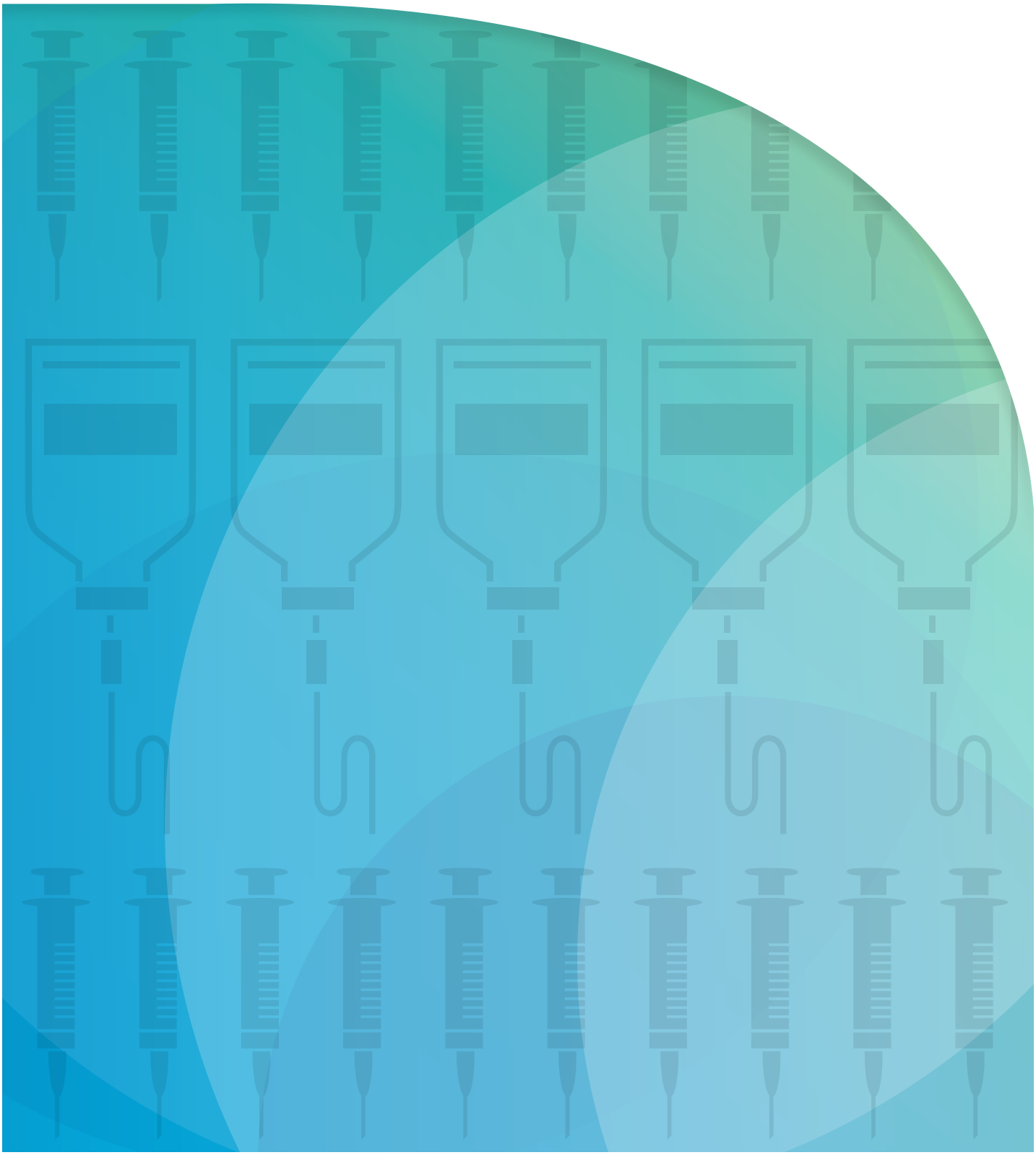
National Standard for

User-applied Labelling of Injectable Medicines, Fluids and Lines



AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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The *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* (Labelling Standard) and support materials are available on the Commission web site at www.safetyandquality.gov.au.

The Labelling Standard supersedes the *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines*, first edition (August 2010) and second edition (February 2012).

National Standard for

User-applied Labelling of Injectable Medicines, Fluids and Lines

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Acronyms and abbreviations

Anaesthetic Labelling Standard	International Standard ISO 26825:2008 *Anaesthetic and respiratory equipment – user-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*
AS 4940:2002	Australian Standard AS 4940:2002 *User-applied identification labels for use on fluid bags, syringes and drug administration lines*
the Commission	Australian Commission on Safety and Quality in Health Care
the Labelling Recommendations	*National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines*
the Labelling Standard	*National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines*
PMS	Pantone Matching System

Executive summary

Injectable medicines are a high-risk therapy for patients and health professionals. It is reported that 25% of all medication incidents in acute care involve injectable medicines, but nearly 60% of medication errors that result in serious patient harm or death involve injectable medicines (1).

Incomplete or inaccurate labelling of injectable medicines and fluids (and the devices used to deliver them) is a recognised risk to the safe administration of medicines and is potentially preventable. Improved labelling can reduce the risk of error and harm by safely communicating the contents of injectable medicines containers and the patients for whom they are intended (2).

One way of ensuring accurate communication of injectable medicines and fluids information is by standardised user-applied labelling. This *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* (the Labelling Standard) has been developed as a national solution to the risks posed by erroneous administration of injectable medicines. It replaces the 2012 *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines* (the Labelling Recommendations) (3).

Aims

The Labelling Standard is designed to reduce the risk of patient harm from injectable medicines by helping healthcare professionals identify the correct:

- injectable medicine or fluid (container)
- route of administration of the injectable medicine (conduit)
- patient for whom the medicine is intended.

The Labelling Standard sets out the requirements for label format, content and placement. The aim is to:

- promote safer use of injectable medicines
- provide standardisation for user-applied labelling of injectable medicines
- provide minimum requirements for user-applied labelling of injectable medicines.

The Labelling Standard addresses one recognised risk point in the safe administration of injectable medicines by preventing medicine administration errors, such as wrong patient, wrong route, wrong medicine or wrong dose. It applies alongside other safe medicines practices.

Practice principles

The Labelling Standard is based on the following practice principles:

- All medicines and fluids removed from the manufacturer's or hospital pharmacy's original packaging must be identifiable.
- All containers (e.g. bags, syringes) containing medicines leaving the hands of the person preparing the medicine must be labelled.
- Only one medicine at a time should be prepared and labelled before the preparation and labelling of a subsequent medicine.
- Any medicine or fluid that cannot be identified (e.g. in an unlabelled syringe or other container) is considered unsafe and should be discarded.

Labelling requirements

The Labelling Standard sets out the requirements for user-applied labelling of:

- containers of injectable medicines and fluids (bags, bottles and syringes) that can no longer be identified by their original packaging
- conduits used to deliver injectable medicines and fluids (administration lines, invasive monitoring lines, catheters and burettes)
- non-injectable fluids that can no longer be identified by their original packaging, including topical solutions, and oral and inhalational liquids.

The Labelling Standard identifies:

- what should be labelled
- what should be included on the label
- where the label should be placed
- where the Labelling Standard applies.

The Labelling Standard expands on the Labelling Recommendations (4) to include:

- labelling of containers in perioperative settings (including cardiac catheter and interventional radiology units)
- colour coded preprinted medicine labels for use on dedicated continuous infusion lines
- liquid medicines for oral, enteral and inhalational use
- labelling of non-injectable medicines and fluids prepared in the same area as injectable medicines.

National Safety and Quality Health Service Standards

Implementation of the Labelling Standard is a mandatory requirement for meeting the National Safety and Quality Health Service Standards (5).

Health services that are verifying their activities against the National Safety and Quality Health Service Standards are required to implement the Labelling Standard as outlined in this document and the accompanying source documents.

National policy

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for maintaining the Labelling Standard, and for identifying and reducing national barriers to its implementation. The Labelling Recommendations (on which this Labelling Standard is based) were endorsed by Australian health ministers in 2010 for use in Australian health services (6).

Safe use of medicines is a key component of quality use of medicines, which forms part of Australia's National Medicines Policy (7).

1 Introduction

1.1 Administration errors with injectable medicines

Injectable medicines are a therapy that pose a high risk for patients. The preparation of injectable medicines for bolus injection or infusion is complicated, and there are many opportunities for error (8). Preparation of a syringe for bolus injection has been estimated to have as many as 40 discrete steps (9). It is reported that 25% of all medication incidents in acute care involve injectable medicines, and nearly 60% of medication errors that result in serious patient harm or death involve injectable medicines (1).

Incomplete or inaccurate labelling of injectable medicines and fluids (and the devices used to deliver them) is a recognised risk to the safe administration of medicines (10-18). Omitting information such as the name of the medicine, or medicine dose or patient name, or not using a label at all, can result in the wrong medicine being administered, or medicines being administered by the wrong route or to the wrong patient (see box below for examples).

Examples of errors made as a result of an unlabelled container

Wrong medicines administered

Medicine swaps with fatal consequences include contrast media and chlorhexidine (2), glutaraldehyde and spinal fluid (2), lignocaine with adrenaline and adrenaline 1 mg/mL (19), and pethidine and syntometrine*(20). Other medicine swaps have been reported between botulinum toxin and triamcinolone; heparin 25 000 units in 5 mL and 'heparinised saline' 50 units in 5 mL (21, 22); and 0.9% sodium chloride flush and:

- heparin for infusion (23)
- aminophylline (12)
- midazolam (24)
- vecuronium (25).

Wrong route errors

Medicines administered via the intrathecal route instead of intravenously with fatal consequences include bortezomib (three cases) (26) and vincristine* (27). A woman in labour injected with chlorhexidine into the epidural space suffered neurological damage* (28). Errors involving unlabelled lines include the connection of oxygen tubing to an intravenous line in a paediatric patient, resulting in a fatal outcome (29).

Wrong patient errors

An unlabelled bag containing magnesium sulfate was accidentally administered to a patient who already had a bag of magnesium sulfate in progress. The unlabelled bag was prepared for another patient. The patient sufferred a respiratory arrest and anoxic encephalopathy as a result of the overdose (30).

* Australian incidents

In the majority of cases, actual harm to patients is limited by routine checking of infusions and prescriptions at handover (16). However, there are many reports of administration errors resulting from inadequate labelling causing harm – including death.

An unpublished review of incidents reported by public hospitals to an Australian incident management system database from 2003 to 2009 found a number of incidents involving injectable medicines. They included unlabelled or incorrectly labelled bags or syringes, the assumption that unlabelled syringes/bags contained 0.9% sodium chloride, unlabelled insulin administration devices, lines not labelled with route of administration, lines not labelled or incorrectly labelled with medicine content, labels placed incorrectly, and no burette labels applied.

1.1.1 Administration errors in the perioperative area

The complex circumstances surrounding medicines administration in perioperative areas allow opportunity for errors (31, 32). In operating rooms, a multidisciplinary clinical team interacts with medicines in different ways and at different times. Solutions may be routinely drawn up into syringes and poured into sterile basins for transfer from nonsterile original containers to sterile fields. In addition, patients will transfer through various clinical areas requiring multiple handovers between healthcare providers.

Inconsistent labelling of injectable medicines before patient transfer has been reported in operating rooms (20, 33, 34), as has poor and inconsistent labelling of injectable medicines on sterile fields (2, 35). Medicine labelling has been cited as a contributor to the frequent errors relating to administration of injectable medicines in anaesthetic practice (17, 18, 36, 37). Similar opportunities for error occur in interventional cardiology and radiology units, where products on sterile fields at any one time may include skin preparation fluids, local anaesthetics, contrast media and medicines (such as heparin). Injection of a hazardous medicine or fluid stored in an unlabelled container in the interventional sterile field is preventable (38). Studies on perioperative sterile fields indicate that medicines and containers, including syringes, are more likely to be labelled correctly when preprinted medicine labels are available (4, 39).

1.2 Support for safe labelling practices

Safely communicating the contents of injectable medicines containers and the patient for whom they are intended, through improved labelling, can reduce the risk of error and harm (2). A number of international organisations and individual researchers (16, 40-42) have made recommendations regarding safe labelling practices, including the recommendation to standardise labelling of injectable medicines and administration lines. International organisations that have recommended actions for safer labelling practices include the:

- World Health Organization (43)
- former National Patient Safety Agency in the United Kingdom (5, 21, 27, 44-47)
- Joint Commission in the United States (48, 49)
- Institute for Safe Medication Practices in the United States (2, 12, 29, 30, 50-52)
- Institute for Safe Medication Practices Canada (19, 53, 54).

Evidence shows that putting processes into place that are designed to improve safety is more successful at reducing harm than simply trying harder to avoid error. Standardised labelling is one of many processes that contribute to the safe administration of injectable medicines (55). Other processes that may be considered to improve safety include use of bar codes, uniform colour coding and development of safer connecting non-Luer devices for intrathecal, epidural and regional injection (56-60).

1.2.1 Standardisation and colour coding of medicine labels

Although labelling medicine infusion lines is a well-recognised strategy for preventing medication errors, standardised label design studies are limited, and there are varying degrees of uptake of user-applied labelling systems.

Simulation studies have shown that a standard system of labelling intravenous bags and syringes, lines and syringe pumps – including medicines labels (61), and the use of colour coded labels on the bag with additives and the line (62) – can significantly improve identification of the correct medicines.

The international Anaesthetic Labelling Standard (ISO 26825:2008 – *Anaesthetic and respiratory equipment – user-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*) introduced in 2008 provides guidance on implementing a standardised user-applied labelling system (63). It covers the colour, size, design and general properties of the label, and the typographical characteristics of the wording for the medicine name. The aim of the standard is to reduce the errors relating to administration of injectable medicines in anaesthetic practice.

1.3 National Safety and Quality Health Service Standards

Implementation of the Labelling Standard is a mandatory requirement for meeting the National Safety and Quality Health Service Standards (5).

Health services seeking accreditation under the Australian Health Service Safety and Quality Accreditation scheme are required to provide evidence of Labelling Standard implementation.

Implementing relevant action items in the National Safety and Quality Health Service Standards will assist clinicians to safely prescribe, dispense and administer injectable medicines. The two criteria of particular relevance to safe administration of medicines are:

- Governance and Systems for Medication Safety
- Medication Management Processes.

These encompass, but are not restricted to, the following processes:

- Undertake regular assessments of injectable medicines management procedures in all clinical areas to identify risks and take action to reduce these risks (47, 48) (Safety Standard 4.5).
- Develop, implement and maintain protocols and policies for prescribing, preparing and administering injectable medicines and fluids, including checking processes. This may include a policy to promote procurement of injectable medicines with inherent safety features, including safe labelling (Safety Standard 4.2).
- Educate the relevant clinical workforce in prescribing, preparing, administering and monitoring injectable medicines and fluids, including staff who supervise and check these processes (Safety Standard 4.9).
- Verify that the members of the clinical workforce who handle injectable medicines have medication authority that is appropriate to their scope of practice (Safety Standard 4.3).
- Ensure that healthcare professionals have timely access to information and decision tools relevant to injectable medicines. Take action to regularly review and improve the materials (Safety Standard 4.9).
- Regularly monitor, report on and investigate medication incidents, and take action to reduce adverse medication incidents (Safety Standard 4.4).
- Identify high-risk medicines and regularly review their administration to reduce related patient harm (Safety Standard 4.11).

1.4 National Medicines Policy

The Commission is responsible for maintaining the Labelling Standard, and for identifying and reducing national barriers to its implementation. The Labelling Recommendations (on which this Labelling Standard is based) were endorsed by Australian health ministers in 2010 for use in Australian health services (6).

Safe use of medicines is a key component of quality use of medicines, which forms part of Australia's National Medicines Policy (7).

1.5 Labelling Standard context

The Labelling Standard describes the minimum requirements for safe user-applied labelling of injectable medicines, fluids and lines. Health services are encouraged to put in place additional strategies that reflect the particular risks associated with local conditions, including patient population and procedures provided. Examples include:

- using prefilled syringes and premixed solutions in standard strengths wherever they are available (e.g. Therapeutic Goods Administration–registered products, compounded product sourced from a licensed manufacturer or other aseptic compounding unit) and have been assessed as suitable by the relevant governance committee
- barcoding preprinted container labels, particularly for small syringes, and syringes in syringe drivers and pumps. Barcoding is already in use in anaesthesia to assist identification (55).

Adequate labelling represents one step in the overall process of preventing medicine administration errors associated with injectable medicines. Labelling should be undertaken alongside other clearly defined quality and safety processes, consistent with existing policies and standards.

1.6 Labelling Standard structure

This document provides guidelines for labelling medicines and fluids removed from their original packaging, and transferred to containers and conduits at patient administration. The scope is clearly defined, and governance, label properties and appearance (specifically, colour coding) are introduced early in the document.

Considerations for labelling containers are described and tabulated with label inclusions, examples and placement details. This format is repeated for lines and catheters. The perioperative area has particular requirements and is covered in its own section, followed by other specific considerations (e.g. blood products, renal dialysis and radiopharmaceuticals). This Labelling Standard includes a glossary of terms, label specifications (Appendices 1 and 2), and a description of integration with other standards (Appendix 3). A large number of individuals and facilities have contributed to the Labelling Standard and they are acknowledged. Appendix 4 gives an overview of the development process.

2 Scope of the Labelling Standard

The purpose of the Labelling Standard is to improve patient safety. Clear labelling of injectable medicines and fluids by the user at the point of delivery should help to reduce the risk of medicine administration errors.

2.1 Inclusions

The Labelling Standard sets out the requirements for user-applied labelling of:

- containers for injectable medicines and fluids (bags, bottles and syringes) in which the medicine can no longer be identified by its original packaging
- conduits (administration lines, invasive monitoring lines, catheters and burettes) that are used to deliver injectable medicines and fluids
- non-injectable fluids that can no longer be identified by their original packaging, including topical solutions, and oral and inhalational liquids.

The Labelling Standard identifies:

- what should be labelled
- what should be included on the label
- where the label should be placed
- where the Labelling Standard applies.

Figure 1 shows examples of injectable medicines, containers and conduits that require user-applied labelling.

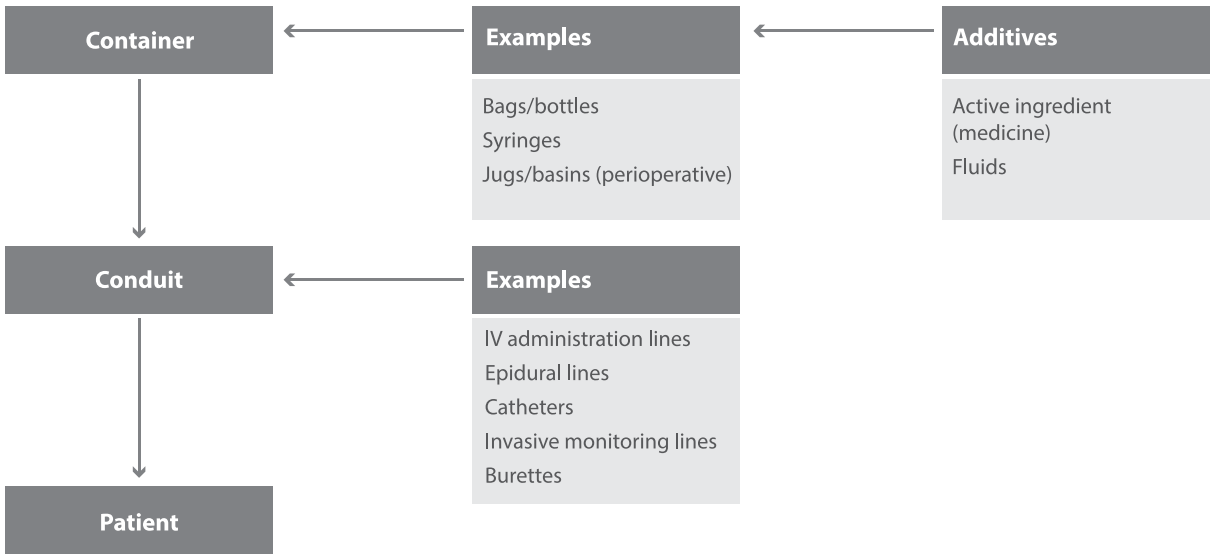


Figure 1 Examples of containers and conduits for injectable medicines that require user-applied labelling

The Labelling Standard applies to:

- all health services where injectable medicines and fluids are administered. These include, but are not limited to, hospitals (including day procedure units), primary care services (such as ambulance services) and community health services (such as immunisation clinics)
- all clinical areas where injectable medicines and fluids are administered
- all injectable medicines and fluids prepared in the ward or clinical area, including perioperative areas
- injectable medicines, defined as any sterile medicine intended for administration by bolus injection, perfusion or infusion by the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intra-ocular (46). This list is not exhaustive, and other routes of injection should also be considered in the context of the Labelling Standard (e.g. intraosseous and intraperitoneal)
- liquid medicines for oral, enteral and inhalational use (see Section 7.6)
- non-injectable medicines and fluids that are prepared in the same area as injectable products, including solutions for topical use (see Section 7.6)
- user-applied labelling of containers and conduits for any medicine or fluid in the perioperative area. In addition, the Anaesthetic Labelling Standard (ISO 26825:2008) applies to syringes containing medicines used during anaesthesia (63) (see Section 6 for labelling in the perioperative area).

2.2 Exclusions

The Labelling Standard does not apply to the labelling of:

- topical products prepared when injectable medicines are not present; however, the same principles of identification translate to topical use of medicines, solutions, chemicals and reagents
- injectable medicines and fluids prepared by hospital pharmacy departments – these must comply with the Society of Hospital Pharmacists of Australia's *Guidelines for Medication Prepared in Australian Hospital Pharmacy Departments* (64)
- injectable medicines and fluids prepared by external manufacturers or compounding centres (e.g. cytotoxic preparations, premixed solutions and prefilled syringes) – these must comply with Therapeutics Goods Order No. 69 (65)
- injectable medicines and fluids that are not directly administered to the patient – the labelling of any container that cannot be used to administer an injectable medicine directly to the patient (e.g. ampoules and individual patient multidose vials) is the responsibility of the manufacturer as mandated by Therapeutic Goods Order No. 69 (65)
- extemporaneously dispensed radiopharmaceuticals – best-practice guidelines for preparation of radiopharmaceuticals provide strict protocols for extemporaneous dispensing of a radiopharmaceutical prescription for a named patient. The end product is a syringe containing radioactive material with the whole unit enclosed in lead casing; this constitutes the original container (66). Additional user-applied labelling is not required, provided the syringe or its contents are not removed from the original container.

3 General requirements for labelling

This section outlines the requirements that apply to user-applied labels for all injectable medicines. Sections 4–7 provide additional requirements for labelling containers, conduits and non-injectable medicines, and labelling in perioperative areas.

3.1 Governance

- All user-applied labels for medicines, fluids and lines must be approved by the relevant governance committee.
- One central committee should be responsible for the governance of processes related specifically to labels within each hospital or health service, including
  - the introduction of new labels
  - the approval of a range of preprinted labels
  - version control
  - inventory control
  - procurement
  - the maintenance of stock levels.
- Availability of an appropriate range of preprinted Labelling Standard labels is fundamental to successful implementation of the Labelling Standard. An adequate supply of labels must be established and maintained in all clinical areas, consistent with area requirements.

3.2 Properties of labels

3.2.1 Label quality

Labels should be printed on material of a quality that is durable and fit for purpose. Labels are required to:

- remain intact for the duration of use
- remain attached to the container or line for the duration of use
- be written on in ink (where required) and the writing remain legible for the duration of use.

Replace labels that are damaged or displaced during use.

Labels may be repeatedly exposed to fluids during use and, in the case of containers used in perioperative areas, handled many times during a procedure. The quality of label stock and facings must be able to withstand this exposure for the duration of the label's use.

3.2.2 Label adhesive

Adhesive strength should be appropriate to the label purpose.

All labels must adhere to the container/line and remain adhered for the duration of use. For the majority of containers, it is preferable that the label remains adhered to the container after use for audit purposes (see Australian Standard AS 4940:2002) (67, 68).

However, certain types of labels should be able to be peeled off after the medicine is administered or the procedure is complete, and should be ordered with adhesive designed for this purpose (see Section 7).

These are:

- burette labels, to be removed after the medicine has run through the burette
- abbreviated container labels for use in the perioperative sterile field on reusable containers (e.g. stainless steel bowls)
- locked catheter labels that are required to be removed when the medicine lock is removed from the catheter (e.g. when the anticoagulant lock is removed from a dialysis catheter) without disturbing the dressing and introducing infection risk.

3.2.3 Label readability

All labels should be easily legible. A large, clear, sans serif font should be used (69). The label and font size of prepopulated labels is set to ensure consistency across the label range. Nonstandard labelling substitutes are discouraged as they contradict the intention of the Labelling Standard. Health facilities must consider the production, implementation, education and evaluation resources for a nonstandard labelling substitute. Where preprinted labels are customised for the health facility (such as for use on the perioperative sterile field), health facilities should ensure size and font are optimal for readability.

3.2.4 Preprinted labels

Health service organisations may use labels that have been preprinted with the medicine name for abbreviated container labels in the closed-practice perioperative environment and for medicine lines labels. See Sections 5.2.2 and 6.6, and Appendix 2 for information on preprinted labels.

Medicine names on preprinted labels should use:

- the active ingredient name
- names consistent with Australian Medicines Terminology (AMT) (70)
- title case (an initial capital letter for every word and lower case for other letters)
- Tall Man lettering for medicines on the National Tall Man Lettering List (69).

3.3 Colour coding

Colour coding can assist with identification; for example, it helps to match fluid bags, syringes and lines with the route of administration. However, colour coding is a relatively weak safety factor (71, 72), and there are risks when health professionals rely solely on colour for medicine identification. The written word is the primary identifier, with colour remaining a secondary identifier.

Two user-applied labelling standards for injectable medicines in Australian hospitals apply alongside each other:

- the Labelling Standard, which colour codes injectable medicines labelling according to route of delivery (target tissue)
- Anaesthetic Labelling Standard ISO 26825:2008, which describes colour coding, according to medicine class, for labels that are preprinted with medicine names (63).

The Australian and New Zealand College of Anaesthetists *Guidelines for the Safe Administration of Injectable Drugs in Anaesthesia* (73) recommends that any medicines used during anaesthesia should be labelled consistent with the Anaesthetic Labelling Standard ISO 26825:2008.

3.3.1 Route of administration

The Labelling Standard colour codes container or conduit labels according to the route of administration and target tissue (see Table 1, modified from AS 4940:2002) (67, 68).

There are container and line labels reserved for the identification of medicines and fluids to be given via routes that are not identified by any of the other labels ('Miscellaneous' in Table 1; e.g. intraosseous, intraperitoneal). They should not be used when the correct label is simply not available. Health facilities are expected to maintain stock labels appropriate to use.

Table 1 Colour coding of user-applied labels for target tissue

Target tissue type	Route of administration	Colour	PMS colour
Intra-arterial	Intra-arterial	Red	1787
Intravenous	Intravenous	Blue	2985
Neural	Epidural/intrathecal/regional	Yellow	Pantone Yellow
Subcutaneous	Subcutaneous	Beige	723
Intragastric	Enteral	Green	361
Respiratory	Inhalational	White	n/a
Miscellaneous	Other routes	Pink	806

n/a = not applicable; PMS = Pantone Matching System

3.3.2 Medicine class

The Anaesthetic Labelling Standard (ISO 26825:2008) classifies medicines according to medicine class. It should be implemented in all areas where medicines are administered in syringes during anaesthesia.

Colour coding of medicine labels in the Labelling Standard is based on the Anaesthetic Labelling Standard (ISO 26825:2008) (see Table 2 on page 12), and preprinted medicine labels consistent with the Anaesthetic Labelling Standard (ISO 26825: 2008) should be used for:

- dedicated continuous infusion lines (see Section 5)
- containers in closed-practice environments (see Section 6).

The above areas extend beyond anaesthesia. Additional colour coding of teal green (Pantone Matching System [PMS] 3255) has been developed to be used in association with anticoagulant/antiplatelet medicines.

Medicines of opposite action, including antagonists, should have the centre of the label with full colour (i.e. behind the medicine name), with a coloured border with diagonal stripes.

For example, labels for glyceryl trinitrate and sodium nitroprusside will be coloured violet (PMS 256) with a violet and white diagonal-stripe border; naloxone will be coloured blue (PMS 297) with a blue and white diagonal-stripe border (see Table 2 on page 12).

Medicines in the Anaesthetic Labelling Standard (ISO 26825:2008) miscellaneous category (such as frusemide) should be printed with black text on white background. The exception is for high-risk medicines, which should be printed with red text on a white background.

Table 2 User-applied label colours for syringes containing medicines used during anaesthesia (adapted from ISO 26825:2008)

Medicine class	Colour		Colour identifiers[a]	Medicine examples	Label examples[b]
Induction agents	Yellow		RGB: 255.255.0 CMYK: 0.0.100.0 PMS: Process yellow C	Propofol, ketamine	propOFol
Benzodiazepines	Orange		RGB: 255.102.0 CMYK: 0.60.40.0 PMS: 151	Diazepam, midazolam	Midazolam
Benzodiazepine antagonists	Orange with white diagonal stripes			Flumazenil	Flumazenil
Muscle relaxants	Fluorescent red or warm red Exception: suxamethonium (red name reversed out of a black bar on the upper half of the label)		RGB: 253.121.86 or 245.64.41 CMYK: 0.52.65.1 or 0.75.90.0 PMS: 811	Suxamethonium, pancuronium, vecuronium	Vecuronium Suxamethonium
Relaxant reversal agents	Fluorescent/warm red with white diagonal stripes			Neostigmine, pyridostigmine	Neostigmine
Opioids	Blue		RGB: 133.199.227 CMYK: 37.11.0.11 PMS: 297	Morphine, fentanyl, pethidine	Morphine
Opioid antagonists	Blue with white diagonal stripes			Naloxone	Naloxone
Vasopressors	Violet Exception: adrenaline (violet name reversed out of a black bar on the upper half of the label)		RGB: 222.191.217 CMYK: 0.12.2.13 PMS: 256	Adrenaline, metaraminol, noradrenaline	Noradrenaline Adrenaline 1 in 400,000
Hypotensive agents	Violet with white diagonal stripes			Sodium nitroprusside, glyceryl trinitrate, phentolamine, hydralazine	Glyceryl Trinitrate

Table 2 *continued*

Medicine class	Colour	Colour identifiers[a]	Medicine examples	Label examples[b]
Local anaesthetics	Grey	RGB: 194.184.171 CMYK: 0.4.9.24 PMS: 401	Procaine, lignocaine, bupivacaine, ropivacaine	Bupivacaine
Anticholinergic agents	Green	RGB: 163.217.99 CMYK: 21.0.46.15 PMS: 367	Atropine, glycopyrrolate	Atropine
Antiemetics	Salmon	RGB: 237.194.130 CMYK: 0.17.42.7 PMS: 156	Droperidol, metoclopramide	Metoclopramide
Anticoagulant/ antiplatelet agents[c]	Teal green	RGB: 34.211.197 CMYK: 64.0.32.0 PMS: 3255	Abciximab, bivalirubin, eptifabatide, tirofiban, urokinase	Urokinase
Heparin[c]	Teal green with solid black border (1–2 mm)	RGB: 34.211.197 CMYK: 64.0.32.0 PMS: 3255	Heparin	Heparin
Protamine[c]	Teal green with black diagonal-stripe border (1–2 mm)	RGB: 34.211.197 CMYK: 64.0.32.0 PMS: 3255	Protamine	Protamine
Heparinised saline[c]	White with teal green border	RGB: 34.211.197 CMYK: 64.0.32.0 PMS: 3255	Heparinised saline	Heparinised Saline
Miscellaneous medicines	Black text on white background		Oxytocin	Sodium Chloride 0.9%
High-risk miscellaneous medicines	Red text on white background		Potassium chloride, insulin	Potassium Chloride

CMYK = cyan, magenta, yellow, black; PMS = Pantone Matching System, RGB = red green blue

a The Pantone Matching System is an example of a suitable commercially available product. ISO 26825:2008 and the Labelling Standard provide RGB and CMYK colours for the convenience of users (not as an endorsement of any products).

b A concentration prompt is optional, except in the case of adrenaline.

c Departure from the Anaesthetic Labelling Standard (ISO 26825:2008)

If a medicine is not described in Table 2, the general principle for attributing the appropriate medicine label colour is to categorise the medicine according to primary therapeutic use rather than pharmacological class. For example:

- Isoprenaline is a sympathomimetic and chronotrope with vasodilatory action. It should be labelled violet with a violet and white diagonal-stripe border on four sides.
- Papaverine is an opioid. However, its principal action is a vasodilator and, therefore, the label should be violet with a violet and white diagonal-stripe border on four sides.
- Beta-blocker labels should be printed with black text on white background, because they do not fit any category precisely. Beta-blockers do not reverse adrenaline but have vasopressor antagonist properties in the myocardium. They also have anti-arrhythmic properties.

Preprinted medicine line labels for dedicated continuous infusion lines

Colour coding applied to preprinted medicine line labels should be consistent with the Anaesthetic Labelling Standard (ISO 26825:2008) and its extension (see Section 5). Labels that are most commonly administered by continuous infusion include, but are not limited to, the examples shown in Table 3. These labels are printed on separate rolls rather than a label sheet, and are therefore presented in alphabetical order in Table 3.

Table 3 Examples of preprinted medicine line labels

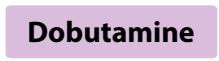
Medicine line	Label
Vasopressor, adrenaline Violet, bold, reverse plate letters in a black bar on upper half of label. Violet on lower half of label	
Miscellaneous B/W, Tall Man lettering	
Miscellaneous B/W, Tall Man lettering	
Anticholinergic Green label with black font	
Hypotensive Violet label with white diagonal-stripe border	
Benzodiazepine Orange label with black font, Tall Man lettering	
Vasopressor Violet label with black font	
Vasopressor Violet label with black font	
Opioid Blue label with black font	
Miscellaneous B/W	
Hypotensive Violet label with white diagonal-stripe border	
Anticoagulant Teal green label with 1–2 mm solid black border	
Miscellaneous/high risk White label with red font	
Hypotensive Violet label with white diagonal-stripe border	

Table 3 *continued*

Medicine line	Label
Induction agent Yellow label with black font	Ketamine
Hypotensive Violet label with white diagonal-stripe border	Levosimendan
Local anaesthetic Grey label with black font	Lignocaine
Miscellaneous B/W	Magnesium
Vasopressor Violet label with black font	Metaraminol
Benzodiazepine Orange label with black font	Midazolam
Hypotensive Violet label with white diagonal-stripe border	Milrinone
Opioid Blue label with black font	Morphine
Opioid antagonist Blue label with white diagonal-stripe border	Naloxone
Hypotensive Violet label with white diagonal-stripe border, Tall Man lettering	niMODIPine
Vasopressor Violet label with black font	Noradrenaline
Opioid Blue label with black font	Oxycodone
Muscle relaxant Fluorescent red label with black font	Pancuronium
Miscellaneous/high risk White label with red font	Potassium Chloride
Induction agent Yellow label with black font, Tall Man lettering	propOFol
Anticoagulant antagonist Teal green label with 1–2 mm diagonal-stripe black border	Protamine
Muscle relaxant Fluorescent red label with black font	Rocuronium
Local anaesthetic Grey label with black font	Ropivacaine
Miscellaneous B/W	Salbutamol
Miscellaneous B/W	Sodium Chloride 0.9%
Miscellaneous/high risk White label with red font	Sodium Chloride 20%
Hypotensive Violet label with white diagonal-stripe border	Sodium Nitroprusside
Muscle relaxant, suxamethonium Fluorescent red, bold, reverse plate letters in a black bar on upper half of label. Fluorescent red on lower half of label	Suxamethonium
Induction agent Yellow label with black font	Thiopentone
Anticoagulant Teal green label with black font	Urokinase
Muscle relaxant Fluorescent red with black font	Vecuronium

B/W = black font on white background

4 Labelling injectable medicine containers

This section outlines the requirements for labelling containers of injectable medicines, including bags, syringes, basins and jugs.

4.1 General considerations for all containers

The following apply to all types of containers:

- Each injectable medicine drawn up in a bag or syringe should be prepared and labelled as a single operation by the same person (74, 75).
- The TOTAL amount of active ingredient (medicine name) added to the container must be identified, including units (e.g. milligrams, or mg).
- The TOTAL volume of fluid in the container must be identified in millilitres (mL).
- The concentration (units/mL) must be identified. The use of ratios to express medicine concentration (e.g. 1:1000, 1:10 000) is associated with medication errors and discouraged (76, 77). The exception is preprinted labels in closed-practice environments, which may be printed with a ratio to be consistent with expression of strength on the original packaging.
- The pharmacy's or manufacturer's labelling of product name, batch number and expiry date must remain visible after the label has been applied (78).
- A duplicate label should be applied to any overwrapper (i.e. outer wrapper) that does not allow clear visibility of the primary label attached to the bag or syringe.

4.2 Fluid bags

Exception

Additional user-applied labelling is NOT required for fluid bags and bottles for infusion when no additional injectable medicines are added before administration. Examples include intravenous fluids (e.g. 0.9% sodium chloride, 5% glucose), premixed solutions (e.g. potassium, heparin infusions) and peritoneal dialysis fluids.

All bags and bottles should be labelled IMMEDIATELY after an injectable medicine is added.

Bag additive labels should be placed on the front of the bag in a way that ensures that the name of the base fluid, the batch number and the expiry date remain visible (78).

Bag additive labels should be placed slightly off centre to ensure that graduations on one side of the bag remain visible to monitor fluid volume delivery.

This Labelling Standard should be cross-referenced to local, institutional or health service policies on use of premixed intravenous injections (e.g. premixed intravenous potassium chloride, heparin, magnesium, amino acids and chemotherapy).

4.3 Syringes

Exceptions

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 (45, 78, 79).

Additional labelling is NOT required for syringes that are prefilled for bolus use or infusion, and labelled by the manufacturer or hospital pharmacy.

All injectable medicines drawn up in a syringe that will leave the hand of the person filling it should be labelled IMMEDIATELY. This includes those intended for bolus use, even if only one injectable medicine is to be administered (2, 45, 48, 78, 79).

Any fluid drawn up to be used as an intravenous flush (e.g. 0.9% sodium chloride) MUST be labelled unless the exception in the above box applies (12, 24, 25). It is acceptable to use the abbreviated 0.9% sodium chloride label for this purpose (Appendix 1).

If multiple syringes are required, they should be prepared, labelled and administered sequentially as independent operations (54, 79).

Place the label parallel to the long axis of the syringe barrel with the top edge flush with (but not covering) the graduations (12, 78). When application of the entire label to the syringe is impractical (e.g. small syringes), the label should be applied as a flag.

Syringe pumps may be labelled consistent with the Labelling Standard. However, labelling the primary container (i.e. the syringe) is a minimum requirement – labelling the syringe pump or driver is in addition to this minimum requirement.

4.4 Containers in open- and closed-practice environments

Containers (bags and syringes) containing medicines that have been removed from their original containers must be identified with full label inclusions, including patient identification details.

The exception to this rule is the closed-practice environment, where:

- 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 preprinted abbreviated container label may be used (see Section 6.1).

Examples of closed-practice environments are operating rooms, endoscopy rooms, cardiac catheterisation laboratories and radiology suites.

4.5 When to discard containers of injectable medicines

Any unlabelled syringe (or other container) containing a solution must be immediately discarded (2, 12, 81).

Any syringe (or other container) where there is doubt regarding its contents must be discarded (2, 12, 81).

Any medicine remaining in the syringe (or other container) at the end of a procedure must be discarded (2, 12, 81).

4.6 Minimum requirements for labelling containers in the open-practice environment

The following shows the minimum labelling requirements for containers (e.g. bags and syringes) in the open-practice environment.

The full range of labels is shown in Appendix 1.

The minimum requirements apply to:

- bags and bottles for infusion where injectable medicines are added in the clinical area before administration
- syringes for bolus use or infusion filled by drawing up injectable medicine from the manufacturer's original container in the clinical area before administration.

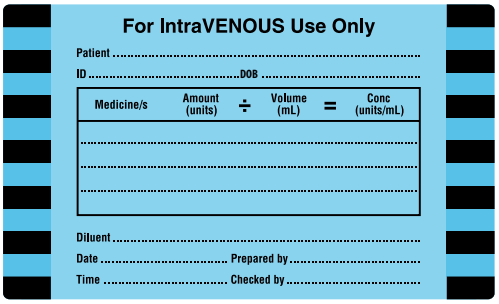
Label inclusions

- Patient name (given and family names)
- Patient identifier (ID) (e.g. medical record number)
- Patient date of birth (DOB)
- Active ingredient/s (medicine/s) added to the bag or syringe
- Amount of medicine/s added (including units)
- Total volume of fluid (mL) in bag or syringe
- Concentration (units/mL)
- Diluent (for syringes)
- Date and time prepared
- Prepared by (signature)
- Checked by (signature)
- Route of administration (where not specified by wording and colour)

Sample label (not to scale)

Label available in two sizes:

- 100 mm × 60 mm
- 60 mm × 50 mm



Label placement – bags and bottles

- Place on front of container
- Ensure fluid name, batch number, expiry date and graduations remain visible (78)

Label placement – syringes for bolus use or infusion

- Place parallel to the long axis of the syringe barrel with the top edge of the label flush with (but not covering) the graduations (12, 78)
- Choose label size and placement to ensure label content is visible on a syringe in a syringe driver or pump
- On small syringes, consider folding the label back on itself (as a flag) or using a clear overlay flag

Exception: syringes containing 0.9% sodium chloride for flushing a line

Label inclusions

Preprinted '0.9% sodium chloride'

Sample label (not to scale)

Sodium Chloride 0.9%

4.7 Minimum requirements for labelling containers in the closed-practice environment

The following shows the minimum labelling requirements for containers (e.g. syringes, basins and jugs) in the closed-practice environment.

The minimum requirements apply to containers of medicines and fluids when patient identity is established and other means of recording, labelling and preparing signatures are available (e.g. operating rooms).

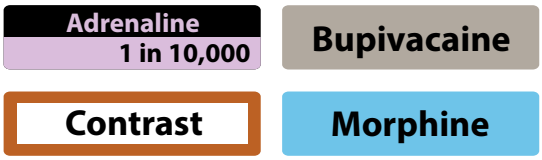
4.7.1 Injectable medicines

Label inclusions

- Active ingredient/s (medicine/s) added to the container
- Concentration (units/mL) optional, except for adrenaline when used as a single medicine

Sample labels (not to scale)

- Preprinted labels should be used where possible (see Figures 3 and 5 on pages 27 and 29 for a wider range of examples)



- Use a generic label when a preprinted label is unavailable

Label placement

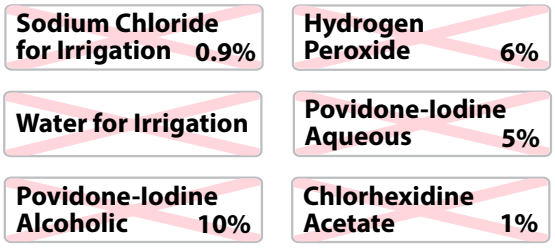
- Use peel-off labels on reusable containers
- Avoid placing on graduations
- Avoid placing on a pouring spout

4.7.2 Non-injectable medicines and fluids

Label inclusions

- Active ingredient/s (fluid/s) added to the container
- Concentration (optional)
- Red (70%) St Andrew's Cross watermark

Sample labels (not to scale)



Label placement

- Use peel-off labels on reusable containers
- Avoid placing on graduations
- Avoid placing on a pouring spout

5 Labelling injectable medicine conduits, lines and catheters

5.1 Burettes

All burettes should be labelled IMMEDIATELY after an injectable medicine is added.

Place the label so that the text is upright and ensure that the burette graduations are not obscured.

Peel-off labels should be used on burettes, and labels must be removed once the medicine has been administered to the patient.

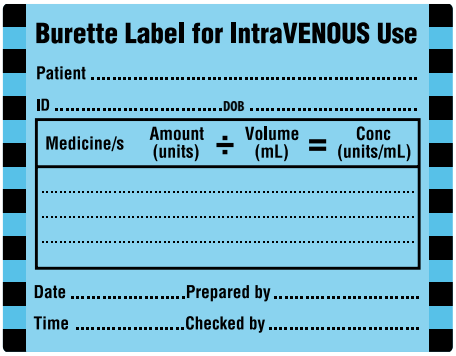
The burette label may be applied temporarily to the syringe containing the medicine that is to be added directly to the burette. The label will then be transferred to the burette.

5.1.1 Minimum requirements for labelling burettes

Label inclusions

- 'Burette Label for IntraVENOUS Use'
- Patient name (given and family names)
- Patient identifier (ID) (e.g. medical record number)
- Patient date of birth (DOB)
- Active ingredient (medicine) added to burette
- Amount of medicine added (including units)
- Volume of fluid added to burette (mL)
- Concentration (units/mL)
- Date and time prepared
- Prepared by (signature)
- Checked by (signature)

Sample label (not to scale)



Label placement

- Use peel-off labels reserved for use on burettes ONLY
- A new label is required for each medicine administration
- Remove label on completion of infusion
- Do not obscure the burette graduations with the label
- Place label so that text is upright
- Label may be applied temporarily to the syringe containing the medicine to be added directly into the burette

5.2 Administration lines

All administration lines and catheters (including extension lines and giving sets used to deliver fluids and/or medicines into a patient by the parenteral route) must be labelled.

5.2.1 Administration lines and catheters to identify route

Administration lines and catheters must be labelled with the relevant route of administration (see Appendix 1) (29, 82, 83).

Labels should be colour coded according to target tissue (see Table 1 on page 11).

The date and time the line was commenced should be documented on the label.

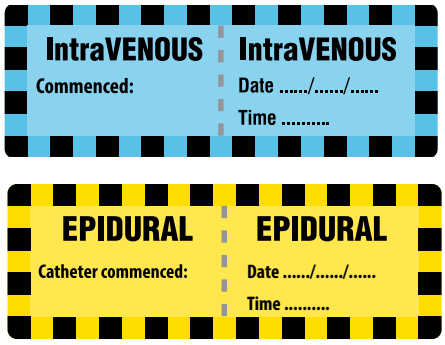
Catheters (e.g. epidural, intrathecal) must be identified when there is a risk of wrong route of administration (e.g. where the patient entry port is distant from the administration site) (27, 43, 46, 51, 53, 54).

Minimum requirements for labelling administration lines: route

Label inclusions

- Route
- Date and time commenced

Sample labels (not to scale)



5.2.2 Administration lines to identify medicine

Administration lines dedicated to continuous infusions must be labelled to identify the medicine within the line.

Preprinted medicine line labels are recommended for commonly used medicines with specifications as follows:

- Use the active ingredient name of the medicine or fluid (not the brand name).
- Colour coding should be consistent with the Anaesthetic Labelling Standard (ISO 26825:2008) (63), and colour should be assigned according to primary therapeutic use rather than pharmacological class. Exceptions are high-risk medicines and anticoagulant/antiplatelet agents.
  - High-risk medicines that fall in the Anaesthetic Labelling Standard (ISO 26825: 2008) (63) miscellaneous category should be printed in red on a white background. Note that high-risk medicines include those with a low therapeutic index, and those that present a high risk when administered by the wrong route or when other system errors occur (84).
  - Anticoagulant/antiplatelet medicines should be printed in black on a teal green background (see Table 2 on page 12).
  - Other medicines in the Anaesthetic Labelling Standard (ISO 26825:2008) miscellaneous category (such as frusemide) should be printed in black on a white background.
- The evaluation of medicine line labelling was conducted using continuous tape printed with a font size of 8 mm, allowing a 2 mm border on either side for printing diversion and leaving a gap of 10–15 mm between images (85). However, if preferred, labels may be printed as individual labels, noting that the medicine name should be printed twice to allow for visibility from both sides when the label is wrapped around the line.

A generic medicine label should be used for infrequently used medicines where a preprinted label is unavailable.

Lines for intermittent infusions may be labelled for medicine content, but the labels must be removed when the infusion is completed.

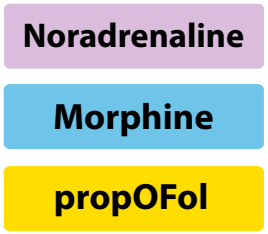
Minimum requirements for labelling administration lines: medicine

Label inclusions

- Active ingredient (medicine) for CONTINUOUS infusions dedicated to a single medicine

Sample labels (not to scale)

- Preprinted labels should be used where possible (see Table 3 on page 14 for a wider range of examples)



- Use a generic label when a preprinted label is unavailable

5.2.3 Label placement for administration lines

Labels should be placed near the injection port on the patient side. Place the labels far enough from the injection port to:

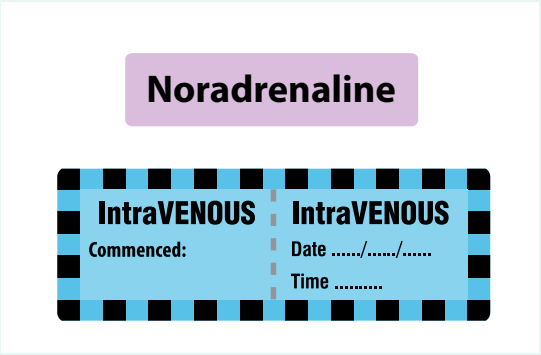
- prevent interference with the mechanics of bolus administration
- prevent introduction of infection.

An exception is made for paediatric patients and for patients who may tamper with the label. In those cases, place the label near the container.

For a multiway port, place the route label near the injection port on the patient side. Place the medicine label before the multiway tap and label each lumen.

Dedicated continuous infusion lines need two labels

Note that the route label and medicine label are separate labels, so a dedicated continuous infusion line should have two labels – one for the route and one for the medicine. For example, an intravenous line delivering noradrenaline would be identified with the following two labels (not to scale), placed adjacent to each other.



5.3 Invasive monitoring lines

All lines must be identifiable, including those where the primary purpose of the line is not for medicine administration (27).

Lines used for invasive monitoring should be identified with a label that is colour coded according to the target tissue (see Table 1 on page 11). For example, intra-arterial monitoring lines have a red label that states 'For Intra-arterial Use Only'.

5.3.1 Minimum requirements for labelling invasive monitoring lines

Label inclusions

- Route
- Date and time commenced

Sample label (not to scale)

Label placement

- Label near the port on the patient side

5.4 Locked catheters

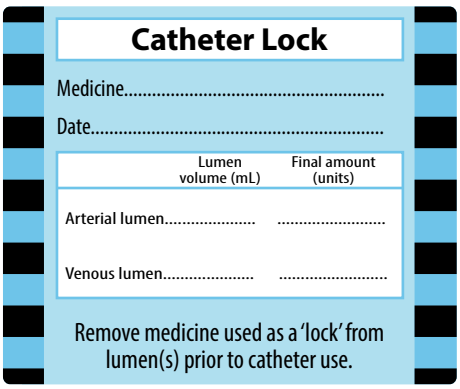
Locked catheters with a medicine 'in situ' to 'lock' the catheter (e.g. dialysis catheter with a heparin lock) must be labelled.

5.4.1 Minimum requirements for labelling locked catheters

Label inclusions

- Active ingredient (medicine)
- Date prepared
- For both the arterial lumen and venous lumen
  - Volume of lumen (mL)
  - Final amount of medicine (units)

Sample label (not to scale)



Label placement

- Label to partially cover the catheter dressing. Place the label close to the catheter but leave part of a breathable dressing uncovered to allow the dressing to function as intended (see Section 7.2).

5.5 Other catheters and lines

5.5.1 Pulmonary artery catheters

Labelling pulmonary artery catheters is not necessary. It is important to differentiate between the central venous and pulmonary artery catheters and a label is provided for the central venous catheter. Pulmonary artery catheters are coloured yellow, and use of an additional label is not expected to improve patient safety (86).

5.5.2 Intracranial pressure monitoring lines

Labelling of the intracranial pressure (ICP) monitoring line is recommended. Although the ICP line is used for monitoring purposes and not for medicines administration, it should be labelled with a yellow intrathecal route label (86).

5.5.3 Extraventricular and lumbar drains

Labelling of the extraventricular drain and the lumbar drain lines is recommended. Health service organisations choosing to label these lines should use a yellow intrathecal route label.

5.5.4 Bladder irrigation lines

The bladder irrigation line may be labelled if there is any possibility that it could be confused with any other line. The pink miscellaneous line label should be used, and the words 'Bladder irrigation' written in the space for 'Route'.

6 Labelling in perioperative areas

Two user-applied labelling standards apply in perioperative areas:

- the Anaesthetic Labelling Standard (ISO 26825:2008) for labelling syringes containing medicines used during anaesthesia (63)
- this Labelling Standard, which applies to
  - user-applied labelling of containers and conduits for any injectable medicine or fluid in the perioperative area where the Anaesthetic Labelling Standard (ISO 26825:2008) is not applicable
  - all non-injectable solutions, chemicals and reagents used in perioperative areas when these are removed from their original containers in a practice area where injectable medicines are used (see Section 7.6) (2, 54, 81).

Both of these standards should be applied as follows:

- Use the Anaesthetic Labelling Standard (ISO 26825:2008) to identify medicines in syringes used for the purposes of anaesthesia.
- Use the Labelling Standard for all other medicine containers and lines in perioperative areas.
- Use container labels with full identification in all open-practice environments, including preparation and recovery areas.
- Use abbreviated container labels on perioperative sterile fields (closed-practice environments).

The two standards complement each other and are used in parallel in the perioperative area (Figure 2).

6.1 Open- and closed-practice environments

In an open-practice environment, full patient and user identification is required for user-applied labelling.

In a closed-practice environment, there is a single patient whose identity is beyond doubt, and the identity of the personnel responsible for preparing and checking medicines is recorded. The operating room in the perioperative area is a closed-practice environment. Here, both the Anaesthetic Labelling Standard (ISO 26825: 2008) and the Labelling Standard identify medicines drawn up into containers with no patient or user identification.

When the patient moves to an open-practice environment where other patients are in the same area (e.g. post-anaesthetic recovery unit), any containers and catheters remaining in place must be fully labelled, with patient and user identifiers, according to the Labelling Standard. This may include lines for continued delivery of infusion fluids with additives, administration and monitoring lines and drugs prepared in syringes to accompany the patient on transfer to another clinical area. Figure 2 demonstrates user-applied labelling in the open- and closed-practice environments of the perioperative area.

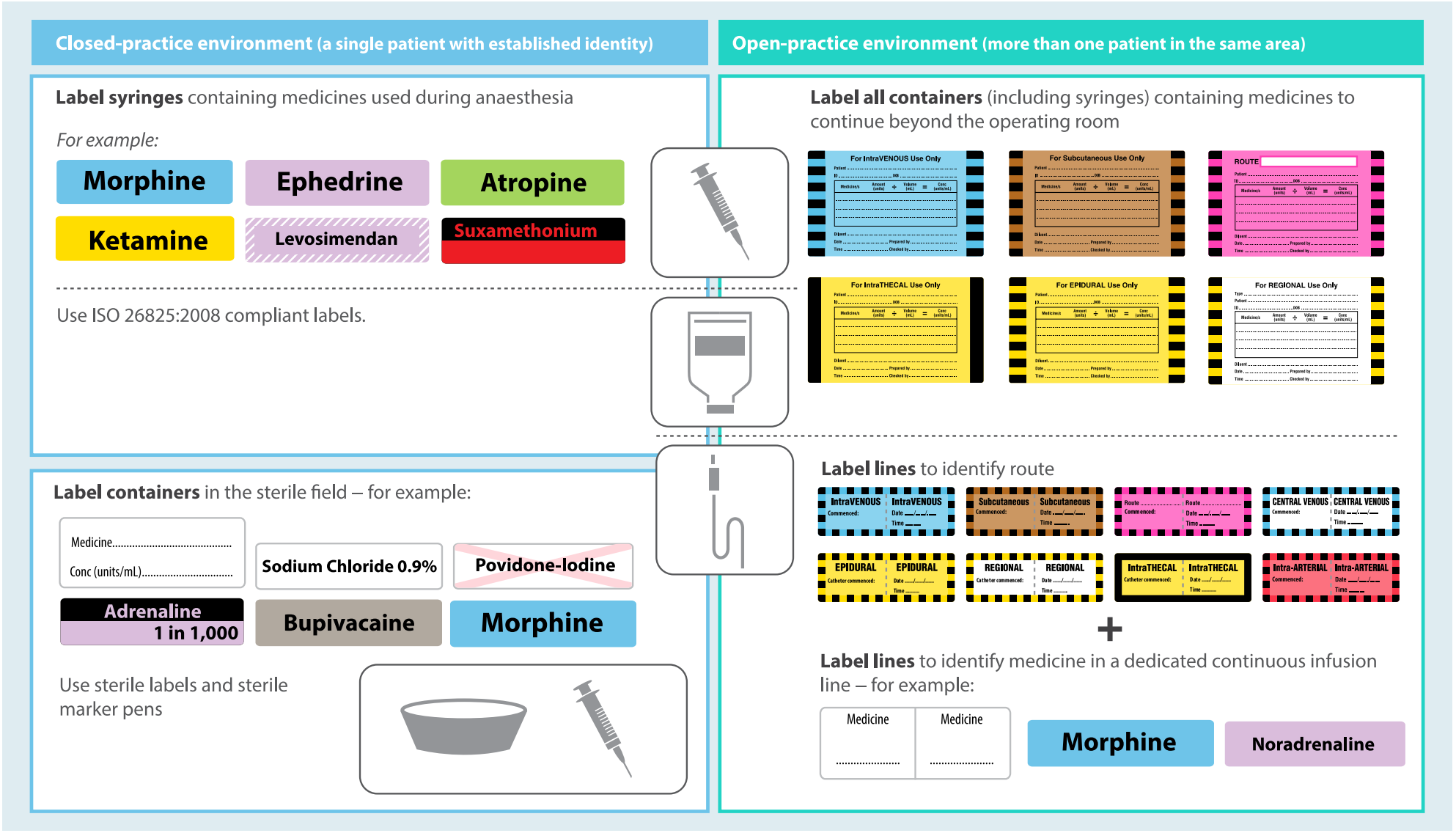
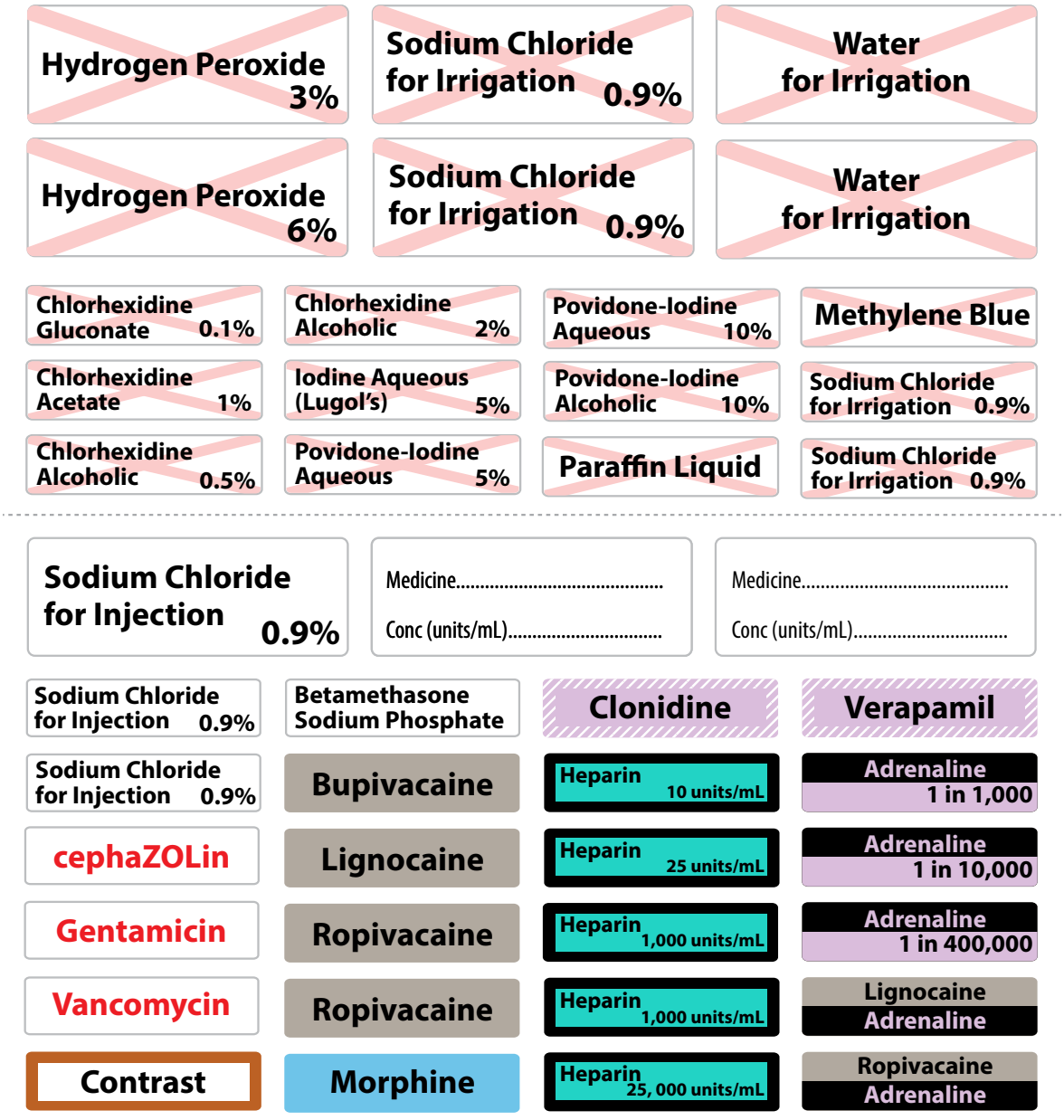


Figure 2 User-applied labelling of medicines and fluids in the open- and closed-practice environments of the perioperative area

6.2 Containers on perioperative sterile fields

On perioperative sterile fields, abbreviated container labels without patient and user identification details, and preprinted with the name of the medicine or fluid, may be used (Figure 3).



Notes:

1. Concentration is optional with the exception of adrenaline and when medicines are available in different concentrations.
2. The St Andrew's Cross to facilitate recognition of non-injectable medicines is to be printed in 70% red behind the medicine name to ensure the name is legible.
3. High-risk medicines that are not associated with a specific colour may be printed in red text on a white background.

Figure 3 Examples of preprinted abbreviated container labels for user-applied identification in the closed-practice environment

Sheets of preprinted labels for medicines and fluids that are frequently used in routine procedures offer the advantage of providing readily available labels that are efficient to select and easy to apply (4). Labels for injectable medicines should be in a separate section on the sheet from labels for non-injectable medicines (see Figure 3 on page 27). In addition, non-injectable medicines should be printed with a red watermarked St Andrew's Cross (87). The full specifications for preprinted abbreviated container labels are in Appendices 1 and 2.

Container or conduit labels for use on the sterile field must be supplied in a sterile package, suitable for aseptic use. Health services may opt to preprint and sterile-pack labels either individually or in sets to cover a procedure or a suite of operating rooms. For sterile label sheets, only labels that are required to be sterile should be included on the sheet.

Where a preprinted label is not available, the generic abbreviated container label should be used, with prompts for the medicine name and concentration (Figure 4).

Figure 4 Generic abbreviated container label for user-applied identification in the closed-practice environment

Sterile marker pens should be available to include concentration information if required and for completion of the generic abbreviated container label.

Do not preprint disposable containers with a medicine name because there is a possibility that the receptacle will be selected for another medicine if it is the only available container.

At the end of a procedure, all medicines prepared for use in the closed-practice environment, including partially used or unused medicines, must be discarded promptly.

6.3 Interventional cardiology, radiology and other low-light procedure areas

The Labelling Standard for user-applied labelling of containers and conduits in the perioperative area also applies to interventional cardiology, radiology and other perioperative settings with low light levels.

The specifications for preprinted abbreviated container labels also apply to labels used in interventional cardiology and radiology.

Catheters are frequently changed during the procedure and do not require labelling. However, all intravenous sheaths, intra-arterial sheaths, intravenous catheters and intra-arterial catheters should be labelled when the patient leaves the procedure room with the sheath or catheter in position. Moreover, the catheter position may vary, and the intra-arterial route label should be used for intra-arterial lines that also enter the intracoronary space.

The number of medicines labels required in interventional radiology is less than that required in cardiology, and some radiology centres may prefer a smaller label set to quicken the label selection process.

Figure 5 shows an example label sheet for interventional cardiology.

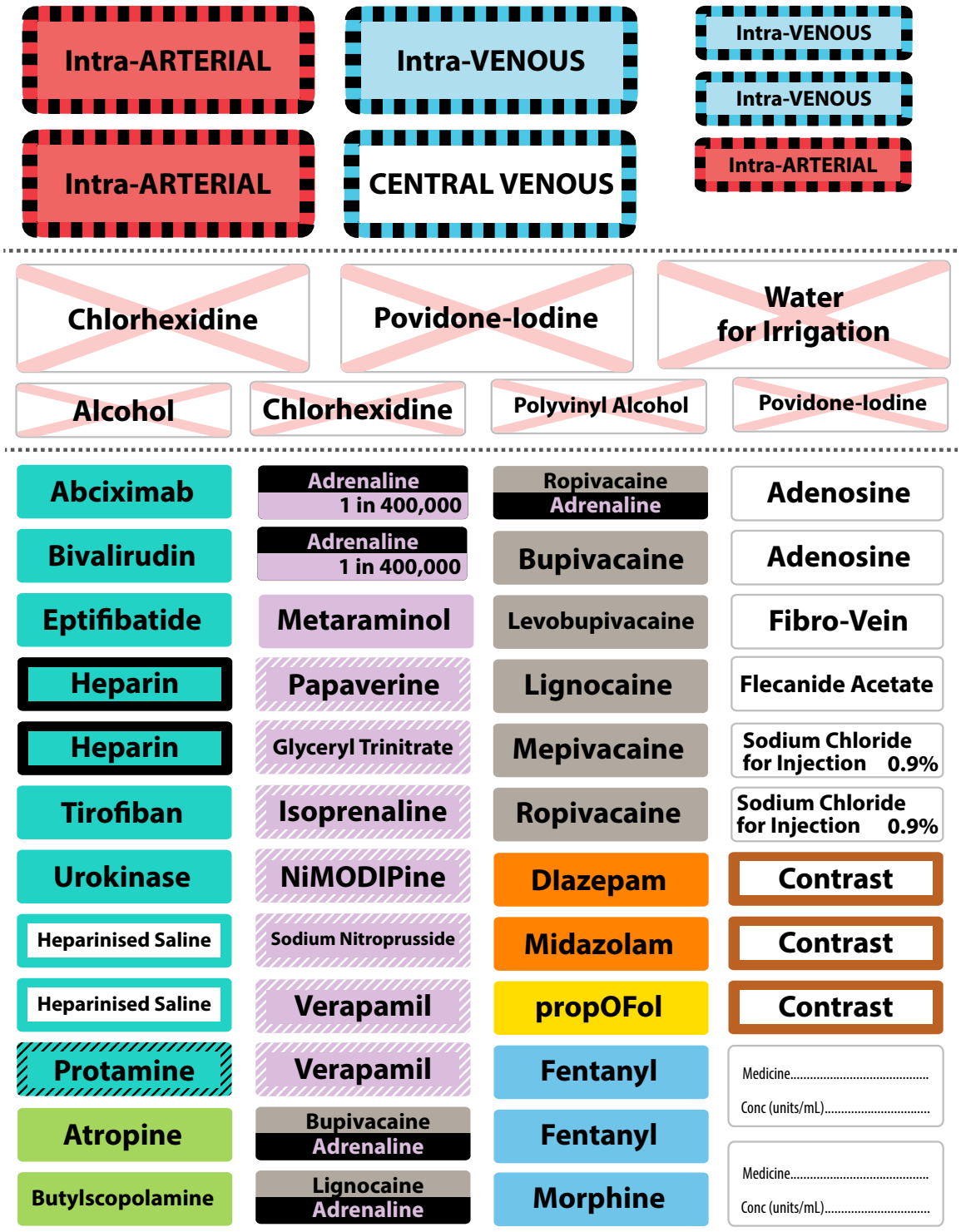


Figure 5 Examples of preprinted labels in cardiac catheter laboratories

6.4 Contrast media

The minimum requirements of the Labelling Standard apply to contrast media. Contrast media labels should use the generic term 'contrast' in closed-practice environments, such as operating rooms. Use a brown (PMS 471) border to assist differentiation of contrast media (Figure 6). A prompt for concentration is not required.

Figure 6 Contrast media abbreviated container label

Combination products, including contrast with a medicine, should be labelled with black type on a white background. For example, phenol with iothalamate meglumine (Conray) should be labelled 'phenol with iothalamate meglumine' in black text on a white background.

Labelling is not required when contrast is decanted directly into a high-speed pump reserved solely for the purpose of contrast injection.

6.5 Reusable containers

Labels with adhesive that attaches throughout the procedure, but can be removed completely at the end of the procedure, should be used on reusable containers such as stainless steel hollowware. Label adhesion to reusable hollowware has been shown to be achievable (88, 89).

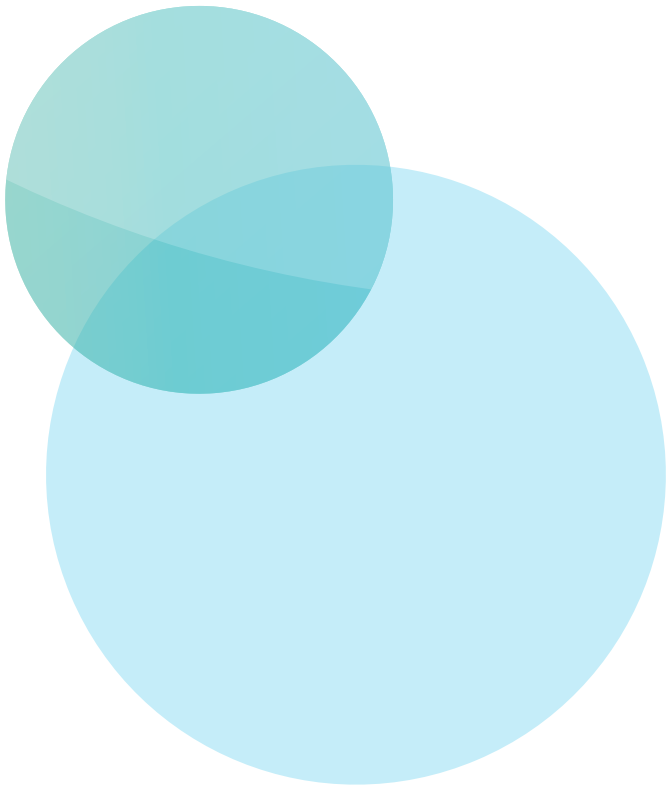
Solvents such as alcohol swabs/solutions and eucalyptus oil may be required to remove adhesive residue from reusable hollowware. These products are flammable and must be used in the cleaning area of the sterilising services unit, away from patients. Eucalyptus oil requires a warm temperature and detergent to remove any solvent residue.

6.6 Using preprinted labels

Composition of customised, preprinted label sheets should be determined according to local requirements and include some generic abbreviated container labels. The content may be determined by the health services or specialty within a service by identifying medicines that are used regularly:

- across a suite of operating rooms
- within one operating room
- for a specific procedure.

Line labels and abbreviated container labels that are supplied in custom procedure packs used on the sterile field in perioperative areas (such as operating rooms and cardiac catheter laboratories) should comply with the Labelling Standard.



7 Specific considerations

7.1 Containers and lines on sterile fields outside the perioperative area

All medicine containers and lines used for medicines removed from their original container on any sterile field should be labelled according to the Labelling Standard (20, 29, 39, 43, 90). This includes sterile fields set up for procedures in clinical areas outside of perioperative areas, such as the administration of an intrathecal injection in a ward area.

Container and line labels applied on the sterile field must be supplied in sterile packaging. Sterile markers must be made available when labels require population at point of use (20, 29, 43).

7.2 Catheter lock

Central venous access devices may be 'locked' with a medicine – that is, a medicine is placed in situ in the portal. Dialysis catheters are one type of central venous access device and may be used for haemodialysis when a fistula for external haemodialysis is unsuitable. The dialysis catheter is generally locked with an anticoagulant such as heparin to maintain patency. In some cases, other medicines may be present (e.g. antibiotics). In general, it is usual to remove the medicine used as a 'lock' in the catheter before using the catheter, particularly in the case of heparin and other anticoagulants.

Catheters with a medicine in situ should be identified for route and medicine content using a blue (PMS 2985) catheter 'lock' line label (Figure 7).

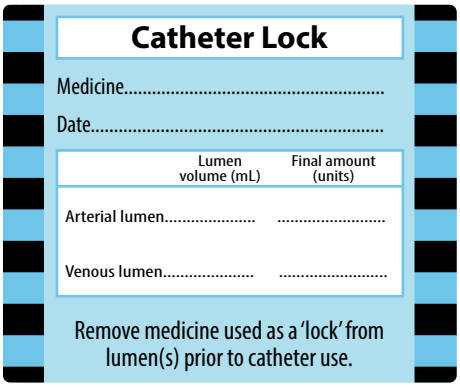


Figure 7 Line label for medicine used to 'lock' a catheter

The suggested label size is 60 mm × 50 mm.

The label should be sited to partially cover the dialysis catheter dressing. In this way, the breathable dressing remains viable, and the label is situated close to the catheter to alert users to the medicine in situ. However, the label should not cover the catheter insertion site. The label should be removed after removing the medicine from the lock. The adhesive used on the label should be strong enough to adhere, but not so strong that it cannot be removed as required.

7.3 Cytotoxic medicines

This Labelling Standard applies to all medicines, including cytotoxic products. In practice, cytotoxics are likely to remain in the original container in which they were prepared for individual patient use. A purple label stating 'cytotoxic' may be used to highlight the presence of a cytotoxic medicine, in addition to the minimum requirements of the Labelling Standard

and consistent with the Clinical Oncological Society of Australia's *Guidelines for the Safe Prescribing, Supply and Administration of Cancer Chemotherapy* (91).

7.4 Radiopharmaceuticals

Labelling the medicine container is a minimum Labelling Standard requirement (see Section 4.6). The exception is radiopharmaceuticals, where the lead casing (secondary container) is labelled in preference to the syringe (primary container) holding the radiopharmaceutical. For the purposes of the Labelling Standard, the syringe containing radioactive material, with the whole unit enclosed in lead casing, constitutes the original container. This must be labelled with a full container label when the syringe is filled and placed in the lead casing.

There is the potential for a syringe to be removed from a labelled casing after manufacture and placed in a different casing when the final calculation of radioactivity is performed. Health service organisations should implement a policy that only one encased syringe is opened at any one time to reduce the risk of a syringe being inadvertently placed in a different (incorrectly labelled) casing.

Lines used for administering radiopharmaceuticals should be identified with route and medicine name labels in accordance with the Labelling Standard.

7.5 Blood products

The minimum requirements of the Labelling Standard apply to blood products. Although not specifically referenced in the Labelling Standards, blood products are injectable medicines and fluids, and should be identified if removed from their original container for patient administration.

Information on the administration of blood products is found in the Australian and New Zealand Society of Blood Transfusion's *Guidelines for the Administration of Blood Products* (92).

7.6 Non-injectable medicines and fluids

The principles in the Labelling Standard apply to the identification of non-injectable medicines and fluids removed from their original container to be administered via non-injectable routes, such as inhalation, oral or enteral, and topical routes.

In all cases, syringes used for non-injectable solutions must NOT be compatible with parenteral entry portals (78, 93).

7.6.1 Oral and enteral route

Only syringes specifically designed for administration of medicines orally or via other enteral (e.g. nasogastric) routes should be used for these purposes. They should be clearly labelled with, for example, 'For Oral Use Only' or 'For Enteral Use Only' (Figure 8) (78, 93, 94).

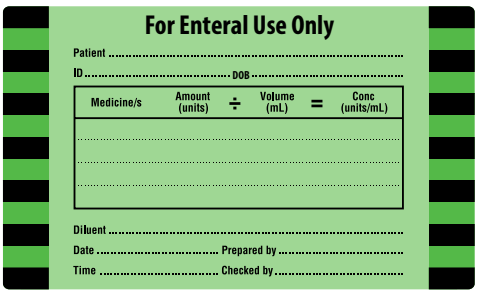


Figure 8 Label for enteral use

7.6.2 Inhalation route

Ideally, medicines for inhalation should be made available in single-use nebules to avoid measurement in a syringe. If a nebuliser solution is measured in a syringe, the syringe should be clearly labelled 'For Inhalation Use Only' (Figure 9).

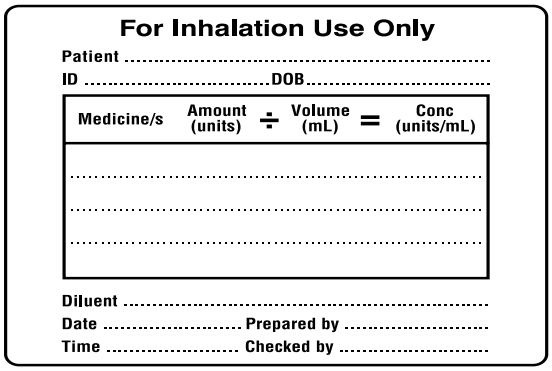


Figure 9 Label for inhalation use

7.6.3 Topical route

Non-injectable medicines and fluids prepared in the same area as injectable products should be labelled, including solutions, chemicals and reagents used topically in perioperative units, interventional cardiology and radiology.

Best practice requires preparing the skin for a procedure and then removing skin preparation solutions from the sterile set-up before commencing the procedure (95-97).

Skin preparations should be labelled when they are removed from their original container, and labels should be provided for this purpose. Label sets should present injectable medicines, skin preparations and irrigation fluids in discrete areas on the same label sheet (see Section 6.2). Non-injectable medicines and fluids should also be identified with a red St Andrew's Cross watermark behind the non-injectable medicine name.

7.7 Labelling at transitions of care

Particular attention should be given to compliance with the Labelling Standard at transitions of care – for example:

- on transfer from a closed-practice to an open-practice environment
- when a patient is transferred during or between shifts in a single clinical area
- on transfer of patients from one clinical area to another
- on preparation of injectable medicines for use en route when moving a patient from one clinical area to another.

7.8 Labelling in an emergency

When injectable medicines are drawn up in a syringe for immediate emergency use (e.g. during resuscitation), 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.

Optimally, use a standard container label in an open-practice environment, and use preprinted abbreviated medicine labels consistent with the Anaesthetic Labelling Standard (ISO 26825: 2008) (or a generic medicine label) in a closed-practice environment (80).

Glossary

Anaesthesia	The practice of administering medicines or gases that block the feeling of pain and other sensations, permitting a range of medical and surgical procedures to be undertaken without causing undue distress or discomfort to the person being operated upon.
Blood products	Plasma derivatives and recombinant products (e.g. albumin, immunoglobulins and clotting factors).
Bolus	Administration of a small-volume, single-dose, sterile solution from a syringe directly into a tissue, organ or vein, for a short period (usually between 30 seconds and 10 minutes) (45).
Catheter	A tube inserted into a body cavity, sometimes to allow medicine administration, including (but not limited to): • angiographic catheter • arterial catheter • cardiac catheter • central venous access device • epidural catheter • implantable port (e.g. Port-a-Cath®) • intraperitoneal catheter or port • intrathecal catheter or port • midline catheter • peripheral intravenous catheter • peripherally inserted central venous catheter • subcutaneous catheter (e.g. soft winged infusion set) • tunnelled catheter (e.g. Hickmans®, Broviac®).
Catheter lock	Medicine is placed in the portal of a central venous access device.
Clinical area	Any area where injectable medicines and fluids are administered, including: • wards • outpatient areas • Hospital in the Home • procedure rooms (e.g. endoscopy rooms) • perioperative environments.
Closed-practice environment	An area where the identity of the patient is beyond doubt and identities of members of the patient care team are recorded.
Conduit	Any line or device through which injectable fluids could be administered.
Container	Any receptacle in which injectable fluids could be held.
Dedicated continuous infusion	A continuous, uninterrupted flow of a single medicine for a relatively long period of time via a conduit that is reserved for that medicine.
Emergency use	Administration of medicines in an emergency; that is, where an unpredicted situation involving the patient arises (e.g. during resuscitation).
Flag labels	A method of attaching labels to small syringes and containers where part of the label is applied to the syringe, leaving an exposed 'flag' portion to ensure that details on the labels can be read, and the syringe markings and contents of the syringe remain visible.

Flush	To purge access devices (e.g. cannulas) before and/or after injection of a medicine, or between injections of different medicines with a sterile solution of diluent such as 0.9% sodium chloride (45).
High-risk medicines	High-risk medicines include: • medicines with a low therapeutic index • medicines that present a high risk when administered by the wrong route or when other system errors occur.
Infusion	Administration (from a syringe, or other rigid or collapsible container, such as a plastic bag) of a volume of sterile solution containing an injectable medicine directly into a tissue, organ, vein or artery, at a constant rate, under gravity or by means of an electronic or mechanical pump or other means of rate control, for a defined period of at least 10 minutes (45).
Injectable medicine	Sterile medicine intended for administration by bolus injection, perfusion or infusion by any of the following routes (45): • epidural • intra-arterial • intradermal • intramuscular • intra-ocular • intraosseous • intrapleural • intrathecal • intravenous • intraventricular • intravesicular • intravitreal • subcutaneous.
Lines	This includes all intravenous giving sets, administration lines, invasive monitoring lines and catheters through which injectable medicines and fluids could be administered.
Open-practice environment	An area where more than one patient may be present and where there may be doubt regarding an intended medication that does not have patient identification.
Operating room	The room in which a surgical procedure is undertaken, with or without the administration of an anaesthetic (98).
Perioperative	The period before, during and after an anaesthetic, surgical or other procedure (98).
Perioperative environment	The service area where the provision of an anaesthetic, or a surgical or other procedure may be undertaken (98).
Post-anaesthetic recovery unit	An area set aside within the perioperative environment that is well planned, well equipped, well staffed and well managed for the safe, immediate management of patients who have recently undergone a surgical or other procedure, irrespective of the type of anaesthesia or sedation (98). Also known as ‘recovery’.
Skin preparation fluid	An antiseptic fluid used to cleanse the skin before surgery or venipuncture.
Sterile field	A specified area, such as within a tray or on a sterile towel, that is considered to be free from microorganisms. An area immediately around a patient that has been prepared for a surgical procedure. The sterile field includes the scrubbed team members, who are properly attired, and all furniture and fixtures in the area.

Acknowledgements

National Injectable Medicines Labelling Project

A project of the Australian Commission on Safety and Quality in Health Care

Details of the project team, advisory committee and pilot hospitals involved in development of the Labelling Recommendations can be found in the *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines* (3).

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Hospitals contributing to evaluation of user-applied labelling implementation

Clinical area	Hospital
Operating room	Calvary Wakefield Hospital, South Australia
Intensive care unit	Barwon Health, Victoria
	Royal Prince Alfred Hospital, New South Wales
	Southern Health (Monash), Victoria
	Tweed Hospital, New South Wales
Perioperative sterile services	Prince of Wales Hospital, New South Wales
	St Vincent's Hospital, New South Wales
Cardiac catheter laboratory	Greenslopes Hospital, Queensland
	Royal Adelaide Hospital, South Australia
	St John of God Hospital, Perth, Western Australia
	St Vincent's Health Melbourne, Victoria
	St Vincent's Private Melbourne, Victoria
Interventional radiology	Prince of Wales Hospital, New South Wales
	St Vincent's Public Hospital, Darlinghurst, New South Wales
Renal dialysis unit	Royal Adelaide Hospital, South Australia

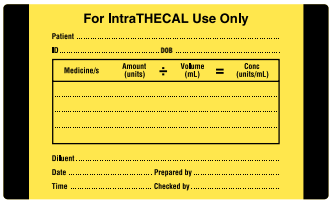
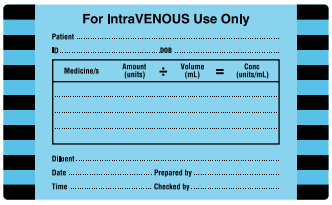
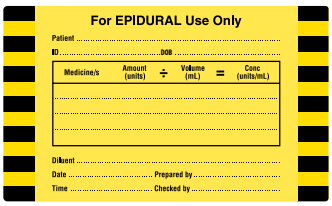
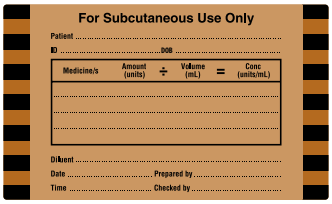
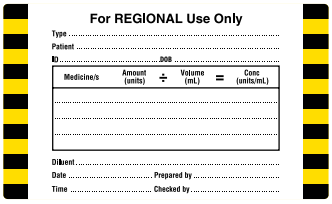
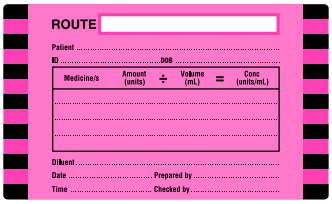
National contributions

The following stakeholders and national peak professional bodies contributed to the development of the Labelling Recommendations, the Labelling Standard, or both:

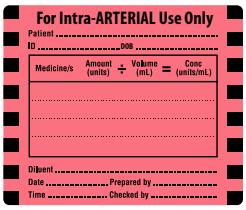
- state and territory health departments
- state and territory safer medicines groups or equivalents
- Australian Association of Nuclear Medicine Specialists
- Australian College of Critical Care Nurses
- Australian College of Nursing
- Australian College of Operating Room Nurses
- Australian and New Zealand College of Anaesthetists, including the Faculty of Intensive Care Medicine
- Australian and New Zealand Intensive Care Society
- Australian and New Zealand Society for Nuclear Medicine
- Australian Nursing and Midwifery Federation
- Australian Pharmaceutical Healthcare Systems
- Australian Private Hospitals Association
- Cancer Council Australia
- Cardiac Society of Australia and New Zealand
- Catheter Laboratory Nursing Council
- Clinical Oncological Society of Australia
- College of Emergency Nursing Australia
- Consumers Health Forum
- Council of Australian Therapeutic Advisory Groups
- Intensive Care Coordination and Monitoring Unit, New South Wales
- Renal Society of Australasia
- Royal Australian and New Zealand College of Radiologists
- SESIAHS Sterilising Services, Randwick Hospitals Campus
- Society of Hospital Pharmacists of Australia
- Women's & Children's Hospitals Australasia.

Appendix 1
Label guide and specifications

Containers: injectable medicines and fluids – route labels

Route	Example	Background	Border	Size
Intrathecal		Pantone Yellow with 70% stipple	Solid black	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Intravenous		Blue PMS 2985 with 70% stipple	Black/blue hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Epidural		Pantone Yellow with 70% stipple	Black/ yellow hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Subcutaneous		Beige PMS 723 with 70% stipple	Black/beige hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Regional		White	Black/ Pantone Yellow hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Miscellaneous		Pink 806 with 70% stipple	Black/pink hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm

Containers: injectable medicines and fluids – route labels *continued*

Route	Example	Background	Border	Size
Intra-arterial		Red PMS 1787 with 70% stipple	Black/red hatched	Small label: 60 mm × 50 mm

PMS = Pantone Matching System
Note: Containers include bags, bottles and syringes.

Containers: open-practice environment (abbreviated label) – flush label

Ingredients	Example	Background	Border	Size
0.9% sodium chloride flush only	**Sodium Chloride 0.9%**	White	Nil	37 mm × 10 mm

Note: Containers include bags, bottles and syringes.

Containers: closed-practice environment (abbreviated medicine labels)

Medicine	Example	Background	Size
Perioperative sterile field	Adrenaline 1 in 400,000 Bupivacaine Adrenaline Bupivacaine Contrast Heparin 25,000 units/mL Fentanyl	Consistent with ISO 26825:2008 and extension to ISO 26825:2008 (see Section 3.3.2)	To be determined by health facility but sufficiently large to accommodate medicine name in legible font size (see Appendix 2)
Cardiac catheter laboratory	Adrenaline 1 in 400,000 Atropine Glyceryl Trinitrate Lignocaine Midazolam Verapamil	Consistent with ISO 26825:2008 and extension to ISO 26825:2008 (see Section 3.3.2)	To be determined by health facility but sufficiently large to accommodate medicine name in legible font size (see Appendix 2)
Non-injectable fluids	Povidone-Iodine Alcoholic 10% Chlorhexidine Acetate 1% Chlorhexidine Povidone-Iodine	Consistent with ISO 26825:2008 and extension to ISO 26825:2008 (see Section 3.3.2)	To be determined by health facility but sufficiently large to accommodate medicine name in legible font size (see Appendix 2)
Generic	Medicine..... Conc (units/mL).....	White	70 mm × 25 mm ('peel-off' for reusable containers)

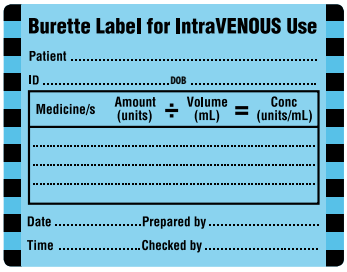
Note: Containers include bags, bottles and syringes.

Containers: non-injectable medicines and fluids – route labels

Route	Example	Background	Border	Size
Enteral	For Enteral Use Only Patient ..... ID ..... DOB ..... Medicine/s | Amount (units) ÷ Volume (mL) = Conc (units/mL) Diluent ..... Date ..... Prepared by ..... Time ..... Checked by	Green PMS 361 with 70% stipple	Black/green hatched	Small label: 60 mm × 50 mm Large label: 100 mm × 60 mm
Inhalational	For Inhalation Use Only Patient ..... ID ..... DOB ..... Medicine/s | Amount (units) ÷ Volume (mL) = Conc (units/mL) Diluent ..... Date ..... Prepared by ..... Time ..... Checked by	White	None	Small label: 60 mm × 50 mm

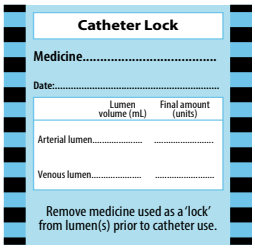
PMS = Pantone Matching System
Note: Containers include bags, bottles and syringes.

Conduits: route label

Route	Example	Background	Border	Size
Intravenous: burette		Blue PMS 2985 with 70% stipple	Black/blue hatched	76 mm × 59 mm ('peel-off')

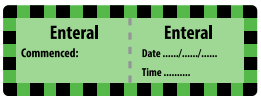
PMS = Pantone Matching System

Lines and catheters: injectable medicines and fluids – route labels

Route	Example	Background	Border	Size
Intrathecal		Pantone Yellow with 70% stipple	Solid black	70 mm × 25 mm
Intravenous		Blue PMS 2985 with 70% stipple	Black/blue hatched	70 mm × 25 mm
Epidural		Pantone Yellow with 70% stipple	Black/yellow hatched	70 mm × 25 mm
Central venous		White	Black/blue PMS 2985 hatched	70 mm × 25 mm
Regional		White	Black/Pantone Yellow hatched	70 mm × 25 mm
Subcutaneous		Beige PMS 723 with 70% stipple	Black/beige hatched	70 mm × 25 mm
Intra-arterial		Red PMS 1787 with 70% stipple	Black/red hatched	70 mm × 25 mm
Miscellaneous		Pink PMS 806U with 70% stipple	Black/pink hatched	70 mm × 25 mm
Dialysis		Blue PMS 2985 with 70% stipple	Black/blue hatched	60 mm × 50 mm ('peel-off')

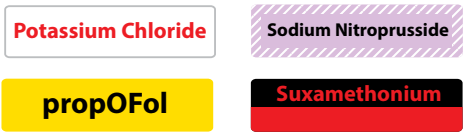
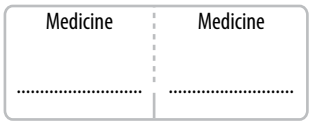
PMS = Pantone Matching System

Lines and catheters: non-injectable medicines and fluids – route label

Route	Example	Background	Border	Size
Enteral		Green PMS 361 with 70% stipple	Black/green hatched	70 mm × 25 mm

PMS = Pantone Matching System

Lines and catheters: medicine labels

Medicine	Example	Background	Border	Size[a]
Preprinted		Consistent with ISO 26825:2008 and extension to ISO 26825:2008 (see Section 3.3.2)		To be determined by health facility
Generic		White	Nil	70 mm × 25 mm

a Label stock used in evaluation was unplasticised PVC tape (see Section 5.2.2).

Appendix 2
Specifications for preprinted abbreviated container labels

- Preprinted medicine labels should be printed with the full generic name of the medicine or fluid (with the exception of contrast media). Labels should be sufficiently large to retain font size and legibility of the medicine name.
- Concentration should be included where this can be specified:
  - Concentration should be expressed as it appears on the original container.
  - Concentration MUST be specified for adrenaline administered as a single medicine. For adrenaline mixed with a local anaesthetic, concentration for both adrenaline and the local anaesthetic may be omitted.
  - Concentration should be specified on label sheets with multiple labels for the same medicine available in different strengths (see Figures 3 and 5 on pages 27 and 29).
- Colour coding should comply with the Anaesthetic Labelling Standard (ISO 26825:2008). Exceptions are as follows
  - Antiplatelet and anticoagulant medicines should be printed in black on a teal green background (see Section 3.3.2).
  - Contrast media labels should be printed in black text on a white background with a brown border (PMS 471) (see Section 6.4).
  - Where two medicines are combined in the original container, such as a local anaesthetic and a vasopressor, the user-applied label will include both medicines and carry appropriate colour coding for both.
- Non-injectable fluids (e.g. solutions for skin preparation) should have a red St Andrew's Cross watermarked behind the fluid name.
- A large, clear (sans serif) font should be used (69). Font size may be determined by the health service. It should be proportionate to the label size (e.g. 20 point for larger labels, 12 point for smaller labels and 11 point for small labels with two medicine names, such as bupivacaine/adrenaline).
- Medicine names should have an initial capital letter and other letters lower case.
- Tall Man lettering should be used for medicines on the National Tall Man Lettering List and presented consistent with the list (69). The National Tall Man Lettering convention should also be used to distinguish between other elements that look alike (78), such as routes of administration (e.g. IntraTHECAL, IntraVENOUS and IntraARTERIAL).
- Label size should be determined by the perioperative facility. Larger labels (55 mm × 20 mm) are suitable for fluids such as water for irrigation and lactated ringers solution. Smaller labels (40 mm × 10 mm) are suitable for other medicines and fluids such as heparin and chlorhexidine.

Appendix 3
The Labelling Standard and other standards

Australian Standard

The Labelling Standard has been developed with consideration of the Australian Standard AS 4940:2002 *User-applied identification labels for use on fluid bags, syringes and drug administration lines* (67, 68).

AS 4940:2002 specifies dimensions, colour (to identify target tissue), borders, background, printing and adhesive qualities of the user-applied labels. The Labelling Standard expands on AS 4940:2002 and includes:

- recommendations regarding label content and label placement
- modifications to label dimensions, background colour and depth, borders, colour, lettering, and label adhesion to ensure its practicability in clinical settings.

Label dimensions

AS 4940:2002 (67, 68) defines dimensions of labels to be applied to bags and another set of dimensions for labels to be applied to syringes. However, these dimensions do not accommodate the range of the various sized bags and syringes used in clinical settings.

The Labelling Standard includes two sizes of labels for application to bags and syringes – small (60 mm × 50 mm) and large (100 mm × 60 mm). These labels contain the same information and are interchangeable. The label selected for use will depend on the container size. For example, the small label may be applied to both syringes and small-volume fluid bags (e.g. mini bags), and the large label may be applied to other fluid bags and larger-volume syringes (e.g. 50 mL).

Background and borders

Modifications to the AS 4940:2002 specifications for background and borders are listed in Table A.1.

Table A.1 Modifications to AS 4940 used in the Labelling Standard: background and borders

AS 4940	Labelling Standard	Rationale for modification
Background colour to be white except for neural route, which is to be yellow	Background is coloured (70% of primary colour)	A coloured background was introduced to increase the visibility of labels applied to fluid bags in clinical settings. This was applied to both labels (small and large). To allow for readability of label content, 70% of the primary colour was chosen. A combination of coloured (70% of primary colour) and white backgrounds was applied to line labels to assist differentiating between similar routes (e.g. intravenous and central venous)
	Yellow background retained for intrathecal and epidural routes. Regional route background colour is white	The white background was applied to the regional route to differentiate between the two other neural routes – epidural and intrathecal
Border pattern to be of squares of alternating black and coloured squares	Alternating black and coloured square borders have been retained in all cases with the exception of the intrathecal route	Using the same border and background for intrathecal and epidural routes was judged to be a source of high-risk error and patient harm, due to similar label design. A solid black border has been introduced to assist in differentiating between intrathecal and epidural
Border to be at least 4 mm in width	Border at least 3 mm in width	The border width was reduced to maximise space for label content
Border to occupy at least 3 sides of the label	Border occupies 2 sides of the label	The border was applied to the lateral sides to retain the border feature and to maximise space available for label content

AS 4940 = Australian Standard AS 4940:2002 *User-applied identification labels for use on fluid bags, syringes and drug administration lines* (67, 68)

Use of colour to identify target tissue/route

Use of colour to identify target tissue/route is aligned with AS 4940:2002 (67, 68), with the exception of intravenous and miscellaneous routes (Table A.2).

Table A.2 Modifications to AS 4940 used in the Labelling Standard: colour for target tissue/route

AS 4940	Labelling Standard	Rationale for modification
Intravenous		
PMS Process Blue	PMS Blue 2985	PMS Blue 2985 was identified as the preferred colour compared with Process Blue both for superior visibility and for retaining legibility of label content
Miscellaneous		
White	PMS Pink 806	Pink was selected as a nonwhite background to highlight the presence of an additive

AS 4940 = Australian Standard AS 4940:2002 *User-applied identification labels for use on fluid bags, syringes and drug administration lines* (67, 68); PMS = Pantone Matching System

The Labelling Standard uses sans serif font, consistent with AS 4940:2002 (67, 68).

Tall Man lettering has been introduced for route labels to improve readability and differentiation between similar route names, such as intraVENOUS and intraTHECAL. This is consistent with (but not part of) the National Tall Man Lettering Standard (69).

International Standard

The International Standard ISO 26825:2008E: *Anaesthetic and respiratory equipment – user-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance* (63) supersedes AS/NZS 4375:1996 *User-applied labels for syringes containing drugs used during anaesthesia* (80). The Labelling Standard complements but does not replace ISO 26825:2008.

The Labelling Standard has extended the use of Anaesthetic Labelling Standard (ISO 26825:2008) colour coding to medicine lines labels and abbreviated container labels used outside anaesthesia, with some modifications. See Table A.3.

Table A.3 Anaesthetic Labelling Standard colour coding to medicines lines labels and abbreviated container labels used outside anaesthesia

Medicine/ medicine class	Colour	Examples
Anticoagulant/ antiplatelet agents	Teal green (PMS 3255; CMYK 64.0.32.0; RGB 34.211.197)	abciximab, bivalirubin, eptifabatide, tirofiban, urokinase  
Heparin	Teal green (PMS 3255; CMYK 64.0.32.0; RGB 34.211.197) with solid black border (1–2 mm)	
Protamine	Teal green (PMS 3255; CMYK 64.0.32.0; RGB 34.211.197) with black diagonal-stripe border (1–2 mm)	
Heparinised saline	White with teal green (PMS 3255; CMYK 64.0.32.0; RGB 34.211.197) border	
Contrast media	White with brown (PMS 471; CMYK 20.70.100.7; RGB 188. 97.36) border	

Appendix 4 Labelling Standard development and maintenance

National Injectable Medicines Labelling Project

The *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* (August 2010) originated from a concept initiated by the New South Wales Therapeutic Advisory Group (NSW TAG) Safer Medicines Group. An advisory committee representing the interests of key clinical groups was established in February 2009 by the Australian Commission on Safety and Quality in Health Care (the Commission) to oversee development of user-applied labelling recommendations for injectable medicines, fluids and lines for national implementation.

Following national consultation, draft labelling recommendations were piloted in public and private health services across Australia.

National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, first edition, November 2010

The first edition of the *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines*, November 2010 (the Labelling Recommendations) (6), reflected:

- NSW TAG Safer Medicines Group work on standardised labelling
- Australian Standard AS 4940:2002 *User-applied identification labels for use on fluid bags, syringes and drug administration lines* (67, 68)
- work by national and international organisations
- relevant peer-reviewed literature
- published case reports
- unpublished incidents
- project advisory committee review
- pilot testing.

Reasons supporting the final recommendations were provided in the supporting implementation and education materials. The development process raised a number of issues relating to labelling practice. These were addressed in sections outlining additional strategies to improve medicine administration safety and extending the Labelling Recommendations to improve practice.

National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, second edition, February 2012

The second edition of the Labelling Recommendations in February 2012 (3) reflected the patient identification requirements in the National Safety and Quality Health Service Standards (5). Standard 5: Patient Identification and Procedure Matching requires that 'at least three approved patient identifiers are used when providing care, therapy or services' (5). To comply with the standards, the Labelling Recommendations container labels were revised to include patient date of birth as a third patient identifier. The revision was valid from November 2011.

National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines, 2015

The *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* (the Labelling Standard) incorporates issues identified and addressed during national implementation of the Labelling Recommendations.

The Labelling Recommendations Reference Group was established to advise the Commission on implementation and maintenance of the Labelling Recommendations. Decisions are recorded in the Labelling Recommendations Issues Register (86).

A series of evaluations has been undertaken to assist health services to design labels and address issues raised during implementation. The following resolutions were proposed during this process, which were then included in the Labelling Standard:

- preprinted labels on perioperative sterile fields
- label adhesion requirements for reusable hollowware containers in operating rooms
- standardised medicine line labels for dedicated continuous infusions
- preprinted container labels in cardiac catheter laboratories and radiography suites
- segregation and differentiation of labels for non-injectable medicines and fluids.

Many health services contributed to piloting and evaluation, which resulted in these changes (see Acknowledgements).

Evaluation of preprinted labels for identification of medicines and fluids on the perioperative sterile field (reports 1 and 2)

Evaluation of preprinted label sheets on the perioperative sterile field at Calvary Wakefield Hospital in 2012 (4) found that preprinted labels were easy to use, provided they were manufactured with materials that were durable and fit for purpose.

Preprinted labels are well accepted in the perioperative sterile field. However, the Labelling Recommendations Reference Group (LRRG) acknowledged that injectable and non-injectable medicines and fluids could be more clearly differentiated within the same practice area. Ideally – and within best-practice guidelines, such as those described by the Australian and New Zealand College of Anaesthetists (99) – user-applied labelling of non-injectable fluids would take place before the patient enters the operating room or procedure area. However, it still may be necessary to identify non-injectable medicines and fluids in the operating or procedure room where injectable medicines are used, and a way of differentiating between them is necessary. The following methods were evaluated and endorsed:

- use of a red St Andrew's Cross applied as a watermark across the labels of non-injectable medicines and fluids
- segregation of the two medicine and fluid types within the one label sheet.

Evaluation of label adherence to hollowware containers in operating rooms (reports 1 and 2)

Adhesive strength is dependent on the use of disposable or reusable containers in the operating room. Stronger adhesive is appropriate for disposable containers because there is no requirement to remove labels. Reusable containers (e.g. stainless steel) will require labels to adhere for the duration of the procedure and then be removed entirely for the container to be cleaned and sterilised for reuse (5, 6). Label stock and adhesives suitable for reusable hollowware containers have been evaluated in two bench-top trials.

Evaluation of standardised medicine line labels for dedicated continuous infusions

Preprinted, standardised medicine labels (using colours and formatting described in the Anaesthetic Labelling Standard [ISO 26825: 2008]) on dedicated continuous infusion lines for commonly used medicines were implemented in intensive care units at four sites and evaluated through a survey of clinical staff (85). The findings support the national standard requirement for identifying medicines in dedicated continuous infusion lines.

Evaluation of standardised medicine syringe labels in interventional cardiac catheter and radiology laboratories

Evaluation of preprinted labels was conducted within interventional cardiology and radiology. These specialist perioperative areas differ from operating rooms in two main respects:

- The interventionist manages the majority of medicine administrations at the same time as performing a clinical procedure.
- Both tasks are often required to be undertaken in low-light conditions to allow for simultaneous review of angiography or other radiology.

Preprinted medicine line labels were well accepted in interventional cardiology and radiology, and a series of recommendations was made for user-applied labelling based on trial outcomes. A full list is detailed in the trial report (100), but the following approach to colour coding was adopted across all medicine labels following consultation with the LRRG.

Colour of sterile preprinted medicine labels should be consistent with colour coding in the Anaesthetic Labelling Standard, with the following exceptions:

- antiplatelet agents/anticoagulants to be labelled with teal green (Pantone Matching System [PMS] 3255)
- heparin to be teal green with a black border
- protamine to be teal green with a black diagonal-stripe border
- heparinised saline to have a teal green border (PMS 3255)
- contrast to have a brown border (PMS 471).

Labelling Standard maintenance

There is an agreed process for maintenance of the Labelling Standard, which involves states, territories and private health services.

The Labelling Standard Issues Register will continue to record issues reported by health service organisations on the Commission's web site. These issues will be referred to the Commission's advisory groups, including the Labelling Standard Reference Group, formerly the LRRG (see Acknowledgements).

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