Government of **Western Australia**
Department of **Health**

OPERATIONAL DIRECTIVE

Enquiries to:	Dr Amanda Ling	**OD/IC number:**	OD 0350/11
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Subject: **UPDATED: NATIONAL RECOMMENDATIONS FOR USER-APPLIED LABELLING OF INJECTABLE MEDICINES, FLUIDS AND LINES**

Superseded by OD 0385/12

AMENDMENT TO OD0332/11:

The Australian Commission on Safety and Quality in Healthcare have provided feedback regarding WA modifications to the National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (Labelling recommendations), identified in Operational Directive 0332/11.

In light of the Commission's feedback the WA Department of Health has amended Operational Directive 0332/11 to align with the national recommendations with respect to label size and layout. WA modification relating to label size and attachment 2:Visual guide to label size have been removed from the Operational Directive, with WA Hospitals to comply with label sizes identified in the national labelling recommendations .

WA modification to the label stippling of beige, blue and red labels addresses an identified safety issue with readability, and as such this modification remains a part of the WA Operational Directive.

Hospitals are required to comply with the national recommendations (including the WA modification identified in this Operational Directive) by March 31 2012.

The information below is as per the previous Operational Directive with the removal of the modification related to label size.

On 12 November 2010 Australian Health Ministers noted and approved the Australian Commission on Safety and Quality in Health Care (ACSQHC) *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (*Labelling Recommendations*)* for implementation in Australian Hospitals.

All WA public hospitals and health care facilities are required to commence implementation of the minimum requirements (see p2) set out in the Labelling Recommendations immediately.

User applied labels used within WA public hospitals and health care facilities must comply with the national recommendations (including WA modification identified in this Operational Directive) by **March 31 2012**.

1. ACSQHC. National Recommendations for User-applied labelling of Injectable Medicines, Fluids and Lines.

BACKGROUND

Labelling is a recognised risk in the safe administration of injectable medicines. Preparation of injectable medicines for bolus injection or infusion is complicated with multiple opportunities for error. Labelling of injectable medicines is often not done or incomplete, omitting information such as name of medicine, medicine dose, patient name or time of preparation [1].

It has been shown that errors in injectable medicine administration are less likely to occur when a single person is responsible for preparing and labeling each injectable medicine, and that medicines in well labelled syringes are more likely to have been prepared correctly.[1]

THE LABELLING RECOMMENDATIONS

The Labelling Recommendations were developed by the ACSQHC to (a) assist health care professionals to identify the correct medicine and/or fluid and its correct administration route/conduit at all times, and (b) set out requirements for label inclusions and label placement.

The Labelling Recommendations address one recognised risk point in the safe administration of injectable medicines and complement other facets of safe medicines practice, building on the Australian Standard® (AS 4940 – 2002): User-applied identification labels for use on fluid bags, syringes and drug administration lines.

The Labelling Recommendations were developed in consultation with all states and jurisdictions, and are strongly endorsed by the WA Therapeutic Advisory Group (WATAG) and the WA Medication Safety Group (WAMSG). They are also supported by the Australian New Zealand College of Anaesthetists (ANZCA).

Adherence to the Labelling Recommendations will minimise preventable medication administration errors (such as wrong route, wrong medicine, wrong dose and wrong patient) and improve safe medicine use.

Minimum Requirements:

The following minimum requirements defined by the Labelling Recommendations (page 2) are to be implemented across WA Health:

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

* Specifications for printing labels are outlined below.

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LABELLING MEDICATIONS USED FOR ANESTHAESIA

The Labelling Recommendations' scope does not include labelling injectable medicines drawn up in SYRINGES for use during ANAESTHESIA. For labelling instructions in these situations, WA health professionals, public hospitals and health care facilities are to comply with the Australian / New Zealand Standard®: User-applied labels for use on syringes containing drugs used during anaesthesia (AS/NZS 4375).

AS/NZS4375 is available from the WA Health library service or respective hospital libraries. These standards specify size and wording of labels as well as recommended standardised colour codes for ease of recognition of medications used in the perioperative setting.

The Labelling Recommendations apply to the user-applied labelling of containers and conduits for any medicine or fluid in the perioperative area where AS/NZS 4375 is not applicable. Use of the Labelling Recommendations and AS/NZS 4375 does not preclude health services and clinical teams from using other strategies that reduce the risk of error in the perioperative setting (for example, using the colour red on syringes to differentiate IV muscle relaxants).

POTENTIAL ERRORS RELATED TO ORAL / ENTERAL SOLUTIONS

There is a recognised risk of serious medication errors resulting from accidental parenteral administration of solutions intended for an oral / enteral delivery. Whilst this operational directive addresses the labelling of injectable medicines, fluids and lines, WA Hospitals are to ensure strategies are in place that address the risk of non injectable solutions being given via the parenteral route.

ACCESSING THE LABELLING RECOMMENDATIONS

The Labelling Recommendations are attached and can be accessed at:
http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06_UaLIMFL

IMPLEMENTATION RESOURCES

A range of support materials, resources and tools to assist in implementation of the Labelling Recommendations have been developed, including:

- An Implementation Guide, Explanatory Notes and a Slide Presentation:
  http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06_LabRec-SupMat
- A series of posters:
  http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06_LabellingPosters

PRINTING SPECIFICATIONS

The recommended labels can be accessed in EPS (for professional printing) format here:
http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06_LabellingRecommendations

Specifications for printing the necessary labels are available on page 20 of the Labelling Recommendations. WA health services and hospitals must follow these specifications, including WA modifications identified below, and advise their printing services accordingly.

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WESTERN AUSTRALIAN MODIFICATION TO THE LABELLING RECOMMENDATIONS

Stippling to Beige, Blue and Red Labels

The Labelling Recommendations specify a 70% stipple (70% shade of the labels primary colour) to the background of container, conduit and line labels.

Following feedback regarding the legibility of written information on certain coloured labels, **beige** (subcutaneous), **red** (intra-arterial) and **blue** (intravenous) container, conduit and line labels used in Western Australia will employ a stipple of 50% to the background area (the area inside the border) of the label. Border colours must not be altered from those specified in the Labelling Recommendations.

AUDIT AND EVALUATION

It is highly recommended that compliance with the Labelling Recommendations be audited, including pre- and post-implementation audits. To assist health services and clinical teams the following resources are attached:

1. A sample audit tool. Sites are encouraged to adapt the tool to suit their local requirements.
2. Suggested content for a staff survey on adherence to labelling protocols, and awareness, implementation and adherence to the Labelling Recommendations. This survey can be carried out using tools such as Survey Monkey (www.surveymonkey.com).

ISSUES REGISTER

The Office of Safety and Quality in Healthcare will maintain an issues register regarding the Labelling Recommendations.

These may be notified via email: safetyandquality@health.wa.gov.au

Attachments:

1. Australian Commission on Safety and Quality in Health Care *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines.*
2. Sample Labelling Recommendation audit tool.
3. Sample staff survey questions.

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This information is available in alternative formats upon a request from a person with a disability.

Superseded by OD 0385/12

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

August 2010

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTHCARE

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

Incorporating recommendations for labelling of (1) injectable medicines and fluids (bags, bottles and syringes) and (2) conduits (administration lines, invasive monitoring lines, catheters and burettes) where these labels are applied by the user at the point of patient delivery to identify medicines which can no longer be identified by their original packaging.

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Executive Summary

Labelling of injectable medicines and fluids, and the devices used to deliver these, has been identified as a patient safety issue. Safe use of medicines is a key component of Quality Use of Medicines (QUM), which forms part of Australia's National Medicines Policy.[1] QUM involves judicious selection of treatment options (including no treatment), appropriate choice of medicine when medicine is required and safe and effective use of medicines.[1]

The National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (*Labelling Recommendations*) aim to enhance patient safety with clear, practical labelling and identify:

- **What should be labelled**
- **What should be included on the label**
- **Where the label should be placed**

Aims

The *Labelling Recommendations* aim to assist health care professionals to identify the correct medicine and/or fluid at all times (container) and the correct route of administration of that injectable medicine (conduit) (Figure 1, page 5). They also set out requirements for label inclusions and label placement. The *Labelling Recommendations* should assist in preventing medicine administration errors, e.g. wrong route, wrong medicine, wrong dose, and improve safe medicine use in relation to injectable medicines and fluids.

These *Labelling Recommendations* for user-applied labelling of injectable medicines, fluids and their lines address one recognised risk point in the safe administration of injectable medicines and apply alongside other facets of safe medicines practice. The *Labelling Recommendations* aim to:

1. Promote safer use of injectable medicines
2. Provide standardisation for user-applied labelling of injectable medicines
3. Provide minimum requirements for user-applied labelling of injectable medicines (see below)

Minimum Requirements

The *Labelling Recommendations* define the following minimum requirements:

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

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Introduction

Labelling is a recognised risk in the safe administration of injectable medicines. Preparation of injectable medicines for bolus injection or infusion is complicated with multiple opportunities for error.[2] Preparation of a syringe for bolus injection is a recognized weak step in intravenous (IV) therapy[2] and has been estimated to have as many as 41 discrete steps,[3] while preparation of medicines for infusion may take 10 times longer than the preparation of a syringe for bolus injection.[4]

Labelling of injectable medicines is often not done or incomplete, omitting information such as name of medicine, medicine dose, patient name or time of preparation.[5-11] In the majority of cases actual harm to patients is limited by routine checking of infusions and prescriptions at handover.[11] However, harm and death from medicine administration errors as a result of inadequate labelling is an issue across the world.

In operating rooms there are problems in labelling injectable medicines prior to patient transfer[12, 13] and poor and inconsistent labelling of injectable medicines on the sterile field.[14, 15] Medicine labelling is a contributor to the frequent errors related to administration of injectable medicines in anaesthetic practice.[16-19]

Medicine swaps related to non-labelling of containers holding an injectable medicine have been reported. Medicine swaps with fatal consequences have involved mix-ups between contrast media and chlorhexidine,[14] glutaraldehyde and spinal fluid,[14] lignocaine with adrenaline and adrenaline 1 mg/mL,[20] and pethidine and syntometrine.[21] Other medicine swaps have been reported between bupivacaine with adrenaline and adrenaline 1 mg/mL,[7] botulinum toxin and triamcinolone,[22] 0.9% sodium chloride flush and heparin for infusion,[23] heparin 25000 units in 5mL and 'heparinised saline' 50 units in 5mL.[24] In particular, problems have arisen where an unlabelled syringe was assumed to be a 0.9% sodium chloride flush. Reports of medicines given with the assumption they were 0.9% sodium chloride include aminophylline,[7] midazolam[25] and vecuronium.[26]

Non-labelling of injectable medicines has contributed to wrong route administration, sometimes with fatal consequences.[20] The identification of lines that may be used for medicine administration is often also overlooked. In one case, oxygen tubing was accidentally connected to an intravenous line in a paediatric patient with a fatal outcome,[27] while in another case contrast media was administered into an arterial line with no long term sequelae.[28]

Non-labelling has resulted in medicines being given to the wrong patient. In one case, an unlabelled bag containing magnesium sulfate was given to a patient who already had an existing bag of magnesium sulfate running. The patient had a respiratory arrest and developed anoxic encephalopathy.[29] In a similar case, a nurse was preparing fluids for maintenance and fluids with 40 mg of magnesium sulfate added at the same time for two different patients. The nurse accidentally placed the additive label on the wrong bag and gave the magnesium sulfate bag instead of maintenance fluids to a patient who already had a bag of magnesium sulfate running. The patient died.[29]

Incidents in Australia mirror closely the types of incidents reported internationally. In one case, a newborn died following a mixup of unlabelled syringes when syntometrine was accidentally given to the labouring mother instead of pethidine.[21] Other data shows problems with labelling infusions prior to transfer from the operating room.[13] Reviews of incidents reported in the Australian Incident Monitoring Study (AIMS) have identified medicine labelling problems as a contributory factor to administration errors.[16, 17] An unpublished review of incidents reported by public hospitals to an incident management system database from 2003 to September 2009 found a number of incidents regarding injectable medicines. Reported incidents related to a range of problems including unlabelled or incorrectly labelled bags or syringes, assumption that unlabelled syringes/bags are 0.9% sodium chloride, unlabelled insulin administration devices, lines not labelled for route of administration, lines not labelled or incorrectly labelled for drug content, labels placed incorrectly, and no burette labels applied. It was noted that problems with labelling of injectable fluids, medicines and lines are often identified at points of transition of care when a different staff member assumes care for the patient.

A survey conducted in over 1000 nurses by the American Nurses Association showed 68% of nurses felt more consistent syringe labelling would reduce medicine administration errors.[5, 6] A number of international organisations (including the World Health Organization,[30] National Patient Safety Agency in the United Kingdom, [24, 25, 28, 31-34] the Joint Commission in the United States,[35, 36] and the Institute for Safe Medication Practices in the United States[7, 14, 27, 29, 37-39] and Canada[20, 40, 41]) and individual

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researchers[11, 42-44] have made numerous recommendations regarding safe labelling practices, including the recommendation to standardise labelling of injectable medicines and administration lines. In support of recommendations for safe and standardised labelling practices it has been shown that errors in injectable medicine administration are less likely to occur when a single person is responsible for preparing and labelling each injectable medicine,[9] and that medicines in well labelled syringes are more likely to have been prepared correctly.[45]

Development Process

Draft Labelling Recommendations *(August 2008)* were developed by a Working Group of NSW Therapeutic Advisory Group (NSW TAG) Safer Medicines Group. On the basis of this draft, the *Labelling Recommendations* have been further developed within the 'National Injectable Medicines Labelling Project' by NSW TAG, supported by the Australian Commission on Safety and Quality in Health Care (ACSQHC), for implementation at a national level.

An Advisory Committee (Appendix 3c), representing the interests of key clinical groups, was established in February 2009 to oversee and support the development of the *Labelling Recommendations* for national uptake, including the implementation plan and accompanying education materials.

As part of the development process, national consultation was undertaken involving all State and Territory health departments, all Australian Safer Medicine Groups and 13 professional bodies within Australia (Appendix 3d). The consultation informed a review of the *Labelling Recommendations* prior to their testing in public and private facilities across Australia in metropolitan and rural areas. Twelve clinical areas, each representing a different environment (Appendix 3e), took part in testing to determine the final set of *Labelling Recommendations*.

Recommendations in this document have been derived from a number of sources. Firstly, a number of recommendations are based on those made by national and international organisations (including published case reports) and these have been referenced throughout. Secondly, a number of recommendations have been derived from unpublished incidents as described above. These cannot be referenced but full details are provided in the 'Explanatory Notes' as part of the supporting educational material. Thirdly, recommendations have been derived from the experience of the expert Advisory Committee and the pilot testing process. Reasons underpinning these recommendations are explained fully in the supporting educational material.

The development process has raised a number of further issues relating to labelling practice. It has not been possible to progress these issues within the scope of the project but they are described to prompt further research and practice change to promote safe use of medicines (Extending the *Labelling Recommendations* to Improve Practice, page 13).

The *Labelling Recommendations* have been developed with consideration of the Australian Standard relating to user-applied labels for injectable medicines - AS 4940: User-applied identification labels for use on fluid bags, syringes and drug administration lines.[46, 47]

The Standard specifies dimensions, colour, border design and adhesive qualities of the labels. During the development and pilot testing of the *Labelling Recommendations* in the clinical setting, modification of these specifications became evident.

A second Australian Standard sets out requirements for labels attached by the user to syringes used during anaesthesia: AS/NZS 4375: User-applied labels for use on syringes containing drugs used during anaesthesia.[48] The *Labelling Recommendations* complement and do not replace the use of AS/NZS 4375 in the anaesthetic environment.

See Appendix 2 for further information regarding these Standards.

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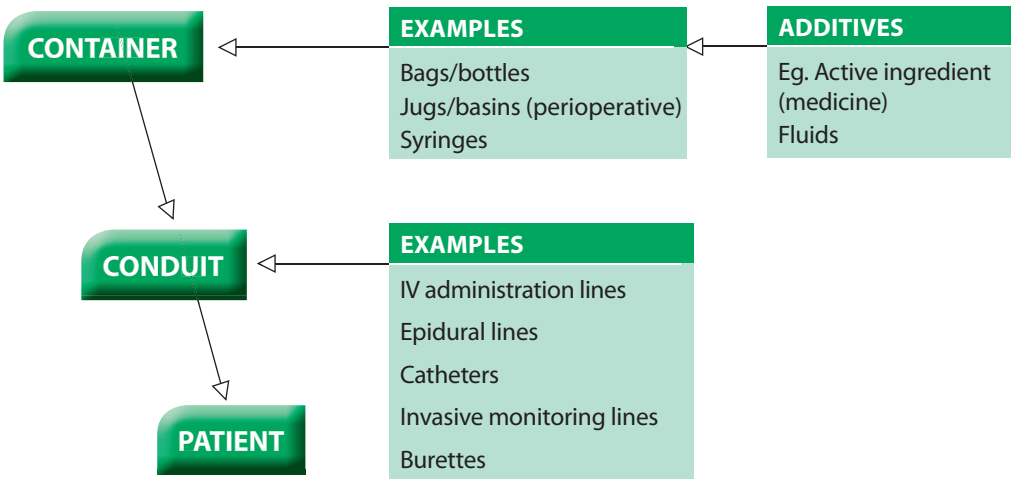
Scope

1. The purpose of the *Labelling Recommendations* is to enhance 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. The *Labelling Recommendations* identify:
   - What should be labelled
   - What should be included on the label
   - Where the label should be placed.
2. The *Labelling Recommendations* apply to ALL clinical areas within Australia where injectable medicines and fluids are administered.
3. The *Labelling Recommendations* apply to ALL injectable products prepared in the ward or clinical area and include recommendations for labelling containers and conduits (Figure 1).

Figure 1: Injectable Products and Lines



4. The *Labelling Recommendations* apply to 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 intraocular.[32] Note: This list is not exhaustive. Other routes of injection should be considered in the context of the *Labelling Recommendations*, e.g. intraosseous and intraperitoneal.
5. Appropriate labelling represents one step in the overall process of preventing medicine administration errors associated with injectable medicines. However, they do not obviate the need for other quality and safety processes, including those described under 'Additional Strategies to Improve Medicine Administration Safety' (page 12).
6. The *Labelling Recommendations* do **NOT** apply to enteral, topical or inhalational routes, although the principles translate to these routes of administration (page 13).

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Scope of the *Labelling Recommendations* for:

a) Labelling injectable medicines and fluids in the perioperative area

For recommendations on labelling injectable medicines drawn up in SYRINGES for use during ANAESTHESIA refer to 'The Australian/New Zealand Standard®: User-applied labels for use on syringes containing drugs used during anaesthesia (AS/NZS 4375)'.[48, 49]

The *Labelling Recommendations* (Table 1) apply to the user-applied labelling of containers and conduits for any medicine or fluid in the perioperative area where AS/NZS 4375 is not applicable.[48]

b) Labelling injectable medicines and fluids prepared by hospital pharmacy departments

Labelling of injectable medicines and fluids prepared by hospital pharmacy departments must comply with the National Coordinating Committee on Therapeutic Goods (NCCTG) 'Standard for the Preparation of Pharmaceuticals in Australian Hospital Pharmacy Departments'[50] and practice guidelines developed by the Society of Hospital Pharmacists of Australia.[51, 52]

c) Labelling injectable medicines and fluids prepared by external manufacturers or compounding centres

Injectable medicines sourced from an external compounding centre or manufacturer (e.g. cytotoxic preparations, pre-mixed solutions and pre-filled syringes) must comply with Therapeutics Goods Order 69.[53]

d) Labelling injectable medicines and fluids not directly administered to the patient

The labelling of any container which cannot be used to administer an injectable medicine directly to the patient, e.g. ampoules and individual patient multi-dose vials, is the responsibility of the manufacturer as mandated by Therapeutic Goods Order 69[53] and is outside the scope of these *Labelling Recommendations*.

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General Considerations

Table 1 provides details for labelling injectable medicines, fluids and lines (including label inclusions, selection and placement) and should be read in conjunction with these General Considerations.

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; approval of a range of pre-printed labels; version control; inventory control; procurement; and maintenance of stock levels.
- Availability of a full range of pre-printed labels supported by the *Labelling Recommendations* is fundamental to the implementation of the *Labelling Recommendations*. Stock levels of pre-printed labels must be established and maintained in all clinical areas according to the requirements of that area.

2. LABELLING CONTAINERS OF INJECTABLE MEDICINES

a) General considerations for labelling ALL containers of injectable medicines (e.g. bags and syringes):

Expressing total amount, volume and concentration

- The TOTAL amount of active ingredient (medicine name) added to the bag or syringe must be identified, including units (e.g. mg).
- The TOTAL volume of fluid contained in the bag or syringe must be identified in millilitres (mL).
- The concentration (units/mL) must be identified.
- Expressing medicine concentration as a ratio (e.g. 1;1000, 1:10,000) is UNACCEPTABLE and a recognised source of medicine administration error.[56, 57]

Colour coding for route of administration

- Figure 2 explains a standardised colour system applied in the *Labelling Recommendations* to help match the container or conduit to the route of administration based on target tissue (modified from AS 4940).[46, 47]
- The primary means of identification of route of administration for fluid bags, syringes and lines is by text. Colour coding ASSISTS in matching containers and conduits with the same route of administration. However, colour coding is a relatively weak safety factor[58-60] and does NOT replace text as the primary means of identification.

Figure 2: Colour coding of user-applied labels for target tissue (modified from AS 4940[46, 47])

TARGET TISSUE	ROUTES OF ADMINISTRATION	COLOUR	PANTONE MATCHING SYSTEM (PMS)
Intra-arterial	Intra-arterial	Red	1787
Intravenous	Intravenous	Blue	2985
Neural tissue	Epidural / Intrathecal / Regional	Yellow	Pantone Yellow
Subcutaneous tissue	Subcutaneous	Beige	723
Miscellaneous	Other routes	Pink	806

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Process of medicine and label preparation

- Each injectable medicine drawn up in a bag or syringe should be prepared and labelled as a single operation by the same person.[61, 62]
- The Medication Safety Self Assessment® for Australian Hospitals recommends preparation and labelling of medicines for paediatrics/neonates, chemotherapy and selected high risk medicines should be independently checked by a second person who signs the label.[63]

Label placement

- The pharmacy or manufacturer's labelling of product name, batch number and expiry date must remain visible after the label has been applied.[64]
- A duplicate label should be applied to any over wrapper (i.e. outer wrapper) which does not allow clear visibility of the primary label attached to the bag or syringe.

b) Additional considerations for labelling fluid bags (and bottles):

- All bags (and bottles) should be labelled IMMEDIATELY an injectable medicine is added.
- Bag additive labels should be placed on the FRONT of the bag in a way that ensures the name of base fluid, batch number and expiry date remain visible.[64]
- These recommendations should be cross referenced to local, institutional or health service based policies on the use of pre-mixed intravenous injections, e.g. pre-mixed intravenous potassium chloride, heparin, magnesium, amino acids and chemotherapy.

c) Additional considerations for labelling syringes:

- All injectable medicines drawn up in a syringe (that 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.[14, 32, 35, 64, 65]
- Any fluid drawn up to be used as an IV flush (e.g. 0.9% sodium chloride) MUST be labelled unless 'special circumstances' apply (See 'Special Circumstances').[7, 25, 26]
- If multiple syringes are required, they should be prepared, labelled and administered sequentially as independent operations.[41, 65]
- Place the label parallel to the long axis of the syringe barrel with the top edge flush with (but not covering) the graduations.[7, 64]
- When application of the entire label to the syringe is impractical (e.g. small syringes), apply label as a 'flag' (see Glossary of Terms).

d) When to discard containers of injectable medicines

- Any unlabelled syringe (or other container) containing a solution must be immediately discarded.[7, 14, 36]
- Any syringe (or other container) where there is doubt regarding its content must be discarded.[7, 14, 36]
- Any medicine remaining in the syringe (or other container) at the end of a procedure must be discarded.[7, 14, 36]

e) Special Circumstances

- Labelling is not required when 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 and that same person administers the medicine IMMEDIATELY. [32, 64, 65]
- Provision for signatories is not required on the label where other means of recording labelling and preparation are available.
- The patient name and identifier are not required when a SINGLE patient is receiving an injectable medicine, there is NO possibility that the identification of the patient is unknown and the medicine is prepared in the presence of the patient.
- Where injectable medicines are drawn up in a syringe for immediate emergency use (e.g. during resuscitation), standard operating procedures in emergency care should ensure that the principles

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in the *Labelling Recommendations* are followed to the extent possible. Pre-printed active ingredient (generic medicine) labels from AS/NZS 4375 should be considered[48].

3. LABELLING CONDUITS (LINES AND CATHETERS)

a) Additional consideration for labelling burettes:

- All burettes should be labelled IMMEDIATELY an injectable medicine is added.
- Use 'peel-off' labels reserved for use on burettes ONLY (see Table 1).
- Place label so that text is upright and ensure that the burette graduations are not obscured.
- Burette labels must be removed once the medicine has been administered to the patient.

b) Labelling administration lines and catheters to identify route:

- The route of administration must be identified on all administration lines.[27, 66, 67]
- The date and time that the line is required to be changed must be identified.
- Labels should be colour coded according to target tissue (see Figure 2).
- Catheters (e.g. epidural, intrathecal) must be identified where there is a risk of wrong route administration (e.g. where the patient entry portal is distant from the administration site). [28, 30, 33, 38, 40, 41]

c) Labelling invasive monitoring lines to identify route:

- All lines must be identifiable, including those where the primary purpose of the line is not for medicine administration.[28]
- The date and time that the line is required to be changed must be identified.
- Labels should be colour coded according to target tissue (see Figure 2).

d) Labelling lines to identify active ingredient (medicine)

- Administration lines dedicated for continuous infusions must be labelled to identify the active ingredient within the line.

e) Additional considerations for labelling lines

- Label near the injection port on the patient side.
- Place label far enough from the injection port to:
  - Prevent interference with the mechanics of bolus administration.
  - Prevent introduction of infection.
- Exception: For paediatrics and patients that may tamper with label; place label near container.

4. LABELLING IN DIFFERENT CLINICAL SETTINGS

a) Labelling on the sterile field

- All medicine containers, including jugs, basins and syringes, should be labelled according to the *Labelling Recommendations*.[14, 20, 36, 41, 68]
- Container/conduit labels to be used on the sterile field must be packaged and sterilised.
- Sterile markers must be made available on the sterile field.[14, 20, 41]
- All labelled containers on the sterile field must be discarded after the procedure.

b) Labelling at transitions of care

Particular attention to compliance with the *Labelling Recommendations* is sought for:

- Labelling when care of patient (including medicine administration) is transferred during or between shifts in a single clinical area.
- Labelling on transfer of patients from one clinical area to another.
- Preparation of injectable medicines for use 'en route' from one clinical area to another.

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Labelling Recommendations

Table 1: Labelling requirements for containers (e.g. bags, syringes, basins and jugs) and conduits (e.g. lines, catheters and burettes).

Minimum requirements for user-applied labelling of injectable medicine containers and conduits where the contents can no longer be identified by the original packaging.

WHAT SHOULD BE LABELLED	LABEL INCLUSIONS	SAMPLE LABEL(NOT TO SCALE) (See Appendix 1: Label Guide and Specifications for full complement of available labels)	LABEL PLACEMENT
Containers			
Bags and bottles for infusion where injectable medicines are added in the clinical area prior to administration **Syringes** for bolus use or infusion filled by drawing up injectable medicine/s from the manufacturer's original container in the clinical area prior to administration	> Patient name (given name and family name) > Patient identifier (ID), e.g. URN, MRN > Active ingredient/s (medicine/s) added to the bag or syringe > Amount of medicine/s added (including units) > Volume of fluid (mL) - total 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)	For IntraVENOUS Use Only Patient ..... ID ..... Medicine/s | Amount (units) ÷ Volume (mL) = Conc (units/mL) Diluent ..... Date ..... Prepared by ..... Time ..... Checked by ..... Label available in two sizes: 100 x 60mm and 60 x 50mm	**Fluid bags and bottles** > Place on front of container. Ensure fluid, batch number and expiry date remain visible.[64] **Syringes** > Place parallel to the long axis of the syringe barrel with the top edge of the label flush with (but not covering) the graduations.[7,64] > Choose label size and placement to ensure label content is visible on a syringe in a syringe driver or pump > Consider flagging labels on small syringes.
Fluid bags and bottles for infusion where no additional injectable medicines are added prior to administration, e.g. intravenous fluids (e.g. 0.9% sodium chloride, 5% glucose), pre-mixed solutions (e.g. potassium, heparin infusions) and peritoneal dialysis fluids **DO NOT** require additional labelling. Syringes pre-filled for bolus use or infusion labelled by manufacturer or hospital pharmacy **DO NOT** require additional labelling.			
Syringes containing 0.9% sodium chloride for the purpose of flushing a line	> Pre-printed 0.9% sodium chloride label	0.9% Sodium chloride	Place parallel to the long axis of the syringe barrel with the top edge of the label flush with (but not covering) the graduations.[7,64]
Containers (e.g. basins, jugs and syringes) on the sterile field where patient identity is established and other means of recording, labelling and preparation signatories are available (e.g. operating rooms).	> Active ingredient/s (medicine/s) added to the container > Amount of medicine/s added (including units) > Volume of fluid (mL) – total in container > Concentration (units/mL)	Medicine ..... Amount (units) ..... Volume (mL) ..... Conc (units/mL)	> Use 'peel-off' labels > Avoid graduations > Avoid pouring spout
In all other circumstances, package and sterilise appropriate container/conduit labels for use on the sterile field.			

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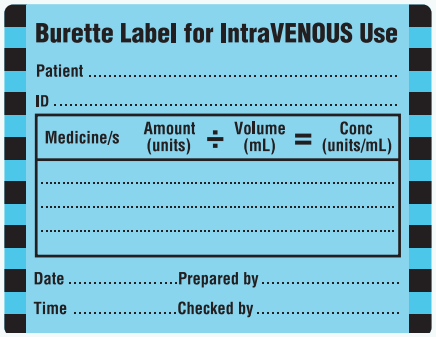
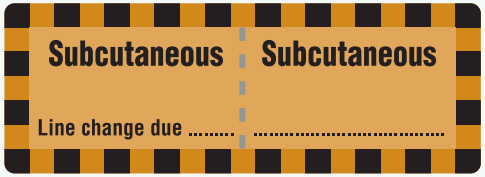
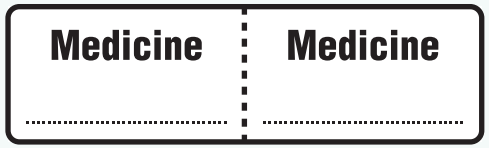
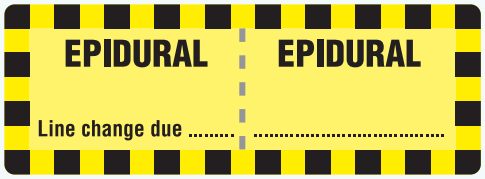
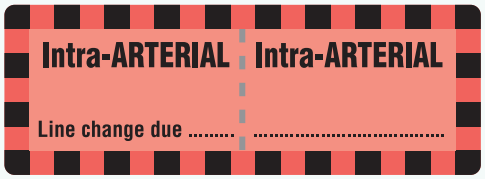
Conduits

Burettes	> The wording 'Burette Label for IntraVENOUS Use" > Patient name (given name and family name) > Patient ID e.g. URN or MRN > Active ingredient (medicine) added to burette > Amount of medicine added (including units) > Volume of fluid added to the burette (mL) > Concentration (units/mL) > Date and time prepared > Prepared by *(signature)* > Checked by *(signature)*		> Use 'peel-off' labels reserved for use on burettes ONLY > A new label is required for each medicine administration > Remove obsolete label before applying new label > Do not obscure the burette graduations with the label > Place label so that text is upright
Administration lines This includes extension lines and giving sets used to deliver fluids and/or medicines into a patient by any parenteral route.	> Route > Line change due		> Label near the injection port on the patient side
	> Active ingredient (medicine) for dedicated CONTINUOUS infusions		> Label near the injection port on the patient side in addition and adjacent to the line route label
Catheters	> Route > Line change due		> Label near the injection port on the patient side
Invasive monitoring lines	> Route > Line change due		> Label near the port on the patient side

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Additional Strategies to Improve Medicine Administration Safety

> The *Labelling Recommendations* do not replace or obviate the need for other clearly defined quality and safety processes relating to the administration of injectable medicines and fluids. The following processes adapted from NHS National Patient Safety Agency (NPSA) Alert Number 20 (28 March 2007), 'Promoting safer use of injectable medicines'[32] should be considered:

- Undertaking risk assessments of injectable medicines procedures and products in all clinical areas to identify high risks, and develop an action plan to minimise them.
- Keeping up-to-date protocols and procedures for prescribing, preparing and administering injectable medicines and fluids, including checking processes.
- Training of all staff involved in prescribing, administering and monitoring of injectable medicines and fluids, including training of those staff that are supervising and checking these processes.
- Assuring timely access to up-to-date technical information on injectable medicines by health care professionals.
- Implementing a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features including 'safe' labelling.
- Undertaking audits of all practices associated with injectable medicines. For example using the Medication Safety Self Assessment for Australian Hospitals.[63] This may be accessed via http://mssa.cec.health.nsw.gov.au/MSSA_introduction.html.

> Abbreviations used on labels should comply with the *National terminology, abbreviations and symbols to be used in the prescribing and administering of medicines in Australian hospitals.*[69]

> Use Tallman lettering to distinguish between instructions that look alike.[64] For routes of administration this will be IntraTHECAL, IntraVENOUS and IntraARTERIAL etc.

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Extending the *Labelling Recommendations* to Improve Practice

- To assist infection control and medicine stability for injectable medicines labelling could include:

  a) Date and time commenced

  b) Expiry date when the medicine is to be used beyond 24 hours

  c) Expiry time when expiration is within 24 hours

  d) Wording 'Do not use after...'[35]
- Labelling of lines to identify route could support infection control by including date/time of line insertion.
- Scheduled 'change' dates and times (including tubing change expiry dates and times) should comply with local policies and be determined by each institution.
- Extension to General Consideration 3d (page 9): Lines used for intermittent infusions may be labelled for medicine content. Labels to identify the active ingredient must be removed on completion of infusion.
- Consider pre-printing line labels to identify the active ingredient (medicine) for commonly used medicines. Note: The use of colour in pre-printed medicine line labels should comply with the colour-coding for medicines in AS/NZS 4375.[48]
- The principles in the *Labelling Recommendations* could be applied to the labelling of syringe pumps. However, labelling of bags/bottles, syringes and administration lines according to the *Labelling Recommendations* is a minimum requirement and labelling of syringe pumps would be in addition to these requirements.
- The *Labelling Recommendations* could be extended to include all solutions, chemicals and reagents used in perioperative units.[14, 36, 41]
- Hospitals and health services are encouraged to procure pre-filled syringes and pre-mixed solutions wherever they are available [e.g. Therapeutic Goods Administration (TGA) 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. Wherever possible, standard strengths of these products should be purchased.
- Consider bar-coding pre-printed labels.
- Consider preparation of surgical packs with sterile markers, blank labels and all anticipated pre-printed labels.

Labelling non-injectable solutions

- Non-injectable solutions must NEVER be given via the parenteral route.
- Some of the principles in the *Labelling Recommendations* apply to the labelling of non-injectable medicines drawn up in syringes to be administered via non-injectable routes such as inhalation, oral and other enteral routes.
- ONLY syringes specifically designed for administration of medicines orally or via other enteral routes (e.g. nasogastric) should be used for these purposes. They should be clearly labelled with 'For Oral Use Only', 'For Enteral Use Only', etc. [64, 70, 71]
- Syringes used for non-injectable solutions must NOT be compatible with parenteral entry portals.[64, 70]

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Glossary of Terms

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.
BOLUS	Administration from a syringe of a small volume of a single dose of a sterile solution directly into a tissue, organ or vein, over a short period, usually, between 30 seconds and 10 minutes.[32]
CATHETER	A tube inserted into a body cavity allowing injection of medicine, including but not limited to: Angiographic catheter Arterial catheter Butterfly cannula Cardiac catheter Central venous catheter Epidural catheter Implantable port (e.g. Port-a-Cath®) Intraperitoneal catheter or port Intrathecal catheter or port Midline catheter Peripheral intravenous catheter (PIV) Peripherally inserted central venous catheter (PICC) Subcutaneous catheter Tenckhoff catheter Tunnelled catheter (e.g. Hickmans®, Broviac®)
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
CONDUIT	Any line or device through which injectable fluids could be administered.
EMERGENCY USE	Administration of medicines in an emergency, i.e. 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 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. cannulae) before and/or after injection of a medicine or between injections of different medicines, e.g. with a sterile solution of diluent, such as 0.9% sodium chloride.[32]
INFUSION	Administration (from a syringe, or other rigid or collapsible container e.g. 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 by other means of rate control, over a defined period of at least 10 minutes.[32]
INJECTABLE MEDICINE	Sterile medicine intended for administration by bolus injection, perfusion or infusion by any of the following routes: Intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intraocular.[32]
LINES	This includes all intravenous giving sets/administration lines/invasive monitoring lines/catheters through which injectable medicines and fluids could be administered.
OPERATING ROOM	The room in which a surgical procedure is undertaken, with or without the administration of an anaesthetic.[72]
PERIOPERATIVE	The period before, during and after an anaesthetic, surgical or other procedure.[72]
PERIOPERATIVE ENVIRONMENT	The service area where the provision of an anaesthetic, surgical or other procedure may be undertaken.[72]
POST ANAESTHETIC RECOVERY UNIT (PARU)	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.[72] Also known as 'Recovery'.
STERILE FIELD	**1** A specified area, such as within a tray or on a sterile towel, that is considered free of microorganisms. **2** 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.

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Appendices

Appendix 1: Label Guide and Specifications

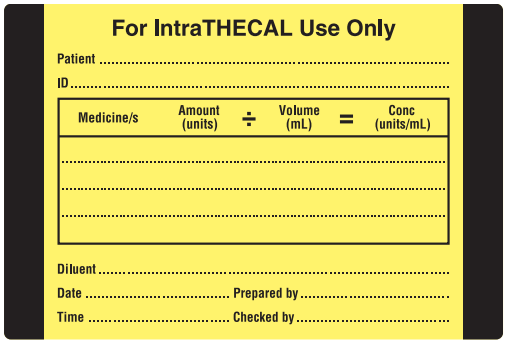
1A. LABEL GUIDE

Containers

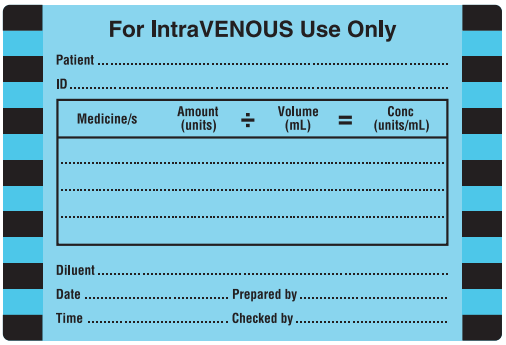
Bag, bottle and syringe labels
Two sizes available: 100mm x 60mm for bags and large syringes (e.g. 50mL) and
60mm x 50mm for syringes and small bags (e.g. 50mL and 100mL)

Route/Label

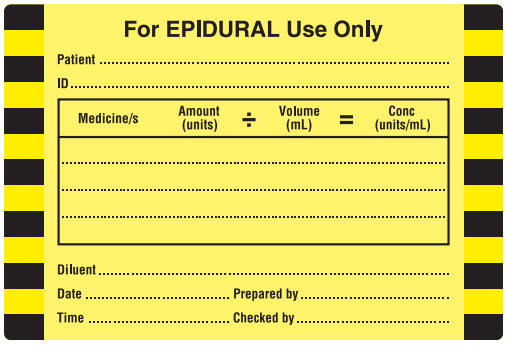
Intrathecal



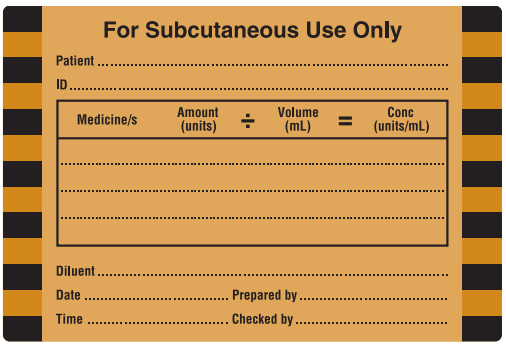
Intravenous



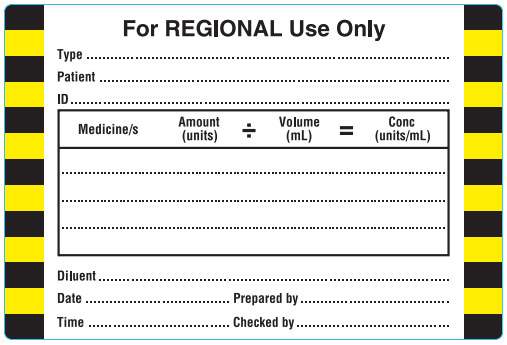
Epidural



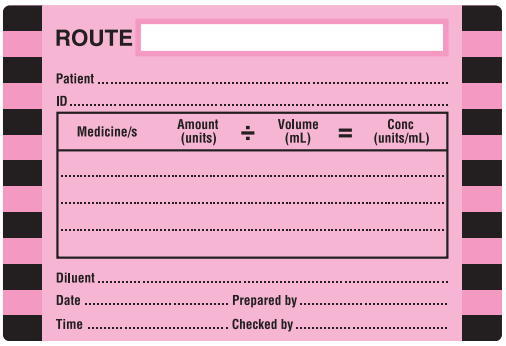
Subcutaneous



Regional



Miscellaneous route



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Additional container labels

0.9% sodium chloride flush

0.9% Sodium chloride

Abbreviated container label

For containers on the sterile field in the operating room where patient identity is established and alternate provision is made for signatories

Medicine .....

Amount (units) ..... Volume (mL) .....

Conc (units/mL) .....

Conduits

Intravenous - Burette

Burette Label for IntraVENOUS Use

Patient .....

ID .....

Medicine/s	Amount (units) ÷	Volume (mL) =	Conc (units/mL)
.....			
.....			
.....			

Date ..... Prepared by .....

Time ..... Checked by .....

Line and catheter labels

Route/Label

Intrathecal

IntraTHECAL	IntraTHECAL
Line change due	.....

Intravenous

IntraVENOUS	IntraVENOUS
Line change due	.....

Epidural

EPIDURAL	EPIDURAL
Line change due	.....

Central venous

CENTRAL VENOUS	CENTRAL VENOUS
Line change due	.....

Regional

REGIONAL	REGIONAL
Line change due	.....

Subcutaneous

Subcutaneous	Subcutaneous
Line change due	.....

Intra-arterial

Intra-ARTERIAL	Intra-ARTERIAL
Line change due	.....

Miscellaneous route

Route	Route .....
Line change due	.....

Medicine/Label

Medicine	Medicine
.....	.....

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1.B LABEL SPECIFICATIONS

Containers

Bag, bottle and syringe labels

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

Additional container labels

Type	Background	Border	Size
0.9% sodium chloride	White	Nil	37mm x 10mm
Abbreviated container label	White	Nil	70mm x 25mm

Conduits

Intravenous -Burette	Blue PMS 2985 with 70% stipple	Black/blue hatched	76mm x 59mm

Line and catheter labels

Route	Background	Border	Size
Intravenous	Blue PMS 2985 with 70% stipple	Black/blue hatched	70mm x 25mm
Central venous	White	Black/blue PMS 2985 hatched	70mm x 25mm
Intrathecal	Pantone Yellow with 70% stipple	Solid black	70mm x 25mm
Epidural	Pantone Yellow with 70% stipple	Black/yellow hatched	70mm x 25mm
Regional	White	Black/Pantone yellow hatched	70mm x 25mm
Subcutaneous	Beige PMS 723 with 70% stipple	Black/beige hatched	70mm x 25mm
Intra-arterial	Red PMS 1787 with 70% stipple	Black/red hatched	70mm x 25mm
Miscellaneous route	Pink PMS 806U with 70% stipple	Black/pink hatched	70mm x 25mm
Medicine	**Background**	**Border**	**Size**
Medicine	White	Nil	70mm x 25mm

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Appendix 2: The *Labelling Recommendations* and Australian Standards

- The *Labelling Recommendations* have been developed with consideration of the Australian Standard relating to user-applied labels for injectable medicines – AS 4940: User-applied identification labels for use on fluid bags, syringes and drug administration lines.[46, 47]
- AS 4940 [46, 47] specifies dimensions, colour (to identify target tissue), borders and background, printing and adhesive qualities of the user-applied labels. The *Labelling Recommendations* supplement the Standard by making recommendations regarding label content and label placement.
- During the development and piloting testing of the user-applied labels according to the AS 4940 [46, 47] modifications were required to assist with implementation in the clinical setting, as outlined below:

1. Dimensions:

- AS 4940 [46, 47]defines dimensions of labels to be applied to bags and another set of dimensions for labels to be applied to syringes. These dimensions did not accommodate the range of the various sized bags and syringes used in the clinical setting, identified during the pilot test. To allow for the selection of a label suitable for the sized syringe or bag being used, identification of specific 'bag' labels and 'syringe' labels has not been retained in the *Labelling Recommendations*.
- The *Labelling Recommendations* include 2 sizes of labels for application to bags and syringes (small: 60 x 50mm and large: 100mm x 60mm). These labels contain the same information and are therefore interchangeable. The label selected for use will be dependent on the size of the bag or syringe. 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. 50mL). For these reasons the *Labelling Recommendations* do not align with the label dimensions requirements of AS 4940.[46, 47]

2. Background and Borders:

AS 4940[46, 47]	LABELLING RECOMMENDATIONS	RATIONALE FOR MODIFICATION
Background colour to be white except for neural route which is to be yellow	Background is coloured (70% of primary colour, see Appendix 1: Label Guide and Specifications)	To increase the visibility of labels applied to fluid bags in the clinical setting, a coloured background has been introduced. This was applied to both labels (small and large). 70% of the primary colour was chosen to allow for readability of label content. A combination of coloured (70% of primary colour) and white backgrounds have been applied to line labels to assist with the differentiation 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.	Use of the same border and background for intrathecal and epidural routes was highlighted as high risk of error due to lack of differentiation in label design. A solid black border has been introduced to assist in the differentiation intrathecal and epidural.
Border to at least 4mm in width	Border at least 3mm in width	The border width was reduced to maximize space for label content
Border to occupy at least 3 sides of the label	Border occupies 2 sides of the label	Border assigned to the lateral sides as to retain the border feature and maximise space available for label content

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3. Use of colour to identify target tissue/route

Use of colour to identify target tissue/route is aligned with AS 4940[46, 47] with the exception of intravenous and miscellaneous (see below).

AS 4940[46, 47]	LABELLING RECOMMENDATIONS	RATIONALE FOR MODIFICATION
Intravenous		
PMS Process Blue	PMS Blue 2985	PMS Blue 2985 was identified as the preferred colour over Process Blue in terms of providing a visible and retaining legibility of label content. (see 2. Background and Borders)
Miscellaneous		
White	PMS Pink 806	Pink was selected as a non-white background to highlight the presence of an additive (see 2. Background and Borders)

4. Printing

Sans serif font has been used, aligned with AS 4940.[46, 47]

The use of Tallman lettering has been introduced to improve readability and differentiation between similar route names (e.g. intraVENOUS and intraTHECAL).

5. Adhesive Qualities

Adhesive qualities of the labels are aligned with AS 4940.[46, 47]

AS/NZS 4375: User-applied labels for use on syringes containing drugs used during anaesthesia[48]

This Standard sets out requirements for labels attached by the user to medicine-filled syringes to identify contents during anaesthesia. These labels are colour coded and document the medicine name.

- AS/NZS 4375[48] is internationally recognised as a standard for colour coding user applied labels for syringes containing injectable medicines used during anaesthesia.
- The *Labelling Recommendations* complement and do not replace AS/NZS 4375.[48]

The AS/NZS 4375[48] is supported by the Australian and New Zealand College of Anaesthetists[73] and has been adopted by the International Organization for Standardization in ISO 26825:2008E: Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colours, design and performance.[74]

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Appendix 3: Acknowledgements

a) The National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (August 2010) are derived from a concept initiated by New South Wales Therapeutic Advisory Group Safer Medicines group. The original draft produced by the group informed the consultation process at project commencement.

b) New South Wales Therapeutic Advisory Group Project team:

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c) Advisory Committee: National Injectable Medicines Labelling Project

Development of the *Labelling Recommendations* was overseen by an Advisory Committee comprising:

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Faculty of Medical and Health Sciences
University of Auckland
Auckland NZ

Mr Graham Bedford
Policy Team Manager
Australian Commission on Safety and Quality in Health Care
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Duality of interest

Professor Alan Merry is Chair of the Quality and Safety and Research Committees of ANZCA and a Board member and Shareholder of Safer Sleep Systems who produce a drug safety system using clear labels and bar codes (www.safersleep.com).

No other duality of interest declared.

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d) National Consultation

The *Labelling Recommendations* were developed with consultation of the following stakeholders across Australia.

- All State and Territory Health Departments
- All State and Territory Safer Medicine Groups
- The Council of Australian Therapeutic Advisory Groups

and the following national professional bodies:

- Australian and New Zealand College of Anaesthetists (ANZCA)
- Australian and New Zealand Intensive Care Society
- Australian Nursing Federation
- APHS (Australian Pharmaceutical Healthcare Systems)
- The Australian Private Hospitals Association
- Cancer Council Australia
- Clinical Oncological Society of Australia
- Consumers Health Forum
- Faculty of Intensive Care Medicine, ANZCA
- Intensive Care Coordination and Monitoring Unit
- Royal College of Nursing Australia
- The Society of Hospital Pharmacists of Australia
- Women's & Children's Hospitals Australasia

e) Pilot test clinical areas and hospitals

HOSPITAL	CLINICAL AREAS	FUNDING/LOCATION
Princess Alexandra, QLD	Anaesthetic care unit (ACU)	Public/Tertiary/Metropolitan
	Operating room (OR)	
	Post anaesthetic recovery unit (PARU)	
The Canberra Hospital, ACT	Intensive care unit (ICU)	Public/Tertiary/Metropolitan
Princess Margaret Hospital for Children, WA	Adolescent ward	Public/Tertiary/Metropolitan
Mt Gambier Health Service, SA	Paediatric/Maternity ward	Public/District
John Hunter Hospital, NSW	Medical ward	Public/Tertiary/Metropolitan
The Wesley Hospital, QLD	Surgical ward	Private/Metropolitan
St Vincents and Mercy Private Hospital, VIC	Day surgery ward	Private/Metropolitan
Coffs Harbour, NSW	Oncology unit	Public/Base
	Procedure room (endoscopy)	
	Emergency department	

f) Project support

- **Stirling Fildes**, Mitcham, Victoria 3132 www.stirlingfildes.com.
  Provision of all label artwork and print and supply of labels for pilot testing.
- **ITL Healthcare Pty Ltd**, Chelsea Heights, Victoria 3196 www.itlhealthcare.com.
  Packaging and sterilisation of labels for pilot testing on the sterile field.
- **Go Media Design**, Surry Hills, NSW 2010 www.gomedia-design.com.au.
  Graphic design and preparation of recommendations and related educational materials.

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Attachment 2

NATIONAL RECOMMENDATIONS FOR USER-APPLIED LABELLING OF INJECTABLE MEDICINES, FLUIDS AND LINES- AUDIT TOOL.

Date:
Area:
Auditor:

IV	Subcutaneous
Intra-arterial	Other
Epidural/Intrathecal/Regional	

Please indicate Y,N, or N/A

Patient	1	2	3	4	5	6	7	8	9	10
Labelling information of injectable medicines										
1. Does this patient have a syringe of injectable medicine insitu? (eg. PCA, NIKI, epidural)										
Does the syringe have a label attached?										
Is the total amount of active ingredient included on the label in units (eg. mg)										
Is the total volume of fluid contained in the syringe included on the label in mls?										
Does the medication order match the information on the label?										
Is the label signed by 2 staff ?(nursing or medical)										
Is the label placed correctly so as not to obsure syringe graduations?										
2. Does this patient have a fluid bag or bottle insitu that has injectible medicine added to it? (eg. Iron infusion)										
Does the bag or bottle have a label applied to it?										
Is the label applied to the front of the bag or bottle?										
Is the label applied correctly so as not to obscure manufacturer's product name, batch no. and expiry date?										
Does the medication order match the information on the label?										
Is the label signed by 2 staff ?(nursing or medical)										
3. Does this patient have a burette with injectable medicine added to it insitu?										
Does the burette have a peel off label applied to it?										
Is the total amount of active ingredient included on label in units (eg. mg)										
Is the total volume of fluid contained in burette included on label in mls?										
Does the medication order match the information on the label?										
Is the label signed by 2 staff ?(nursing or medical)										
Is the label placed correctly so as not to obsure burette graduations?										
Labelling information for administration lines and catheters										
4. Does this patient have an IV line?										
Does the IV line have a label attached?										
Is the route of administration identified?										
Is the label colour coded with a blue label?										
Does the label identify the date and time that the line is due to be changed?										
5. Does this patient have a CVC or PICC line?										
Does the CVC or PICC line have a label attached?										
Is the route of administration identified?										
Is the label colour coded with a blue label?										
Does the label identify the date and time that the line is due to be changed?										

6. Does this patient have a neural tissue line? (eg. epidural, intrathecal, regional)
Does the neural line have a label attached?
Is the route of administration identified?
Is the label colour coded with a yellow label?
Does the label identify the date and time that the line is due to be changed?

7. Does this patient have a subcutanoues line?
Does the subcutaneous line have a label attached?
Is the route of administration identified?
Is the label colour coded with a beige label?
Does the label identify the date and time that the line is due to be changed?

8. Does this patient have a monitoring line insitu? (eg. intra-arterial line, pulmonary-swan ganz)
Does the monitoring line have a label attached?
Is the route of administration identified?
Is the label colour coded with a red label?
Does the label identify the date and time that the line is due to be changed?

Labelling continuous infusion administration lines

9. Does this patient have an administration line dedicated for continuous infusions?
Does the line have a label attached?
Does the label identify the active ingredient within the line?
Is the route of administration identified?
Is the label colour coded?
Does the label identify the date and time that the line is due to be changed?

Audit tool kindly supplied by Armadale Health Service

Attachment 3

Suggested Staff Survey Questions to evaluate the *Labelling Recommendations*.

Please note: the following questions are suggestions only. Health services and teams are encouraged to amend these questions to suite their requirements.

www.surveymonkey.com is a free tool for carrying out surveys.

1. **Which area or specialty within _____ health service / hospital do you work in?**

   - ED
   - Surgical Wards
   - Medical Wards
   - ICU
   - *Etc…*

2. **Are you aware there *are National Recommendations for User- Applied Labelling of Injectable Medicines, Fluids and Lines*?**

   - Aware and familiar
   - Aware but not much detail
   - Not aware

3. **In the area where you mainly work do you ensure that all injectable medications and fluids that are removed from the manufacturer's original packaging are identifiable?**

   - Yes, always
   - Most of the time
   - Not always
   - Never

4. **Are you or your ward actively promoting and ensuring that all containers (eg. bags, syringes) that have injectable medication which leaves the hands of the person who prepared it, is labelled?**

   - Yes, always
   - Most of the time
   - Not always
   - Never

5. **During the preparation and drawing up of injectable medicine do you and your work area ensure that the labelling is done as a single operation by the same person?**

   - Yes, always
   - Most of the time
   - Not always
   - Never

6. **More than one injectable medication is often due to be administered at the same time. Do you and the area where you work promote and ensure that only one injectable medication is prepared at one time?**

   - Yes, always
   - Most of the time
   - Not always
   - Never

7. **Labelling should occur IMMEDIATELY after an injectable medicine is added to a syringe, bag/ bottle or burette. In your work area how often does this occur?**

	Always	Most of the time	Never
Syringe			
Bag/bottle			
Burette			

8. **Any medication or fluid that cannot be identified should be considered unsafe and discarded immediately. Is this a rule that you and your area of work adhere to and actively promote?**

   - Yes, always
   - Most of the time
   - Not always
   - Never