



Short title: Medication safety

1. Purpose

This guideline is intended to assist medical practitioners providing anaesthesia in all aspects of safety associated with use of medications involved in anaesthesia/sedation/local analgesia.

It is also intended to assist healthcare facilities to ensure safe handling, documentation, and appropriate access to medications used in anaesthesia.

This guideline does not override state and national jurisdictional requirements and are intended to complement them.

2. Scope

This document is intended to apply to all medical practitioners providing anaesthesia and to all healthcare facilities in which anaesthesia and sedation services are provided.

The guideline pertains to the management and use of medications in the procedure room/operating theatre. It does not apply to other medication storage facilities within the operating theatre complex although many of the principles regarding storage would apply.

The term anaesthesia in this document refers to anaesthesia, sedation, regional analgesia or local anaesthesia.

3. Background

The safe administration of drugs in anaesthesia encompasses the timely administration of medication to patients, the prevention of drug administration errors, and measures to reduce the opportunity to misdirect drugs.

Estimates of the frequency of 'medication errors' range from 1 in 20 administration events¹, to 1 in 133² anaesthesia episodes. Many of these reported events were protocol or process errors (including mislabelling or omission of an appropriate drug), however a proportion of these errors will result in an adverse event for the patient. More than 3 million anaesthetics are administered in Australia and New Zealand annually suggesting a substantial contribution to iatrogenic adverse events.

Anaesthetists should be aware of the particular challenges of medication administration in the perioperative environment and their responsibility to implement safe practices. Anaesthetists are often solely responsible for the prescription, preparation, dispensing and labelling, administration, documentation, and monitoring of clinical effects of high risk medications. At times these drugs are administered in a time critical manner in stressful situations.

Safe drug administration includes both correct administration practices as outlined above, but also timely administration (e.g. prompt correction of hypotension or bradycardia) and adherence to protocols where appropriate (e.g. antibiotic administration).

Improvements in safe drug delivery depend on an appreciation of the causes of errors related to drug management and use, and on active adoption of techniques accepted as likely to reduce such events, including regular audit and review of practices.

Drugs used in anaesthesia may be the target for diversion or abuse. Secure storage and access precautions assist to mitigate misdirection. However, a careful balance needs to be achieved to ensure timely access for anaesthetists to these drugs in clinical practice so that patient safety is not compromised.

4. General principles

- 4.1 The aims of safe administration of medications in anaesthesia are:
- To administer the correct medication to the correct patient, in the correct dose, by the correct route, at the correct time.
 - To accurately record this information in the anaesthesia record or patient's drug administration chart, and any legally required register of drug dispensing.
 - To minimise the opportunities for substance abuse and/or diversion.
- 4.2 Medical practitioners providing anaesthesia should have a detailed understanding of the pharmacology of the medications they prescribe or administer, together with an understanding of potential complications of drug administration and management of such complications.
- 4.3 Medical practitioners providing anaesthesia should have a comprehensive understanding of the systems and processes involved in drug prescription and administration, including awareness of relevant legislation in the jurisdiction of practice.
- 4.4 Medical practitioners providing anaesthesia should have an awareness of the contribution of human factors to medication errors and take steps to manage these³.
- 4.5 Collaboration with hospital pharmacists and medication safety groups will assist in ensuring appropriate availability and safe presentation of medications.
- 4.6 Regular audit of medication handling and reporting of medication administration errors will promote development of procedures for safe management and use of medications.

5. Recommendations

5.1 Purchasing decisions on anaesthesia drugs

- 5.1.1 Management of purchasing and inventory should include consideration of factors relevant to minimising the risk of drug error. The development of a 'purchasing for safety' policy is encouraged. Hospital pharmacy purchasing strategies can also have a significant impact on availability of essential medications when there are interruptions to supply.
- 5.1.2 If feasible, a designated pharmacist should liaise with a designated (clinical) drug safety officer in the department of anaesthesia or pain medicine over all decisions on relevant drug purchasing and presentation. In the absence of an anaesthesia department an anaesthetist should be nominated/designated to undertake such liaison.
- 5.1.3 The labelling and packaging of drugs should facilitate their identification. When a drug is available from more than one manufacturer, the clarity of the labelling and the avoidance of look-alike packaging or labelling should be considered when making purchasing decisions. Ampoule and vial labelling should conform to applicable national or international standards as these are adopted.
- 5.1.4 Changes to the packaging or labelling of drugs should be widely communicated to all those involved in their storage and administration.
- 5.1.5 There should be clear segregation of drugs of different concentrations but similar

physical presentation (e.g. local anaesthetics, heparin).

- 5.1.6 Wherever practicable drugs should be purchased or supplied in concentrations that minimise the need for dilution prior to administration. Certain drugs are particularly dangerous when undiluted and these should ideally be supplied in bags of fluid, pre-diluted to concentrations suitable for safe administration.
- 5.1.7 Consideration should be given to supplying selected drugs for intravenous use in prefilled and pre-labelled syringes rather than in ampoules. Relevant factors include the frequency of use of the drug in routine anaesthesia, the availability of stability data supporting an adequate shelf life, data identifying particular drugs with frequent error and patient harm, and the cost-effectiveness of prefilled syringes for drugs which may otherwise be routinely prepared for emergency use but often discarded.
- 5.1.8 In New Zealand decisions about purchasing are made by PHARMAC, the New Zealand government agency which determines funding and purchase of medicines. Whilst its consultation and processes should enable the best possible practices for purchasing and supply in consideration of such issues as safety, labelling and dosages, this is outside the direct control of anaesthetists practising in New Zealand.

5.2 Storage of anaesthesia drugs

- 5.2.1 Storage and documentation of ampoule and vial use must comply with the regulations of the appropriate jurisdictional authority. In particular, drugs with abuse potential should be secured in a locked environment when access is not required. However, the medical practitioner providing anaesthesia should be able to access sufficient quantities of critical drugs immediately and independently during episodes of patient care. Medications that must be available immediately in any anaesthetising location include epinephrine/adrenaline and other vasoactive agents, propofol, muscle relaxants and local anaesthetics.
- 5.2.2 Anaesthesia drug drawers and workspace should be organised formally with attention to orderliness and the position of ampoules. Where possible drugs of the same class should be stored in adjacent compartments. Standardisation within each institution, and ideally, each region, is highly desirable.
- 5.2.3 Many drugs used in anaesthesia are hazardous if inadvertently administered. It is important to separate drugs which are potent, and less frequently used, often emergency drugs, from those used routinely in anaesthesia. As a minimum safety measure they should be stored in a separate drawer or container within the anaesthesia cart whilst recognising that some of these medications must be immediately accessible.
- 5.2.4 Drugs and ampoules which maybe confused because of similar appearance or drug name and are of different pharmacological classes, should be clearly flagged or stored apart.
- 5.2.5 Anaesthesia trolleys should contain the minimum number of medications required to provide safe care. The goal should be to reduce complexity and eliminate redundancy at all times.
- 5.2.6 Drugs should be stored in ways designed to facilitate their identification and minimise the risk or error of misidentification. Consideration should be given to storing them in their original packaging until just before they are drawn up. Special care should be taken with ampoules, vials or packages that look similar, have similar names, or have labels that are difficult to read or are of similar appearance. As medication suppliers and thus ampoule/vial presentations frequently change, periodic review of medication storage in the anaesthesia cart is essential.
- 5.2.7 When anaesthetic and analgesic drugs are to be used outside a healthcare facility, for

example in responding to an external emergency, handling of controlled drugs must comply with jurisdictional requirements. Consideration should be given to secure storage for transport, documentation of dispensing and administration of drugs and disposal of unused medications.

5.3 Labels

- 5.3.1 All injectable drugs should be labelled when drawn up according to the relevant National Standards⁴. This includes an understanding of closed-practice (e.g. operating theatre, single patient) and open-practice (e.g. post anaesthesia care unit, multiple patients) environments.
- 5.3.2 The legibility of labels on ampoules and syringes should be optimised according to relevant national or international standards in respect of some or all of font, size, colour and the information included.
- 5.3.3 Self-adhesive pre-printed labels for application to syringes should be colour-coded by class of drug and conform to national or international standards. The relevant international standard, the Anaesthetic Labelling Standard, is ISO 26825:2008 – *Anaesthetic and respiratory equipment – user applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*. In Australia, the *National standard for user-applied labelling of injectable medicines, fluids and lines* (the Labelling Standard⁴) works in conjunction with the Anaesthetic Labelling Standard and addresses patient risks. It is a mandatory requirement for meeting the National Safety and Quality Health Service Standards in hospitals and day care facilities. Every anaesthetising location should hold a complete set of relevant pre- printed labels for stocked products. Sterile labels should be available for use when performing sterile procedures such as neuraxial blockade, especially if more than one drug is present on the sterile field.

Red coloured barrel/plunger syringes are strongly encouraged when drawing up neuromuscular blocking agents.
- 5.3.4 As a temporary measure, pending the provision of suitable pre-printed labels for syringes, hand-written labels should be prepared, or syringes should be labelled clearly and directly using permanent marker pens.
- 5.3.5 Labelling is not required when the preparation and bolus administration of a single medicine are one uninterrupted process, the syringe does not leave the hands of the person who prepared it and that same person administers the medicine immediately. Nevertheless, even when injectable medicines are drawn up in a syringe for immediate emergency use the principles in the Labelling Standard should be followed where possible – for example, where staff are available to label syringes without compromising the speed of emergency medicine delivery.

5.4 Drawing up and checking drugs before administration

- 5.4.1 Adequate lighting and minimisation of distraction are critical for drawing up and administering drugs.
- 5.4.2 The label on any drug ampoule or syringe should be carefully read before a drug is drawn up or injected. As a minimum, the name, concentration (where dilution has occurred or different concentrations are available) and expiry date of the drug should be checked. This applies to any medication irrespective of the route of administration.
- 5.4.3 A system should be in place within the department for regularly checking drug stock for expired drugs.
- 5.4.4 An agreed and consistent process should be in place to determine whether syringes are labelled *prior to* or *after* a drug is drawn up. Drugs should be drawn up using one

syringe and one ampoule at one time. The label on the ampoule should be checked, and matched to that on the syringe.

- 5.4.5 If there is an interruption to the process of drawing up and checking the ampoule, then the syringe contents should be discarded and the process restarted.
- 5.4.6 If practicable, immediately before it is administered, each drug's identity and dose should be checked. An automated device (for example, a bar code scanner) may reduce the risk of inadvertent delivery of an incorrect medication. Drugs given intrathecally should always be checked with a second person.

5.5 Administration principles

- 5.5.1 Every patient to whom any medication is administered must first be identified clearly and explicitly by the person administering the medication.
- 5.5.2 A complete drug history, including information on allergies and other adverse reactions, should be obtained explicitly from the patient or relative/carer where relevant, and/or the patient's clinical record prior to the administration of any drugs. A "Time Out" (or equivalent) process that includes patient identification and verbal declaration of any known drug allergies must be performed prior to commencement of any procedure.
- 5.5.3 Except in an emergency, when drugs are to be administered by someone other than the medical practitioner providing anaesthesia, all drugs should be administered by either another medical practitioner or under direct medical supervision or strictly according to a written direction or prescription.
- 5.5.4 Except in an emergency, before any drug is administered on behalf of another health professional, explicit communication should take place to ensure that both parties have a shared understanding of the indications, potential contraindications, and any other relevant information.
- 5.5.5 Prescriptions must be legible and include, as a minimum, the generic name of the drug, the dose, the route of administration, the dosage interval and time, and any special instructions, e.g. on dilution, indication, restrictions. Where electronic prescribing is used in a healthcare facility it is essential that all users are adequately trained and confirmed to have proficiency in using the system. The healthcare facility should adequately support practitioners to achieve and maintain such proficiency.
- 5.5.6 To minimise the risk of cross infection between patients, and where relevant for compliance with drug registers, the contents of any one ampoule or vial should be administered to only one patient. The decision to split ampoules rests solely with the anaesthetist and where they deem it necessary it is critical that this is performed in a manner that has the same level of safety as if the contents originated from the original ampoule/vial. This includes the ability to guarantee the contents of any ampoule/vial. Strict processes should be developed to ensure this and to ensure compliance with drug registers.¹
- 5.5.7 Uncluttered surface space and clean trays for each patient, should be provided for drawing up, arranging and holding the drugs used. Care should be taken at all times to adopt best practice to mitigate the risk of transmission of micro-organisms associated with the storage, preparation and administration of medications. Particular attention should be paid to capping syringes, which aids in maintaining micro-sterility. The principles of effective hand hygiene should also be adopted in handling and administering medications.

¹ For further information and explanation refer to PG51(A)BP item 3.8.

- 5.5.8 It is the responsibility of the anaesthetist to minimise the risk of infection by swabbing vial tops and, when appropriate, injection ports with 70% alcohol wipes (see ANZCA professional *PG28(A) Guideline on infection control in anaesthesia*).
- 5.5.9 It is recommended that for each case, the empty ampoules used for that patient, are retained in an accessible receptacle to provide an opportunity for verification should an adverse event or possible administration error occur, including provision of further details such as drug manufacturing batch. Retention of ampoules is particularly important when anaesthetists or trainees are sharing care of a patient.

5.6 Managing medications during anaesthesia

- 5.6.1 The time interval between drawing up a drug and administering it should be as short as practicable.
- 5.6.2 Drugs drawn up should be placed in an appropriate receptacle in a logical and orderly fashion.
- 5.6.3 When an automated dispensing machine is in use timely access to all anaesthetic drugs is crucial (see 5.2.1). A limited supply of anaesthetic drugs should be immediately available.
- 5.6.4 Drugs drawn up that are intended for different routes of administration should be clearly identified and kept separate.
- 5.6.5 Drugs drawn up for emergency use should be located separately in the anaesthesia work space to avoid inadvertent administration. Pre-filled syringes that have been appropriately manufactured, sealed and labelled, and have acceptable shelf lives can enhance safety.
- 5.6.6 Consideration should be given to ensuring rapid access to medications that may be required urgently in the post-anaesthesia care unit.

5.7 Disposal of medications

- 5.7.1 Once drug utilisation has been reconciled at the conclusion of the anaesthetic and the anaesthetic record completed, all partially used ampoules and syringes containing drugs should be safely discarded. Every institution should have a standardised procedure for discarding drugs, in part to minimise the risk of drugs being given unintentionally to successive patients. Disposal of containers, syringes and unused medications is the responsibility of the anaesthetist.
- 5.7.2 Particular attention should be given to appropriate disposal of sharps and contaminated items. Retained glass ampoules themselves pose a sharps hazard, and should be placed in a suitable robust container.
- 5.7.3 Disposal of medications that have the potential for diversion and abuse, such as opioids, benzodiazepine and propofol should be in a manner that minimises this risk. This should be witnessed and documented according to jurisdictional requirements.
- 5.7.4 Medications used in anaesthesia should be disposed of in a manner that minimises potential environmental harm. Hospital waste management policy and local legislative requirements should be adhered to.

5.8 Maintenance of accurate records

- 5.8.1 An accurate record of every drug administration, including the drug name written in full, dose of the drug and the route and time of administration, is essential for safe management of patients. Handwritten records should be clear in order to facilitate review of medication delivery and timing. The anaesthetic record must be signed by

the administering anaesthetist and include the name written in full. Electronic records improve legibility and can improve the accuracy of the record.

- 5.8.2 It is important to be able to demonstrate, if doubt arises, that the drugs recorded as given are the ones that have actually been given. Errors may be possible to correct if they can be identified. This is facilitated by retention of empty ampoules until the end of each anaesthetic, for checking if required.
- 5.8.3 Documentation of administration and discard of controlled medicines should be according to jurisdictional requirements.

5.9 Intravenous infusion of medications

- 5.9.1 Wherever practicable infusion pumps and syringe drivers used for the administration of intravenous drugs should be standardised within an institution.
- 5.9.2 When drugs are given by infusion, the patient end of the infusion line should be labelled and precautions taken with one-way valves to avoid any siphoning of the infused drug. Valve design should be such that the risk of accidental disconnection is minimised whilst also allowing effective disinfection of the surface of the valve/bung. Luer-lock connections should be used wherever possible.
- 5.9.3 The infusion devices used for intravenous medication delivery should be recognisably different from those used for neuraxial or peripheral nerve/plexus delivery of local anaesthetic. Colour-coding for infusions via different routes is also strongly recommended. Compliance with Labelling Standards for infusion lines, e.g. ACSQHC Labelling Recommendations⁴, is strongly recommended.
- 5.9.4 'Smart pumps' and infusion devices with Dosage Error Reduction Software may reduce drug delivery errors. A knowledge and familiarity with the function of such pumps is essential including an understanding of the limitations of the devices particularly with respect to individual patient variation. Their use does not replace the requirement for vigilant preparation and administration and observation of a patient's clinical response.

5.10 Handling of volatile agents

As volatile anaesthetic agents are highly potent and potentially lethal drugs, especially in liquid form, it is important that bottles, including those already opened, are stored securely. Partially filled bottles should be labelled with the date they were accessed. Empty bottles should have their caps removed and be placed in an appropriate disposal container to prevent re-use and inadvertent filling with another liquid.

This document is accompanied by a background paper (PG51(A)BP) which provides more detailed information regarding the rationale and interpretation of the Guideline.

Related documents

The following professional documents should be interpreted in light of this document:

PG06(A) Guideline on the anaesthesia record

PG28(A) Guideline on infection control in anaesthesia

References

1. Nanji KC, Patel A, Shaikh S, Seger DL, Bates DW. [Evaluation of perioperative medication errors and adverse drug events](#). Anesthesiology. 2016;124(1): 25-34. doi:10.1097/ALN.0000000000000904
2. Webster CS, Merry AF, Larsson L, McGrath KA, Weller J. The frequency and nature of drug administration error during anaesthesia. Anaesth Intensive Care [serial online]. 2001;29(5):494-500. From: <http://www.aaic.net.au.ezproxy.anzca.edu.au/Document/?D=2000210>. Accessed 12 October 2016.
3. Mahajan RP. [Medication errors: can we prevent them?](#) British Journal of Anaesthesia. 2011: 107(1): 3-5 doi: 10.1093/bja/aer131.
4. Australian Commission on Safety and Quality in Health Care. National standard for user-applied labelling of injectable medicines, fluids and lines [Internet]. 2016. From: <https://www.safetyandquality.gov.au/wp-content/uploads/2015/09/National-Standard-for-User-Applied-Labeling-Aug-2015.pdf>. Accessed 12 October 2016.

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Promulgated: 2009
Reviewed: 2018
Current document: Apr 2021

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