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

Frequently asked questions

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This paper is available on the Commission web site (www.safetyandquality.gov.au).

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Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for maintaining the *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* (the Labelling Standard) and for identifying and reducing national barriers to its implementation.

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

These frequently asked questions (FAQs) have been raised during implementation of the Labelling Standard (and previous editions of the Labelling Recommendations). They are answered with reference to the Labelling Standard or evaluations of label use contributing to the Labelling Standard and are available on the Commission web site (www.safetyandquality.gov.au).

Implementation of the Labelling Standard is an evolving process. The Commission invites facilities encountering implementation issues that cannot be answered by the Labelling Standard and implementation resources (including these FAQs) to contact their Labelling Standard jurisdictional contact in the first instance, and for health facilities with no jurisdictional contact, the Commission at mail@safetyandquality.gov.au. Issues arising during ongoing implementation that cannot be answered by referring to the Labelling Standard will be recorded, together with responses to them, in a Labelling Standard Issues Register.

1 Implementation

Q1.1 Why is the Labelling Standard important?

Incomplete or inaccurate labelling of injectable medicines and fluids is a recognised risk in the safe administration of medicines. The Labelling Standard helps users identify medicines that have been removed from their original packaging, to promote safer use of medicines through standardisation and best practice.

Each healthcare facility has systems to promote safety in relation to injectable medicines. However, there is potential for error because of variation in policy between facilities. Standardised, field-tested labels provide a system of safer administration for injectable medicines across all health facilities and will help personnel administering injectable medicines as they move between different clinical areas and health facilities.

Q1.2 Are all health facilities required to implement the Labelling Standard?

The Labelling Standard is mandatory for all health facilities where injectable medicines and fluids are administered.

The Labelling Recommendations, which preceded the Labelling Standard, were endorsed by Australian health ministers in 2010. Health services seeking accreditation to the National Safety and Quality Health Service Standards are required to implement the Labelling Standard.

Q1.3 When is the Anaesthetic Labelling Standard used?

The Anaesthetic Labelling Standard (ISO 26825:2008 *Anaesthetic and respiratory equipment – user-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*) describes medicine labels for syringes containing drugs used during anaesthesia. Labels are colour coded according to medicine class and preprinted with the medicine name and a prompt for concentration. The Anaesthetic Labelling Standard should be extended to identify medicines in containers used beyond anaesthesia in closed-practice environments. See Sections 6.2 and 6.3 in the Labelling Standard.

Q1.4 How should we audit user-applied labelling for safety?

Current incident management systems record incidents on a case-by-case basis and can reveal if labelling errors were involved, regardless of whether the incident led to harm, did not lead to harm or was detected before administration. Statistical error rate analysis is not possible without recording the denominator (total number of medicine administrations). However, uptake and compliance with the Labelling Standard may be assessed using the audit tools provided on the Commission web site (www.safetyandquality.gov.au).

Q1.5 Does the Labelling Standard mean we rely on colour coding?

No, you cannot rely on colour coding. Wording is the primary identifier at all times. Colour coding is used to help locate and differentiate items, but is a secondary means of identification (1).

In June 2009, the Institute for Safe Medication Practice (ISMP) in the United States described a situation where oral liquid medicine was administered intravenously because the purple connector for enteral use at the hospital was the same shade of purple as the peripherally inserted central catheter intravenous connectors. The ISMP suggests that reliance on colour coding as a safety feature can instil a false sense of security, and the use of colour alone has led to unintended and sometimes harmful consequences.

Q1.6 Is it possible to make changes to the labels?

The Labelling Standard has minimum requirements. In theory, additional information may be included. However, when introducing new information to labels, consider that:

- increasing information content may reduce label clarity
- information could be recorded elsewhere
- pilot testing and evaluation during implementation did not identify any necessary additional information.

The use of nonstandard labels has the following implications:

- Demonstrated safety benefits from the outcomes and feedback from national piloting and post-implementation evaluation may not be achieved if nonstandard labels are used.
- Economies of scale may be compromised as label manufacturers incur additional set-up and print costs, leading to higher label production costs.
- Implementation and education resources provided and maintained by the Commission would no longer be applicable.
- Health professionals working across a number of hospitals will experience varied national labelling requirements.

Q1.7 Do we need to acknowledge copyright of the Labelling Standard and support materials?

The support materials relating to the Labelling Standard are free to use – for example, to produce a poster for each ward to assist with education. However, a statement acknowledging copyright in the *National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines* to the Commonwealth of Australia is required.

Q1.8 How do we cite the Labelling Standard?

Australian Commission on Safety and Quality in Health Care. National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines. Sydney: ACSQHC, 2015.

2 Clinical application: all containers

Q2.1 Does every bag or bottle of fluid require user-applied labelling?

Only apply user-applied labelling if a medicine is added to the bag or bottle in the clinical area.

A bag of fluid with no additive is described by the manufacturer's original packaging and no further labelling is required on the bag. However, the line should be labelled to identify the route when the infusion is started.

Case report (unpublished)

An anaesthetist added 40 units of oxytocin to a 1-litre bag of normal saline without adding an 'additive' label. A nurse was required to put up another bag of normal saline for a pregnant woman and took a bag that was open from the anaesthetic trolley without realising that it contained oxytocin. The bag was put up and the mistake was realised after the birth of the baby.

Immediate labelling of the bag on addition of oxytocin may have prevented this error.

Note: The Labelling Standard use the term '0.9% sodium chloride'. The term 'normal saline' is retained in case reports if this term was used in the original report.

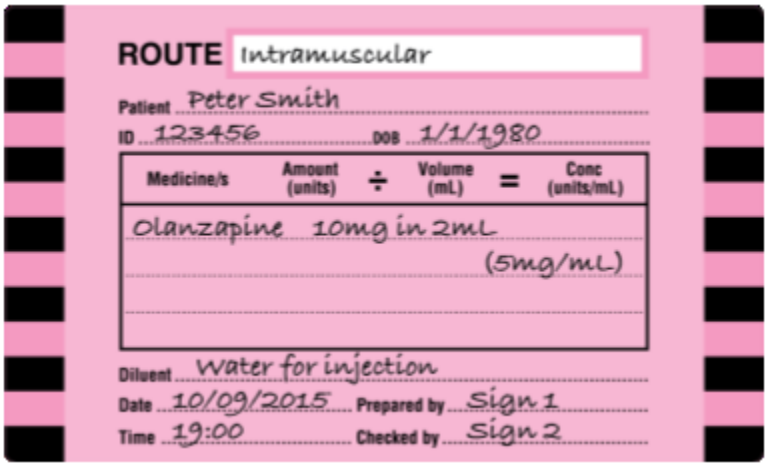
Q2.2 How many patient identifiers are required?

The National Safety and Quality Health Service Standards (Standard 5: Patient Identification and Procedure Matching) require that 'At least three approved patient identifiers are used when providing care, therapy or services'. The Labelling Standard forms part of Standard 4: Medication Safety. All labels that require patient identification include three patient identifiers.

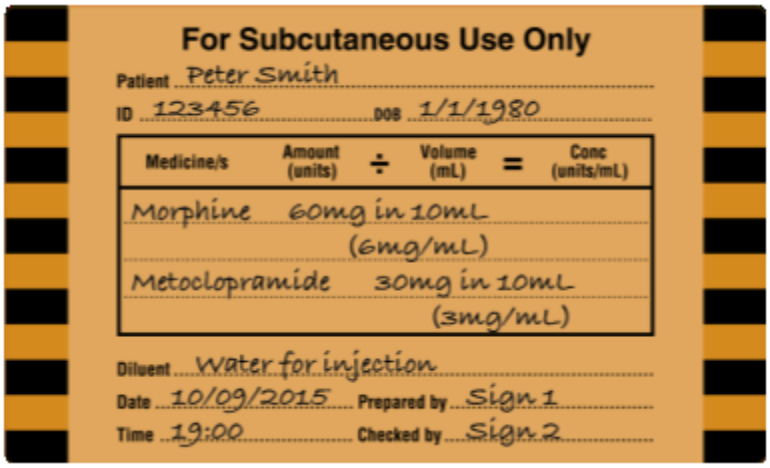
Q2.3 How should the container label be completed?

Container labels should include the medicine(s), amount, volume and concentration.

Example completed container label: miscellaneous



Example completed container label: subcutaneous



2.3.1 Medicine

Use the active ingredient name to identify the medicine.

2.3.2 Amount

Add the **total** amount of active ingredient added to the bag or syringe, including units (e.g. mg).

'Units' refers to the unit of measure (e.g. microgram, milligram, gram, nanogram or international unit) and depends on the active ingredient to be administered.

Use abbreviations for units according to the Australian standard (2).

2.3.3 Volume

The **total** volume of fluid contained in the bag or syringe must be identified in millilitres (mL). The **total** volume of fluid represents the final volume of fluid in the container once the

medicine(s) has been added. For medicines to be administered via an infusion, the total volume represents the starting volume of fluid when the infusion commenced.

2.3.4 Concentration

The concentration of active ingredient must be identified in units per millilitre (units/mL).

The actual quantity of medicine delivered to the patient at any time during administration should be easily accessible. This is easier to determine if concentration is expressed as mass concentration (e.g. mg/mL).

Expressing concentration as a ratio (e.g. 1:1000, 1:10 000) is associated with medication errors and is discouraged (3, 4).

Concentration is often expressed as a ratio on manufacturers' packaging. The Institute for Safe Medication Practice (USA) notes several incidents where the incorrect concentration of epinephrine was selected because of inappropriate conversion to the mass concentration (mg or µg per mL). Inadequate knowledge and unfamiliarity with ratio has led to error-prone conversion to the mass concentration. Any concentration calculation should be duplicated and cross-checked. It may be helpful to create a dose conversion chart that reflects concentrations available in a clinical area (4).

Preprinted labels developed for the sterile field may be printed with the concentration as it appears on the original packaging, acknowledging that the manufacturer's original packaging may display ratio.

Case report

During a day surgery ENT procedure, the surgeon requested local anaesthetic for injection (lidocaine 1% with epinephrine 1:100,000) and was handed a pre-drawn syringe. The surgeon injected the medication into the surgical site. The patient experienced cardiac arrhythmia, which led to cardiac arrest and death, despite full resuscitation measures. Information gathered after the incident indicated that the syringe contained epinephrine 1 mg/mL (1:1,000) intended for topical use, rather than the local anaesthetic for injection that was requested. The syringe containing epinephrine 1 mg/mL was not labelled (5).

Q2.4 How should we complete the container label for multiple medicines?

In some clinical settings, more than one medicine may be drawn up into a single syringe and administered to a patient (e.g. via a syringe driver in palliative care). When using container (syringe) labels, it is important to write each medicine on a new line on the label.

In practice, for the smaller sized label, label design has allowed two lines for medicine name, amount, volume and concentration. Therefore, the smaller container label for syringes and bags (60 mm × 50 mm) will accommodate the required information for up to two medicines.

If three or more medicines are to be administered together via a single syringe, a larger volume syringe and the larger container label should be considered, allowing the required information for three or more medicines to be identified.

Q2.5 How can we monitor the volume of fluid when bag labels are applied to infusion bags?

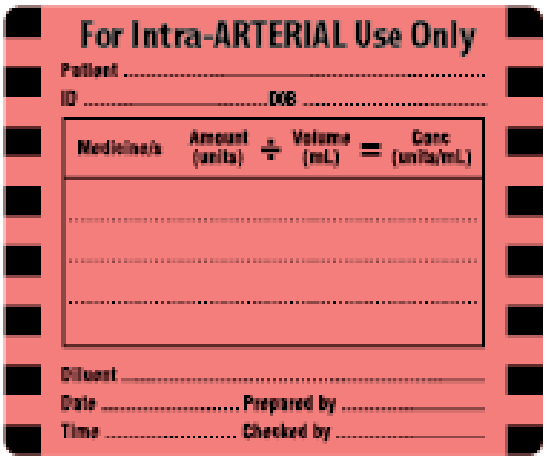
Place the label on the front of the bag slightly to the left or right to ensure the graduations on at least one side of the bag are visible to monitor fluid delivery. Ensure the label does not cover the name of the base fluid, the batch number and expiry.

Q2.6 The intra-arterial line is only used for monitoring – why is a container label provided?

It is essential to identify the intra-arterial line with the route line label regardless of the purpose of the line. In the majority of cases, the line will be used for monitoring and it is important that no medicines are introduced into the line.

Sometimes a medicine may need to be administered via the intra-arterial route (e.g. heparinised saline). The medicine is added to a container (syringe or bag), which is then labelled. The container label to identify a container with a medicine for delivery via the intra-arterial route is red (PMS 1787), includes the words 'For Intra-ARTERIAL Use Only' and has the same prompts as other container labels.

Intra-arterial container label



Administration via the intra-arterial route is specialised and carries high risk. Label availability and storage should be carefully considered.

Q2.7 What container label is used for specific intravenous routes, such as central venous and peripherally inserted central catheter (PICC)?

Container labels for the intravenous (IV) route are to remain as described in the Labelling Standard and not tailored for specific IV routes.

Results of the pilot testing informed this recommendation and noted that:

- keeping the number of different type and size labels to a minimum facilitated the label selection process

- any bag label should be full colour to draw attention to the presence of an additive.

Therefore, a single, fully coloured container label for intravenous bags with additives and syringes is included in the Labelling Standard for containers of medicines for either peripheral or central intravenous administration.

Differentiating peripheral from central intravenous administration is indicated by the line labels. A separate central venous line label is available.

3 Clinical application: syringes

Q3.1 Are there any examples where immediate syringe labelling may have prevented error?

Immediate labelling and checking against the original packaging at the point of drawing up the solution may have prevented the following errors.

Case report (unpublished)

A patient was given intravenous lignocaine with adrenaline solution intended for local anaesthetic infiltration. Local anaesthetic had been drawn up and placed in a kidney dish, unlabelled, with intravenous morphine and midazolam for procedural sedation.

Case report (unpublished)

The anaesthetist reconstituted a muscle relaxant and an anaesthetic medicine, but did not label either syringe. The muscle relaxant was given before anaesthesia and the patient now suffers post-traumatic stress syndrome due to the terror from the relaxant while remaining awake.

Q3.2 Do we need to label the syringe every time?

A key principle of the Labelling Standard is that all syringes, including boluses, flushes and infusions, must be labelled immediately by the person who prepared them.

'Many errors have occurred despite nurses' good intentions to go directly to the patient's beside and administer the medicine in an unlabelled syringe; the nurse may be interrupted and forced to put down the syringe' (6). In these situations, when an unlabelled syringe is put down and is at risk of being left unattended and picked up by another staff member, labelling is paramount to ensure the syringe content is clearly identifiable.

The only exception to this and where labelling is not required is when all of the following apply:

- the preparation and bolus administration of a SINGLE medicine is one uninterrupted process
- the syringe DOES NOT leave the hands of the person who prepared it
- that same person administers the medicine IMMEDIATELY.

This principle is consistent with similar standards and recommendations in the United States and United Kingdom (6-8).

Clinical staff may use a tray (or dish) to transport a syringe from the preparation area to the patients' bedside as part of the medicine administration process. The principles of the Labelling Standard must be applied to syringes carried this way, with the contents being identifiable beyond doubt. If there is doubt over the contents of an unlabelled syringe, the syringe must be discarded.

Q3.3 Do prefilled syringes require labelling?

Prefilled syringes fall outside the scope of the Labelling Standard. Manufacturers of prefilled syringes are governed by Therapeutic Goods Administration (TGA) guidelines for identification of these products.

Q3.4 Should two users be involved in syringe preparation?

It is important that a single person writes the label, draws up the medicine and applies the label. Errors have occurred when more than one person is involved in medicine preparation. The contents of the syringe and the information on the label should be verified by a second person, but that second person is not part of the operation.

Case report (unpublished)

A patient was given 50 micrograms of fentanyl rather than 25 micrograms from an unlabelled syringe. The preparation of the syringe was started by one nurse and completed by another nurse.

Q3.5 How should syringe labels be placed?

Place the label parallel to the long axis of the syringe barrel with the top edge flush with (but not covering) the graduations (1, 6). Information should appear parallel to the long axis of the syringe and from the needle end of the syringe to the plunger. That way, the printing will be the right side up for the 80% of practitioners who are right handed and usually hold a syringe by its plunger in the right hand. Since the person administering the drug will need to observe the syringe's volume scale (graduations), the top of the label should be placed flush against the scale but not cover it. Applying labels in this way improves safety by allowing practitioners to see the patient and drug names without turning the syringe (6).

Case report (unpublished)

Labelling covered the calibrations and the syringe volume was not visible. Because of this, morphine was administered at an incorrect rate.

Q3.6 How do we apply a flag label to smaller syringes?

Place the label parallel to the long axis of the syringe barrel with the top edge of the label flush with (but not covering) the graduations (9-11). Fold the remaining label back on itself.

Make sure the fold does not obscure any information on the label. Unpublished medicine incident reports identified that flag labels that had been folded in a way that split vital information on the label resulted in misinterpretation of concentration and errors in calculation of medicine dose.

Q3.7 Is the empty syringe labelled immediately before drawing up the medicine or immediately after it is filled?

The syringe can be labelled either before or after filling it. Guidelines from the Australian and New Zealand College of Anaesthetists (ANZCA) purposely omit direction on this point. Instead, ANZCA recommends checking the labelling on the ampoule or other original packaging against the syringe label as the medicine is drawn up (12).

All injectable medicines drawn up in a syringe should be labelled IMMEDIATELY. By labelling immediately, the medicine is removed from its original labelled container into a syringe, the original container is immediately available for checking, and no other operations can be performed to distract and potentially lead to incorrect labelling.

Q3.8 Can the ampoule be attached to the syringe after the injectable medicine has been drawn up, instead of using a label?

No. Attaching (taping) an empty ampoule to the syringe as a method of identifying syringe content is discouraged for the following reasons:

- The syringe becomes hazardous to handle.
- The ampoule provides incomplete information (e.g. no patient identification).
- Tape may cover information on the ampoule and graduations on the syringe.
- There is no indication of quantity – if the contents of two ampoules are drawn up into one syringe and only one ampoule is taped, the quantity will be incorrect.
- Handling difficulty may lead to poor compliance.

Q3.9 Why are syringe drivers and pump devices not included in the Labelling Standard?

The syringe itself should be labelled. Syringe drivers and pump devices are excluded from the Labelling Standard because labelling may give rise to errors if the driver or pump label is not updated when a syringe is replaced.

Case report (unpublished)

A patient in the operating room had many infusions in situ, including propofol, Actrapid, normal saline, noradrenaline and morphine. On transfer from the intensive care unit, the patient's blood pressure was high, so the anaesthetist lowered the noradrenaline rate, then turned it off. Approximately 40 minutes into the case, the anaesthetist discovered that the pump labelled morphine had a bag of noradrenaline attached. Therefore, no morphine had been running and the patient had been receiving double the amount of noradrenaline.

Labelling of the primary container (i.e. bag) rather than the pump may have prevented this error.

Note: The Labelling Standard use the term '0.9% sodium chloride'. The term 'normal saline' is retained in case reports if this term was used in the original report.

Q3.10 Do syringes placed in syringe drivers and pumps require labelling?

Yes. Labels should be applied to the syringe, not the syringe pump. Errors have been associated with labelling the driver or pump and leaving the syringe (primary container) unidentified.

A container label with full details must be completed and applied directly onto the syringe containing the medicine or fluid. Labels have been developed to allow as much detail as possible to be placed on the syringe and be available to view through the window of the driver. See Section 4.3 'Syringes' and Section 4.6 'Minimum requirements for labelling containers in the open-practice environment' in the Labelling Standard.

Applying the container label directly to the syringe may require the label to be folded back on itself and applied as a 'flag'. It is important to ensure the medicine name is identifiable without removing the syringe from the driver. Consider the following solutions:

- A clear flag label (similar to the clear covers used to label ophthalmic preparations in pharmacy) may be used to attach a container label to a syringe in a syringe driver. This allows the label to be read while ensuring that graduations remain visible in some syringe drivers or pumps. However, a clear flag may not be physically suitable for all syringe driver/pump arrangements.
- Labels preprinted with medicine name(s) may more easily identify medicines and combinations of medicines frequently administered through syringes in syringe drivers and pumps. The concentration should be completed on preparation and not be preprinted.

Q3.11 Does the syringe label affect a Niki T34 syringe driver operation?

Experience suggests that application of labels to syringes in Niki T34 syringe drivers does not interfere with the device accurately assessing syringe volume. Caesarea Medical Electronics advises:

- The pump identifies syringes by their diameter. Most labels, if applied carefully, do not make a significant difference to the diameter and, mostly, the pump will still identify the syringe correctly. If the label is not flat and smooth, the pump may initially gauge the wrong syringe size (i.e. it will see a larger diameter).
- At all times, the user must check that the correct syringe is displayed before activating the pump. If the incorrect syringe is displayed, initially the user must use the UP/DOWN button to select the correct syringe, then they can proceed.

Q3.12 Do we need to label a saline flush?

Yes. All fluids used to flush lines and catheters must be labelled. Preprinted 0.9% sodium chloride labels have been designed for identification of 0.9% sodium chloride flush.

This is the only preprinted abbreviated label available for use on a container in the open-practice environment. It is provided to assist identification of the 0.9% sodium chloride

flush, which is frequently used but often associated with medication errors and patient harm.

Labelling of syringes containing 0.9% sodium chloride should comply with the Labelling Standard. In the majority of cases, the 0.9% sodium chloride will be drawn up into a syringe that will not leave the operator's hand before the flush is administered, and labelling will not be required.

However, if the 0.9% sodium chloride has been drawn up and the syringe is put down or handed to another staff member, the syringe must be labelled. Any unlabelled, filled syringes must be discarded according to the Labelling Standard, even if the solution is considered to be 0.9% sodium chloride.

The following cases highlight the importance of identifying all filled syringes that leave the hand of the operator before administration, including those containing 0.9% sodium chloride intended for use as a flush.

Case report (unpublished)

A patient was given 50 micrograms of fentanyl instead of normal saline to flush an intravenous catheter. The label from the syringe containing fentanyl fell off, and the syringe was mistaken for a syringe of the same size containing normal saline.

Case report

Prior to a dipyridamole stress test, a syringe of aminophylline 75 mg was filled from a multiple-dose vial, but not labelled. The aminophylline (used for emergency reversal of the effects of dipyridamole) was not needed, but the unlabelled syringe was left in the room with the patient. A nuclear medicine technician arrived to administer an IV dose of thallium. The technician assumed the unlabelled syringe contained normal saline and used it to flush the patient's IV access port. The patient was monitored and experienced no serious adverse effects (1).

Case report

Due to lack of availability of commercially prepared flush syringes, supplies of syringes containing normal saline were prepared each day from multiple-dose vials. Vecuronium had been prepared for a trauma patient but was not labelled and was inadvertently placed with the saline flush syringes. The syringe containing vecuronium was later used to flush the IV line of an alert three-year-old child. The child became flaccid and stopped breathing. She was quickly intubated and ventilated, and permanent harm was averted (13).

Note: The Labelling Standard use the term '0.9% sodium chloride'. The term 'normal saline' is retained in case reports if this term was used in the original report.

4 Clinical application: lines

Q4.1 Are there examples where line labelling may have prevented error?

The following errors may have been prevented if lines had been labelled.

Case report (unpublished)

Intravenous magnesium sulfate intended for the central venous catheter was inadvertently connected to the arterial line. Both lines were sited in the right groin. Neither the arterial nor the intravenous lines were adequately labelled.

Case report (unpublished)

Intravenous rocuronium was accidentally given through an arterial line inserted in the right wrist. The right arm immediately became mottled and redness spread to the elbow. A handwritten Opsite label identified the arterial line, but was not easily visible from the side of the patient. Intravenous fluids were also running in the dorsum of the right forearm.

Case report (unpublished)

A patient received a subcutaneous infusion and an intrathecal infusion for pain management, both controlled by a Gemstar pump. A staff member twice attempted to prime the subcutaneous line, but instead primed the intrathecal line, which was still connected to the patient. Approximately 1 mL was infused before an error was noted.

Case report (unpublished)

Peripheral intravenous and central intravenous lines were unlabelled, and noradrenaline and glyceryl trinitrate were administered through the wrong lines. The patient became hypertensive, with a systolic blood pressure greater than 200 mmHg.

Q4.2 Do we need to label a single intravenous line?

The appropriate route line label must be applied to any line connected to a patient. This recommendation applies even when there is only one administration line in situ. The patient may have other lines introduced on a subsequent occasion. It is the responsibility of the user initiating the line to label for route.

Q4.3 Can the maintenance (intermittent) drug administration line be labelled for medicine content?

It is not necessary to label the medicine in a maintenance line. Infusion lines accommodating intermittent medicine administration are used for different active ingredients. Although these lines may be labelled to identify the active ingredient, medicine labels must be removed when the infusion is complete.

Q4.4 Why is it important to label the medicine in dedicated continuous infusion lines?

A continuous infusion line that must be retained for delivery of a single medicine must not be used for any other medicine (i.e. it is dedicated only to that single medicine). The medicine contained in the line must be clearly identified alongside the route.

Case report (unpublished)

A bag of normal saline was connected to an unlabelled line and the patient became hypertensive and vomited. The fluid bag had been accidentally connected to an unlabelled line containing noradrenaline and the pump containing noradrenaline was commenced in error. The patient received approximately 20 mL of noradrenaline within a minute or two.

Case report (unpublished)

Prior to commencing a frusemide infusion, an unlabelled line containing noradrenaline was accidentally removed instead of the maintenance line. This resulted in a severe drop in blood pressure.

Case report (unpublished)

A patient had a subcutaneous butterfly needle primed with morphine in place. Midazolam was given through the same subcutaneous line, resulting in extra morphine administration and a reduced dose of midazolam. The subcutaneous line was not clearly labelled to indicate that it contained morphine.

Note: The Labelling Standard use the term '0.9% sodium chloride'. The term 'normal saline' is retained in case reports if this term was used in the original report.

Q4.5 Can preprinted labels be used for dedicated continuous infusion lines?

Yes. Labels are provided for identifying the route of, and the medicine used in, dedicated continuous infusion lines. Preprinted labels should be used, where possible. Use a generic label when a preprinted label is unavailable. See Table 3 and Section 5.2.2 in the Labelling Standard, and the preprinted medicine line label guide on the Commission's web site.

The full evaluation report of the suitability of preprinted labels in four intensive care units is available in the evaluation of standardised medicine line labels for medicine in dedicated continuous infusions. In the trial, label specifications were:

- Labels were printed in continuous strips (7 mm wide) on unplasticised PVC tape with tensile strength >14.3 kg/25 mm.
- Font size was 8 mm, allowing a 2 mm border either side for printing diversion. The image width varied according to length of medicine name but did not exceed 70 mm. The gap between images was 10–15 mm.
- Peel adhesive was 600 g/25 mm (± 10%).

Q4.6 Do all lines require route identification when multiple lines are in use?

It is critical to ensure that the medicines in each line can be promptly identified when a number of lines are in place in intensive care settings. Equally, identifying the route is important, particularly with intrathecal and intra-arterial routes.

For intravenous infusion, and where multiple central lines converge into a common central line, label the common line for route and each individual line for medicine.

Q4.7 Where is the line label placed when a multiway port is in use?

Label the route of administration (e.g. intravenous) after the port. Label the medicine before the multiway tap, if possible. Label each lumen if access to this site is unavailable.

Q4.8 Where are line labels placed on lines for paediatric patients?

Place the label near the container for patients who may tamper with the line label, including paediatric patients.

Q4.9 When and how is the catheter lock label used?

Locked catheters that have a medicine in situ to lock the catheter must be labelled – for example, a dialysis catheter with a heparin lock. A label is provided to identify a catheter lock (see Section 5.4 of the Labelling Standard).

The label must be removed when the medicine lock is removed. Therefore, the adhesive used on the label should be strong enough to adhere, but not too strong that it cannot be removed as required.

Case report (unpublished)

A bolus dose of dextrose was given through a new central venous catheter. The line had been surgically placed on the previous day but not labelled to indicate that heparin had been instilled into the line. To administer the dextrose, the patient's central venous catheter was accessed without withdrawing the heparin first, and the patient received a heparin bolus.

Q4.10 Why are there intra-arterial labels when this is a monitoring line?

The intra-arterial line should be identified for route at all times. Even if the line is for monitoring purposes only, it should be labelled to prevent inadvertent medicine administration.

An intra-arterial line label is available to identify the intra-arterial route.

Intra-arterial line label

See also 'Q2.6: The intra-arterial line is only used for monitoring – why is a container label provided?'

Q4.11 Can the medicine name be preprinted on the same line route label?

No. The route identification label remains separate to the medicine (active ingredient) line label. Combination of the two labels is not supported.

There is potential for a combined route/medicine label to be selected and used for the wrong active ingredient. The medicine name would need to be actively changed in this circumstance. Completing a generic label for the correct medicine or selecting a medicine label separate to the route label carries less risk.

Q4.12 Are line labels washable?

Refer to the manufacturer's specifications. Line labels tested during pilot testing withstood reasonable handling but were not water resistant. Any damaged labels will need to be replaced to ensure the line can be identified at all times.

5 Clinical application: general

Q5.1 Can the pink miscellaneous label be used for any route if labels are out of stock?

No. A pink miscellaneous label (headed 'ROUTE' in large bold type with a space adjacent for completion of route) is included to enable safe labelling of all parenteral routes that are not specifically covered by the Labelling Standard. These miscellaneous pink labels are NOT to be used for routes with a dedicated label. Maintenance of adequate stock levels is critical to safe labelling.

Q5.2 When are pink miscellaneous labels used?

The standardised colour system applied in the Labelling Standard defines specific colours to identify the intended target tissue/route of administration (see Table 1 of the Labelling Standard).

For routes of administration that are not explicitly addressed by the target tissues, the pink miscellaneous label is to be used. The intended route of administration must be identified on the label in the white box for ROUTE. Miscellaneous labels are available for containers and lines.

The colour pink was chosen to facilitate visibility in the clinical setting (as opposed to white) and does not imply a specific route of administration.

Q5.3 How should extemporaneously prepared items for individual patient administration be labelled?

Items prepared for individual patients are labelled with all necessary information to identify the patient. No additional labelling is necessary for a medicine that remains in its original container.

Lines attached to the original containers must comply with the Labelling Standard and require a line label to identify the route of administration at commencement of infusion.

Q5.4 How should cytotoxics be labelled?

The Labelling Standard applies to any medicine, including cytotoxic medicines. In practice, these are likely to remain in the original container prepared for individual patient use. A purple label with the wording 'cytotoxic' may be used to highlight the presence of a cytotoxic in addition to the minimum requirements of the Labelling Standard. (See Clinical Oncological Society of Australia (14).)

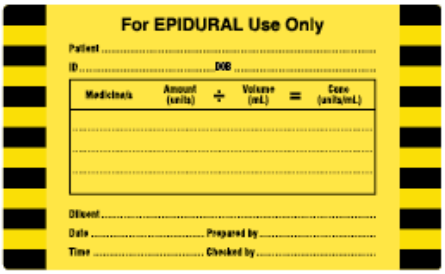
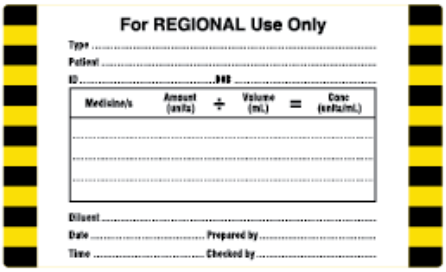
Q5.5 What is the difference between an epidural and regional block? How should the Labelling Standard be applied in these circumstances?

For an epidural regional block, the local anaesthetic is delivered directly into the epidural space via the thoracic, lumbar or caudal area.

A regional anaesthetic block provides local anaesthesia to a discrete area of the body for the management of pain. Common regional anaesthetic blocks include extrapleural or paravertebral blocks, intrapleural blocks, femoral nerve blocks, an epidural block, and a catheter placed directly into the wound.

The Labelling Standard provides specific labels for identification of containers and lines delivering an epidural block. For all other regional blocks, use the 'For Regional Use Only' container label and write the route of the anaesthetic block in the first line of the label prompted by the word 'Type'.

Epidural and regional labels

Label type	Example label
Epidural container label	
Epidural line label	
Regional container label	
Regional line label	

Q5.6 Are standards AS/NZS4375:1996 and ISO 26825:2008 the same?

These two standards are similar but not the same.

AS/NZS4375:1996 is an Australian and New Zealand standard for user-applied labels used on syringes containing drugs used during anaesthesia.

ISO 26825:2008 is an international standard for user-applied labels for syringes containing drugs used during anaesthesia.

In the Labelling Standard, ISO26825:2008 is referred to as the Anaesthetic Labelling Standard.

ISO 26825:2008 draws heavily on and supersedes AS/NZ4375:1996, with additional information regarding label quality, and the differentiation of heparin and protamine from other medicines in the miscellaneous category that are labelled with black text on a white background.

6 Perioperative area: general

Q6.1 What is meant by open- and closed-practice environments?

Details of open- and closed-practice environments

	Open-practice environment	**Closed-practice environment**
Definition	More than one patient may be present, and there may be doubt regarding an intended medicine without patient identification	The identities of the patient and the patient care team are recorded and beyond doubt
Examples	• Intensive care unit • Post-anaesthetic recovery area • Emergency department	• Operating rooms • Endoscopy rooms • Cardiac catheterisation laboratories • Interventional radiology suites
Labelling Standard reference	Section 4.6	Section 4.7
Type of labelling required	Medicines administered in the open-practice environment should be identified with full labelling, including patient and user identification	Medicines administered completely within the closed-practice environment may be identified with abbreviated labelling, without patient and user identification

Medicines prepared and labelled in the closed-practice environment that will move with the patient to an open area must have full container labels. Examples include continued delivery of additives in fluid bags on patient transfer from the operating room to a post-anaesthetic recovery unit, or syringes prepared to accompany the patient on transfer to the intensive care unit. See Section 6.1 ‘Open- and closed-practice environments’ in the Labelling Standard.

Q6.2 Anaesthetists in our hospital use colour coded medicine labels. Is this practice consistent with the Labelling Standard?

Use the Anaesthetic Labelling Standard (ISO 26825:2008, *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*) to identify medicines in syringes used for the purposes of anaesthesia. This is consistent with the Australian and New Zealand College of Anaesthetists *Guidelines for the safe administration of injectable drugs in anaesthesia* (12).

However, the preprinted colour coded Anaesthetic Labelling Standard labels should not be used in the open-practice environment because they do not have patient or user identification.

Use the Labelling Standard for all other medicine containers and lines in the perioperative environment.

Q6.3 Why label all fluids on the perioperative sterile field?

All containers containing medicines or fluids should be labelled on the sterile field, including jugs and basins containing non-injectable fluids. There is a potential for non-injectable fluids to be drawn up into syringes and inadvertently administered. Therefore, where injectable fluids are prepared, all non-injectables should be labelled when they are removed from their original container.

The following errors may have been prevented by correct labelling on the sterile field.

Case report

During coil placement under cerebral angiography to repair a brain aneurysm, a patient was accidentally injected with an antiseptic skin preparation solution, chlorhexidine, instead of contrast media. At the end of the procedure, contrast media should have been injected into the patient's artery for radiographic visualisation. Unfortunately, the chlorhexidine (highly toxic when injected intravascularly) was drawn into the syringe, and administered to the patient. Within two hours, acute, severe chemical injury to the blood vessels of the leg restricted circulation to the muscles, causing profound injury and swelling of the leg. During the following two weeks, the patient's condition deteriorated. She underwent a leg amputation, and suffered a stroke and multiple organ failure, which led to her death. Both solutions were clear and available on the sterile field in unlabelled basins. The hospital's recent decision to switch antiseptics from a brown povidone–iodine solution to a clear chlorhexidine solution was thought to have contributed to the mix-up. Ultimately, labelling of the basins when the solutions were removed from their original packaging may have prevented the error (15).

Case report

A patient died during a surgical procedure to remove a cancerous eye. The malignancy had spread to the brain and spinal fluid was removed to reduce cerebral pressure, and placed in an unlabelled cup. Another unlabelled cup filled with glutaraldehyde, to preserve the patient's enucleated eye, was misidentified as spinal fluid and accidentally injected via the intrathecal route (15).

Q6.4 Can the medicine name be printed directly on the container?

No. Do not preprint disposable containers with a medicine name. The use of preprinted containers has been associated with medication errors. There is a possibility that the container will be selected for another medicine if it is the only one available.

Q6.5 Do contrast media require labelling?

Yes. Contrast media are injectable fluids and should be identified if removed from their original packaging and placed in containers, including syringes. The minimum requirements of the Labelling Standard apply to contrast media, and a label is provided to identify contrast media.

Contrast media abbreviated container label

The generic term ‘contrast’ in the closed-practice environment of the operating room is appropriate; specifying the contrast material by brand or active ingredient name(s) is unlikely to confer a benefit and may be misleading.

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

See Section 6.4 ‘Contrast media’ in the Labelling Standard.

Q6.6 Should each health facility use the preprinted sterile label set illustrated in the Labelling Standard?

Preprinted label sets for use on the perioperative sterile field omit patient and user identification, because this is a closed-practice environment and those details are recorded elsewhere.

The label set illustrated in the Labelling Standard (Figure 3, page 27) is based on label sets created for evaluation purposes by individual health facilities. The exact composition of the customised preprinted label sheet is best determined by the health facility, or specialty within a facility, depending on the local procedures and medicines used.

Q6.7 How are preprinted label sets developed for use in operating rooms?

Most operating rooms will be able to identify a short list of medicines that are used regularly, and a single set of labels may be devised to cover all operations undertaken at the facility. This approach was chosen by hospitals contributing to implementation evaluation. However, facilities may choose to use individually packaged sets of labels specific to each operating theatre within a facility, or even a single set of labels specific to each procedure.

See Section 4.7 ‘Minimum requirements for labelling containers in the closed-practice environment’ and Section 6 ‘Labelling in perioperative areas’ in the Labelling Standard.

The evaluations of preprinted labels on the perioperative sterile field are presented in Report 1 [PDF 740KB] and Report 2 [PDF 1.5MB] on the Commission web site.

Q6.8 How are preprinted label sets developed for use in interventional cardiology and radiology?

Labels may be preprinted with medicine names in interventional cardiac catheterisation laboratories and radiology suites. These are closed-practice environments, where the identity of the patient and patient care team are beyond doubt and recorded.

In these areas, the same sets of medicines are used, following set protocols for the same procedures, and it is possible to devise an appropriate label set that may be applicable to a number of health facilities.

See Section 6.3 'Interventional cardiology, radiology and other low-light procedure areas' in the Labelling Standard.

Q6.9 How are non-injectable medicines and fluids identified on the perioperative sterile field?

Best-practice guidelines require all skin and topical preparations to be retained outside the procedure area (12). However, occasionally it may be necessary to use non-injectable medicines in areas where injectable medicines are used. The non-injectable medicines and fluids are further identified with a red watermarked St Andrew's Cross behind the medicine name. These labels may be included on preprinted sheets of abbreviated container labels (without patient or user identification details) for use in the perioperative area.

On a preprinted label sheet, non-injectable medicines should be clearly separated from injectable medicines. See Section 6.2 'Containers on perioperative sterile fields' in the Labelling Standard for an example.

Q6.10 Can the abbreviated container label be used instead of preprinting any labels for the perioperative sterile field?

Preprinted labels are preferred. They are easy to handle and select, reduce preparation time compared with populating an abbreviated label, and negate the use of sterile marker pens.

However, when no preprinted alternative is available, use the abbreviated container label as a suitable alternative for medicine and fluid identification on the perioperative sterile field.

Q6.11 Can the abbreviated container label be used in the preparation and recovery areas of the perioperative suite?

No. The abbreviated container labels are only for use on the perioperative sterile field, which is a closed-practice environment. Use full container labels in the open-practice environment outside of the operating room where more than one patient may be present, including preparation and recovery areas.

Q6.12 Route identification labels are often included in sterile procedure packs. Do these need to comply with the Labelling Standard?

Yes. All labels intended for user-applied labelling should comply with the Labelling Standard. This includes labels supplied in customised sterile packs (e.g. giving sets). Manufacturers and suppliers of customised sterile procedure packs with labels have been notified of the Labelling Standard where they have made themselves known to the Commission.

Q6.13 Is the sterile field confined to the operating room?

No. The sterile field is any specified area considered to be free from microorganisms, and includes an area immediately around a patient that has been prepared for a surgical procedure.

A sterile field may be established in areas other than the operating room. This sterile field will most probably involve only one patient in a closed-practice environment, where preprinted labels for medicine and route without patient identifiers are acceptable.

Sterile container (e.g. syringe) labels should be used to identify drugs withdrawn from their original containers on a sterile field in an open-practice environment. The appropriate container labels will need to be packaged and sterilised for the purpose.

7 Perioperative area: practical considerations

Q7.1 What are the practical considerations for labels used on the sterile field?

Pilot testing and evaluation of label sets in the perioperative area inform implementation of the Labelling Standard on the perioperative sterile field, and highlight the following considerations:

- Labels must retain their integrity throughout a procedure. Containers may be handled many times during a procedure and may be repeatedly exposed to fluids. Contact label manufacturers for further information on the suitability of their products for use in the perioperative area.
- Labels must adhere to the container for the duration of the procedure. The compatibility of sterile field labels with commonly used medicines may need to be tested. For example, in the pilot test, papaverine released the test label from the container.
- After the procedure, ensure that labels can be removed entirely from any equipment that will be cleaned and sterilised for reuse. Any residue on a stainless steel container will render it unfit for sterilisation.
- Keep label packaging small to minimise waste and facilitate handling.
- Ensure sterile pens are fit for purpose. Writing must remain clearly legible. Some surgical markers have a tendency to run.

Q7.2 Where can hospitals obtain sterilised labels consistent with the Labelling Standard for use on the sterile field?

Several label manufacturers supply labels described in the Labelling Standard. Some of these manufacturers can supply labels that are packaged and sterilised for use on the perioperative sterile field. Please contact individual suppliers for more information.

Q7.3 What method of sterilisation is preferred for paper labels?

Labels for pilot testing were printed, packaged and sterilised in three separate processes. This was chiefly due to the small quantities required. A single process of printing, packaging and sterilisation may be commercially viable for larger label quantities.

Steam sterilisation within local hospital facilities may be appropriate, but there are several issues with the process:

- Print dye may ‘gas’ during heat treatment.
- Print dye may be affected by steam.
- Adhesive properties may be lost.

Ethylene oxide (EO) has the following advantages:

- It is highly unlikely to affect the condition of the labels.

- Header bags will not become brittle and will remain sealed and peelable to open after sterilisation.

Gamma irradiation is an ideal method of sterilisation for paper products. However, for the small-scale pilot, this method was not viable for the following reasons:

- Packaging – certain plastics become brittle after gamma irradiation. Knowledge of the tolerance and acceptability of plastic packaging components following gamma irradiation is required.
- Radiation levels – the correct amount of gamma irradiation to achieve a sterile product requires calculation.
- Testing – a test sterilisation of sample labels and packaging is necessary before proceeding with a full-scale operation.

Q7.4 How are labelled containers handled after a procedure?

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.

7.4.1 Disposable containers

Health facilities that use disposable containers may use, but do not require, 'peel-off' labels.

7.4.2 Reusable containers (e.g. stainless steel hollowware)

Use labels with peel-off adhesive that attaches throughout the procedure, but can be removed completely at the end of the procedure.

For these containers to be cleaned and resterilised, the preprinted and abbreviated container labels must be completely removed without leaving a residue. Evaluations of label adhesion to reusable hollowware containers have been conducted, with results and outcomes presented in Report 1 [PDF 740KB] and Report 2 [PDF 1.5MB].

Solvents such as alcohol (swabs/solutions) and eucalyptus oil may assist adhesive removal. However, these products are flammable and must be used sparingly with care 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.

The time taken to remove adhesive residue is comparable to the time taken to remove blood products and preparation solutions such as povidone–iodine. Adhesive residue removal is an integral part of the cleaning process and should not disproportionately affect time and cost.

8 Special situations

Q8.1 How should labels be applied in an emergency?

The Labelling Standard should be applied in all situations as far as practically possible. However, it is not always practical to identify injectable medicines according to the Labelling Standard when the patient and health professionals may be in an immediate life-threatening situation. Labels designed for use on syringes used during anaesthesia, as per the Anaesthetic Labelling Standard, may be considered to identify the medicine contained in syringes.

The following situations are exempt from labelling in all circumstances, including emergency:

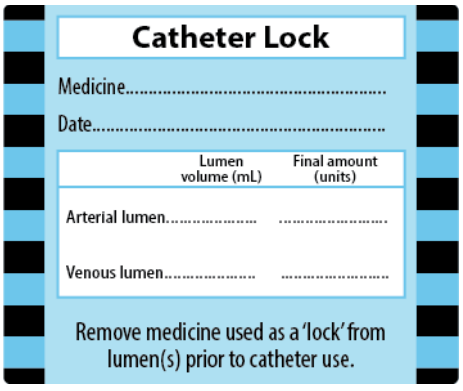
- when a single person draws up and immediately administers a medicine without the syringe leaving the hand
- when fluid bags used for infusion do not have any additional injectable medicines added before administration, such as IV fluids (e.g. 0.9% sodium chloride, 5% glucose) or premixed solutions (e.g. potassium, heparin infusion bags).

Use of preprinted active ingredient labels, consistent with the Anaesthetic Labelling Standard, may be suitable for ambulance services. However, these are not suitable if the patient identity needs to be recorded.

Q8.2 What labelling is required in renal dialysis?

Dialysis catheters should be labelled with the 'Catheter lock' label to identify the medicine in the catheter. This includes a renal dialysis catheter used for haemodialysis.

Catheter lock label



The dialysis catheter is generally 'heparin locked' to maintain patency. Any medicine in the dialysis catheter lock must be removed before use. There is a potential risk of infusing heparin in large doses, resulting in over-anticoagulation, if heparin is not removed from the lock before dialysis. Alteplase may be used as an alternative to heparin to maintain patency. Other medicines may be introduced into the dialysis catheter, including antibiotics and urokinase.

8.2.1 Should syringes containing medicines for haemodialysis cannulation be labelled?

Commonly, sodium chloride and lignocaine are used during the cannulation procedure. This procedure follows the principles of aseptic technique.

Syringe labelling will not be required if each drug is drawn up and administered one at a time without leaving the operator's hand. That is, draw up and administer lignocaine, then draw up and administer 0.9% sodium chloride to flush.

Syringes should be prepared and labelled sequentially. Prefilled sodium chloride syringes and lignocaine syringes are beneficial for this procedure.

8.2.2 How is dialysate labelled when additives are introduced?

The dialysate is a combination of electrolytes, bicarbonate and water that crosses by diffusion from patient to dialyser and vice versa. The dialysate container is identified by a manufacturer's TGA-approved label. Use the blue container label marked 'For IntraVENOUS Use Only' when additives are introduced to the original manufacturer's container.

8.2.3 How should we label medicines given via the extracorporeal route in patients undergoing haemodialysis?

Medicines such as intravenous heparin, iron and antibiotics are sometimes given via the extracorporeal circuit as an infusion, and have the same minimum labelling requirements as every other clinical setting.

Q8.3 Are blood products included in Labelling Standard?

Blood components are not specifically referenced in the Labelling Standard. However, blood products are injectable fluids and should be identified if they are removed from their original container for patient administration. Refer to the Australian and New Zealand Society of Blood Transfusion for information on administration of blood products.

Q8.4 Does the Labelling Standard extend to dental health?

Yes. Any situation in which injectable medicines and fluids are used requires identification.

Q8.5 Can the burette label be used as a temporary syringe label?

Yes, a burette label can be written and applied to a syringe when a medicine is drawn up into a syringe intended for introduction to a burette. When the contents of the syringe are placed into the burette, the burette label should then be removed from the syringe and placed on the burette. It has been suggested that two labels would not make this process inherently safer. The syringe should not be labelled with a burette label in any other circumstance.

Q8.6 How are radiopharmaceuticals labelled?

Radiopharmaceuticals can be labelled on the lead casing (secondary container) that holds the syringe (primary container) that contains the radiopharmaceutical.

It is important to identify the primary container of an injectable medicine, and there are reports of medication error associated with identification of a secondary device (e.g. syringe driver or pump) that remains incorrectly labelled when the primary container is changed.

However, for radiopharmaceuticals, the lead casing enclosing the syringe is of paramount importance for operator safety. Labelling the secondary container allows the content to be identified without unnecessary exposure to the syringe held within the casing.

There is 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. Provided only one encased syringe is opened at any one time, there is no opportunity for a syringe to be inadvertently placed in a different casing that could then be incorrectly labelled. Labelling the secondary container and only removing one syringe at one time will provide operator and patient safety.

Q8.7 How are extemporaneously dispensed radiopharmaceuticals labelled?

A strict protocol for extemporaneous dispensing is followed when preparing a radiopharmaceutical. The end product is for a specific patient according to a prescription and is covered by best-practice guidelines for preparation of radiopharmaceuticals. Additional user-applied labelling (container label) is not required, provided the product is not removed from the original container. In this case, the syringe enclosed in the lead casing constitutes the original container (see Q8.6).

In a similar way, injectable medicines and fluids prepared by hospital pharmacy departments are beyond the scope of the Labelling Standard.

Q8.8 Should administration portals be identified?

Labelling of administration portals is not included in the Labelling Standard. It may be impractical and has potential to compromise infection control procedures. However, it is important to:

- verify the route of the administration portal before medicine administration in the absence of labelling
- label the administration portal when the portal is distant from the point of medicine access (e.g. epidural catheter, tunnelled intrathecal catheter).

9 Non-injectable medicines

Q9.1 Why are oral and enteral medicines included in the Labelling Standard?

The Labelling Standard applies to the identification of non-injectable medicines and fluids to be administered via non-injectable routes, such as oral or enteral routes. See Section 7.6 'Non-injectable medicines and fluids' in the Labelling Standard.

Occasionally, it may be necessary to administer medicines enterally via a bag or syringe. Fluids held in these containers have the potential to be administered in error via the parenteral route. Some examples of these types of errors are described in the following case reports.

Case report

A patient complained of sudden onset of flushing and a heavy sensation in their chest after a lung transplant. It was found that oral cyclosporine was given intravenously via a central line (16).

Case report

Approximately 15 mL of diclofenac dissolved in drinking water was administered into a femoral line that was intended for nasogastric administration (16).

Case report

Oral morphine (100 mg in 5 mL) was dispensed into a 5-mL syringe for accurate measure, but was administered intravenously by mistake (16).

To ensure safe delivery of oral and enteral medicines:

- non-injectable solutions must NEVER be given through the parenteral route
- ONLY syringes specifically designed for administration of medicines orally or through other enteral routes (e.g. nasogastric) should be used for these purposes. They should be clearly labelled 'For Oral Use Only', 'For Enteral Use Only', etc.
- syringes used for non-injectable solutions must NOT be compatible with parenteral entry portals.

Q9.2 Why are inhalational medicines included in the Labelling Standard?

The Labelling Standard applies to the identification of non-injectable medicines and fluids to be administered via inhalation. See Section 7.6 'Non-injectable medicines and fluids' in the Labelling Standard.

Occasionally, it may be necessary to draw up a medicine intended for nebulisation into a syringe before placing it in the nebuliser. For example, salbutamol is most often supplied in nebules; however, bottled solutions are available that require an amount to be withdrawn into a syringe before being placed in the nebuliser. Fluids held in these syringes have the potential to be administered in error via the parenteral route.

Case report (unpublished)

Hydrocortisone, ipratropium and salbutamol intended for inhalation via nebuliser were drawn up into three separate syringes and placed in a kidney dish. None of the syringes were labelled. The medicines were all administered intravenously to a patient. The patient subsequently recovered after treatment in intensive care.

10 Label procurement

Q10.1 Does label quality differ between suppliers?

Label quality will depend on the paper stock. This is not specified in the Labelling Standard, but it is expected that labels will be printed on paper stock of sufficient quality to be durable and fit for purpose. In addition, the paper finish must be suitable to accept handwriting. Ensure the paper stock from an individual supplier is appropriate, and obtain samples before placing an order.

For the perioperative sterile field, label stock may need to be synthetic to ensure the label is fit for purpose. Exposure to fluids requires the quality of the label stock used on the sterile field to be suitable. The following requirements must be met for the duration of the procedure:

- label remains intact
- label remains adhered to the container
- writing remains legible.

Health services are requested to check paper quality and obtain samples before placing an order.

Q10.2 Does adhesive strength vary?

Yes, adhesives come in different strengths. All labels – with the exception of the burette and abbreviated container label for use on reusable containers – must adhere to and remain adhered to the container and line after application. There is no reason for these to be removed. Indeed, for containers, the labels must remain in place for audit purposes.

The burette labels and abbreviated container labels for use on reusable containers need to be removed and should be ordered with adhesive designed for this purpose.

Q10.3 Do custom procedure pack labels need to comply with the Labelling Standard?

Suppliers of custom procedure packs may include labels to identify route of administration and medicines used on the sterile field (e.g. operating rooms and cardiac catheter laboratories). Any labels intended for user-applied labelling should comply with the Labelling Standard.

If you represent a label manufacturer or supplier of custom packs containing labels and require further information on the Labelling Standard, please contact mail@safetyandquality.gov.au

See Section 4.6 ‘Minimum requirements for labelling containers in the open-practice environment’ and Section 4.7 ‘Minimum requirements for labelling containers in the closed-practice environment’ in the Labelling Standard.

Q10.4 Should labels supplied with pharmaceutical products comply with the Labelling Standard?

Yes, all labels intended for user-applied labelling should comply with the Labelling Standard. This includes labels supplied with pharmaceutical products to be completed and applied by the user at patient administration.

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