and thus while providing enhanced security, they are not suitable when medications are required immediately. It is strongly recommended that a supply of medications required in an emergency or urgently is readily available outside an automated storage device.

3.7 **Volatile Agents** – Volatile agents have been identified as drugs of abuse[10] and thus must be stored securely. Case reports of substitution of a cleaning solution for a volatile agent indicate the importance of appropriate storage of partially filled bottles and appropriate disposal of empty containers[11].

3.8 **Splitting of ampoules –** was a not uncommon practice in the past and currently continues but to a lesser extent. There are several driving forces behind this practice, including drug availability/shortages as well as considerations of environmental sustainability.

Drug shortages occur with varying frequency and supplies may be severely limited. In such instances, consideration may be given to conserving supplies, which may include judicious splitting of ampoules.

Subsequent to the release of *PS64(G) Position statement on environmental sustainability in anaesthesia and pain medicine practice* in 2019, which raised concerns regarding wastage and environmental pollution including waterways it was felt that there was some justification in instituting measures to reduce such waste. One of the measures included splitting of ampoules.

The potential risks of this practice are acknowledged but not insurmountable. Rigorous processes that address the risks of cross-infection and documentation requirements need to be developed if the practice of ampoule-splitting is to be performed.

ANZCA recognises the potential for inappropriate coercion of clinicians to split ampoules and strongly opposes this. Any decision to split ampoules lies strictly with the attending anaesthetist.

When administering any medication, it is a requirement that only the intended medication is administered and only to the correct patient. This is achieved by confirming the patient's identity and in addition, accurately identifying the medication by checking its labelling. The content of unopened ampoules is guaranteed. However, once opened and left unattended there is the potential for misuse or replacement with substituted substances. In order to avoid this potential, and the risk of cross-infection, the contents of ampoules should be drawn up into labelled syringes at the one time, and at the beginning of the session/list. This recommendation precludes the storage of opened ampoules for later reuse as the contents cannot be guaranteed.

4. Summary

The current revision has considered the changing environment since the promulgation of the previous version and has reviewed the issues relevant to the broader aspects of the safe management and use of medications in anaesthesia. The recommendations in the accompanying guideline should assist healthcare facilities, administrators, and practitioners to provide safer conditions for their patients.

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ANZCA regional and national committees
Australian Society of Anaesthetists
Faculty of Pain Medicine Board and regional committees
ANZCA Trainee Committee
ANZCA Special Interest Groups (SIGs)

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