

Presentation Summary

- **Labelling for safety**
- **Labelling Recommendations**
 - Aims
 - Minimum requirements
 - Outline and content
- > Application in clinical practice

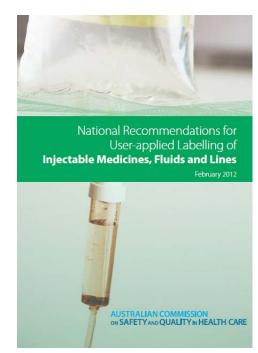
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The Labelling Recommendations standardisation

National Recommendations for User –applied Labelling of Medicines, Fluids and Lines February 2012 (2nd edition)

Read in conjunction with

Labelling Recommendations Issues Register
at www.safetyandquality.com.au



Labelling for Safety

- Labelling of injectable medicines, fluids and delivery devices is a major patient safety issue
- Labelling is often not done or incomplete, omitting information such as:
 - name of medicine
 - medicine dose
 - patient name
 - time of preparation.

Medicine administration errors

Medicine administration errors related to absent or inadequate labelling include:

- > Wrong medicine
- > Wrong route
- > Wrong patient

Medicine administration errors

Medicine administration errors attributable to labelling have been associated with:

- > Patient transfer
- > Sterile field
- > 0.9% sodium chloride flush
- > Line misconnections

Medicine administration errors Case Report 1

10mg morphine was given in error as the clinician thought the syringe contained 0.9% sodium chloride. The unlabelled syringe had a 0.9% sodium chloride ampoule attached.

(unpublished)

Medicine administration errors Case Report 2

A patient was given intravenous (IV) lignocaine with adrenaline solution intended for local anaesthetic infiltration. This syringe had been drawn up and placed in a kidney dish alongside IV morphine and midazolam for procedural sedation.

(unpublished)

The Labelling Recommendations

- A national standardisation for clinical practice in Australia
- Identifies medicines and fluids removed from original manufacturer's packaging prior to patient administration
- Identifies line route



Labelling Recommendations **Development**

- Draft recommendations developed by NSW
 Therapeutic Advisory Group Safer Medicines Group
- National consultation and pilot testing supported by the Australian Commission on Safety and Quality in Health Care commenced in 2009
- Final Labelling Recommendations endorsed by Australian Health Ministers November 2010
- Second edition printed February 2012

Labelling Recommendations **Development**

- Based on:
 - International literature/recommendations
 - Australian Standard AS4940: 2002 User-applied identification labels for use on fluid bags, syringes and drug administration lines.
 - **Expert opinion**
 - Pilot testing
 - Reported medicine administration incidents

Labelling Recommendations **Development**

Pilot testing and consultation was guided by an expert advisory committee:

□ Professor Alan Merry (Chair)

Professor of Anaesthesiology, Fáculty of Medical and Health Sciences

University of Auckland, Auckland, New Zealand

Mr Graham Bedford

Policy Team Manager Australian Commission on Safety and Quality in Health Care Darlinghurst, NSW

■ Ms Julianne Bryce

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Ms Josie Quin

Medication Safety Officer High Risk Medications and Systems, SMPU Safe Medication Practice Unit Royal Brisbane & Women's Hospitals Brisbane, QLD

Ms Diana Shipp

Project Manager NSW Therapeutic Advisory Group Darlinghurst, NSW

Labelling Recommendations Consultation

The draft Labelling Recommendations were circulated to the following groups for comment:

- All State and Territory health jurisdictions
- All State and Territory Safer Medicine Groups
- The Council of Australian Therapeutic Advisory Groups

and 13 national peak 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 On cological 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

Labelling Recommendations **Pilot testing**

The draft *Labelling Recommendations* were pilot tested in 12 clinical areas:

- Adolescent ward
- Anaesthetic care unit
- Day surgery ward
- **Emergency department**
- Intensive care unit
- Medical ward
- Oncology unit
- Operating room
- Paediatric/Maternity ward
- Post anaesthetic recovery unit
- Procedure room (endoscopy)
- Surgical ward

Test hospitals represented private and public institutions in metropolitan and rural areas across Australia

Labelling Recommendations **Aims**

- Provide standardisation for user-applied labelling of injectable medicines
- Provide minimum requirements for user-applied labelling of injectable medicines
- Promote safer use of injectable medicines

Labelling Recommendations Minimum requirements

- Medicines or fluid removed from original packaging must be identifiable
- All containers (e.g. bags and syringes) containing medicines must be labelled on leaving the hands of the person preparing the medicine
- Prepare and label one medicine at a time
- Discard medicines or fluids in unlabelled containers

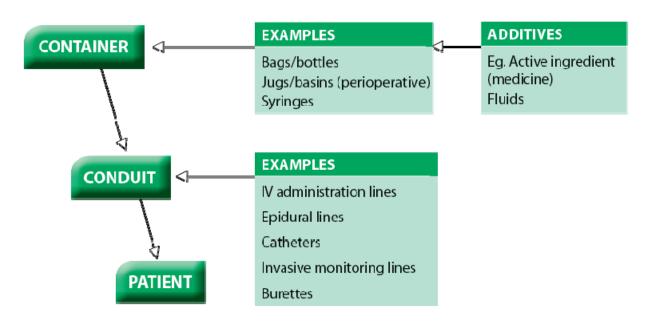
Labelling Recommendations

Outline

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



Labelling Recommendations Scope

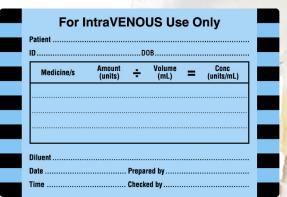


Labelling Recommendations **Exclusions**

- Injectable medicines and fluids:
 - prepared by hospital pharmacy departments, external manufacturers or compounding centres
 - not directly administered to the patient e.g. ampoules
- Administration portals
- Enteral, topical or inhalational medicines
- Syringe drivers and pumps

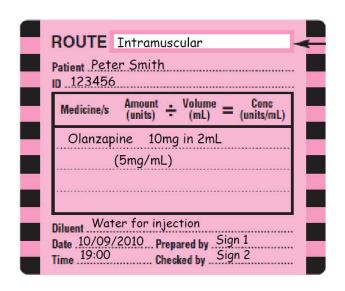
All Containers: Label content

- Patient: Given name and family name
- Identifier (ID): This is the URN or MRN or other local unique patient identifier
- **DOB:** Patient's date of birth
- For each medicine added to the container specify
 - Generic medicine name
 - Amount (total added to the container) including units
 - Volume (the total volume of fluid in the container) in mL
 - Concentration amount / mL
 - Diluent (syringes only)
 - Date and time of preparation
 - Signed by personnel preparing and checking medicine



All Containers: Label content

(examples)



Example of intramuscular route syringe label

*Examples only - Use labels with DOB identifier



Example of subcutaneous route syringe label

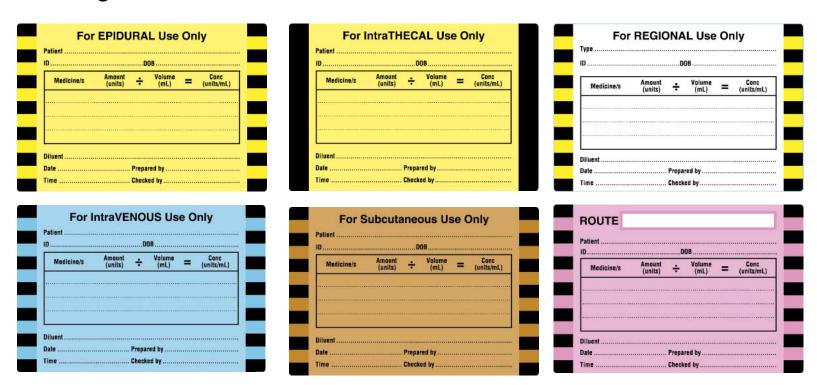
Identifying target tissue/ route of administration

A standard colour system is used to identify the target tissue/intended route of administration*

Target tissue	Route of administration	Colour
Intra-arterial	Intra-arterial	Red
Intravenous	Intravenous	Blue
Neural tissue	Epidural / Intrathecal / Regional	Yellow
Subcutaneous tissue	Subcutaneous	Beige
Miscellaneous	Any other route not specified above	Pink

Bag and syringe labels

Available in 2 sizes for intravenous, epidural, intrathecal, regional, subcutaneous and miscellaneous use.



Bags with additives

- Bags (and bottles) only require user-applied labels when a medicine is added in the clinical/ward area
- Label IMMEDIATELY an injectable medicine is added
- The 'diluent' should be identified on the label if the base fluid contained is not easily identifiable from the original manufacturers label (see label placement).

Bags with additives (continued)

Placement:

> Place labels on the FRONT of the bag to ensure the name of base fluid, batch number and expiry date remain visible.

*Example only

- > Use label with DOB identifier
- > Place label so graduations on either left or right remain visible



Syringes For bolus or infusion

- Label all injectable medicines drawn up in syringes that leave the hand of the operator IMMEDIATELY.
- Prepare and label multiple syringes sequentially in independent operations.

Syringes For bolus or infusion (continued)

Placement

- Place label so graduations on the syringe scale remain visible
- Apply parallel to the long axis of the syringe barrel, top edge flush with scale (*Example only – Use labels with DOB identifier)



Apply label as a 'flag' for small syringes

*Example only - Use labels with DOB identifier



Labelling IV flushes

Label any fluid drawn up in a syringe for use as an IV flush (e.g. 0.9% sodium chloride) unless preparation and bolus administration is one uninterrupted process.

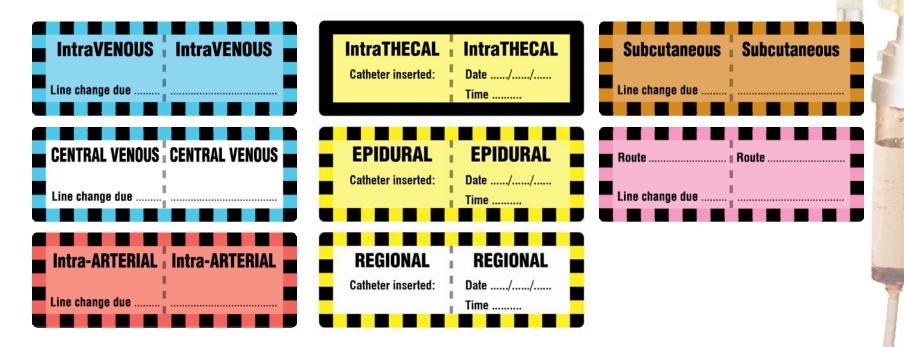
0.9% Sodium chloride

All containers: **Discarding Content**

- Any unlabelled container holding a solution must be immediately discarded
- Any container, where there is doubt over content, must be discarded
- > Any medicine remaining in the container at the end of a procedure must be discarded

Lines and catheters: Route of administration

Available for intravenous, central venous, epidural, intrathecal, regional, subcutaneous and intra-arterial.

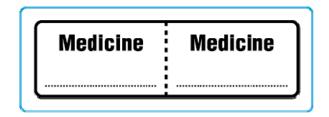


Lines and catheters: Route of administration (continued)

- Labelling administration lines and catheters
 - Label all lines to identify route
 - Add date and time the line change is due
 - Identify catheters where there is a risk of wrong route administration, e.g. the patient entry portal is distant from the administration site
- Labelling invasive monitoring lines
 - Identify all lines, including those not primarily intended for medicine administration.

Lines: Active ingredient

Identify the active ingredient within administration lines dedicated for continuous infusions.

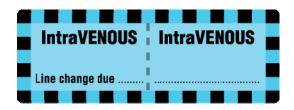


- Labels may be pre-printed. Any colour used should comply with ISO26825:2008
- Lines for other infusions (e.g. intermittent) may be labelled for medicine content. Ensure label is removed on completion of infusion

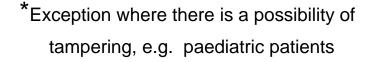
Lines:

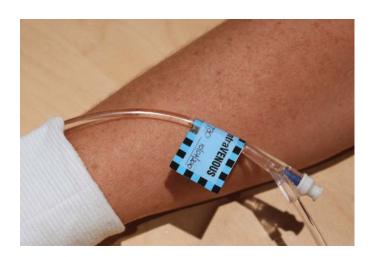
Label Placement

- Route:
 - Use colour coded route label



Label near the injection port on the patient side*





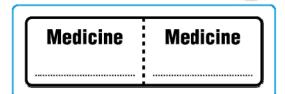
Lines (continued)

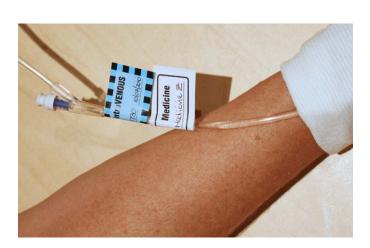
Label Placement

- Active ingredient:
 - Use pre-printed medicine line label or generic medicine line label as shown

Label close to patient entry portal adjacent to route label*

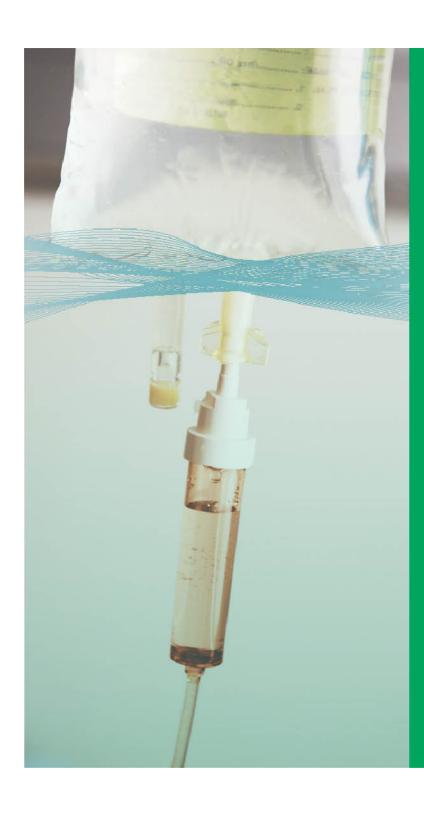
*Exception where there is a possibility of tampering, e.g. paediatric patients





Special circumstances

- Preparation and bolus administration of a SINGLE medicine from a SINGLE syringe is one uninterrupted process - No label required
 - the syringe DOES NOT leave the hands of the person who prepared it, and
 - that same person administers the medicine **IMMEDIATELY**



Burettes

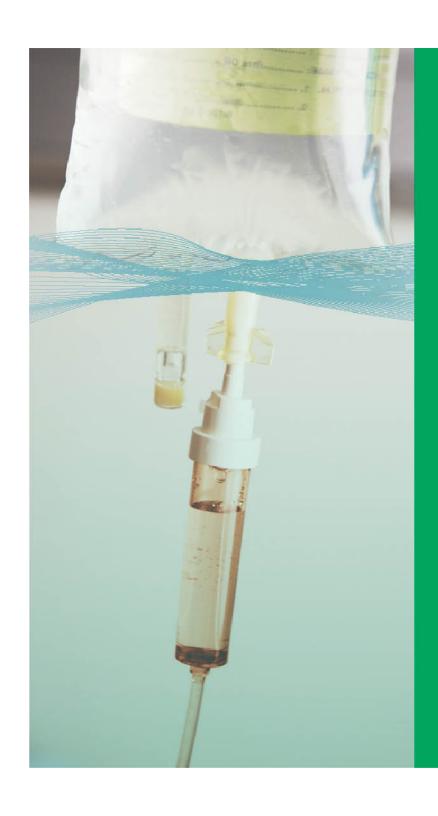
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Burettes

- Use 'peel-off' labels reserved for use on burettes ONLY
- 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

Burette Label for IntraVENOUS Use

^{*}Example only- Use labels with DOB identifier



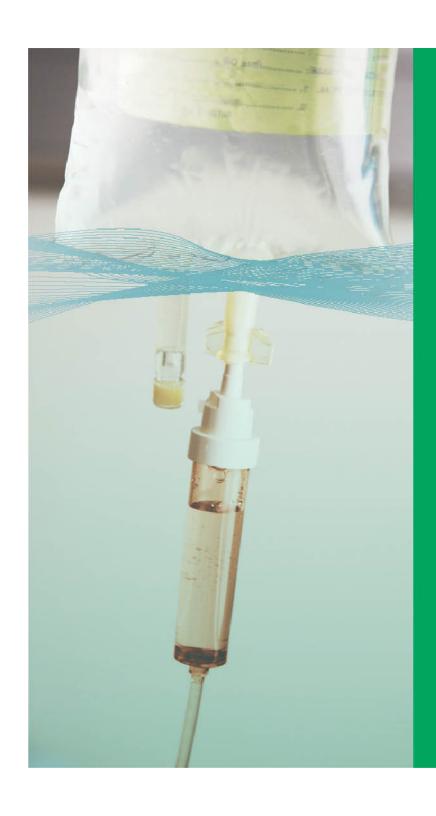
Sterile Field

Sterile field (i.e. aseptic conditions)

- Any container holding medicines or fluids on the sterile field must be identifiable
- In open practice environments use an individually packaged and sterilised container label selected according to route of administration
- In a closed practice environment (where patient identification is established and other means of recording labelling and preparation signatories are available (e.g.operating rooms)}, use the abbreviated container label

Medicine
Conc (units/mL)

Sterile markers must be available sterile field with this label.



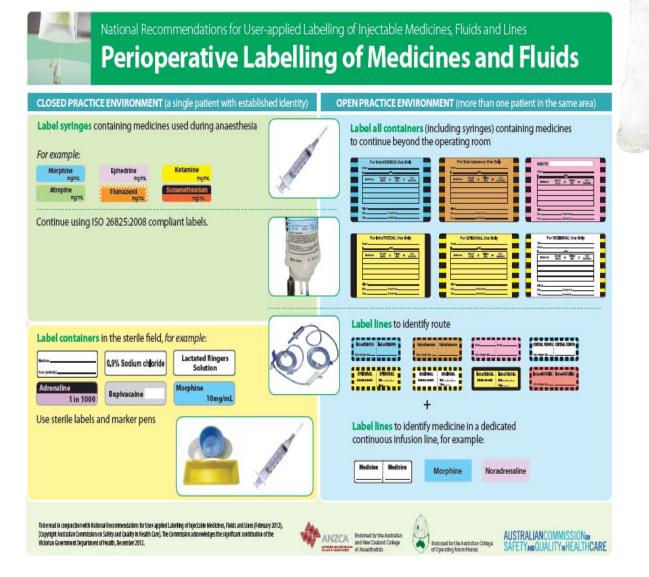
Perioperative environments

Perioperative environments

- Labelling of syringes containing drugs used during anaesthesia to comply with ISO26825:2008
- Labelling of bags, syringes, lines, catheters and invasive monitoring lines in all areas of the perioperative environment, other than drugs in syringes used during anaesthesia, to comply with the Labelling Recommendations
- Use pre-printed labels or the 'peel off' abbreviated container label on sterile field in operating room where patient identity is established and there are other means of recording labelling and preparation signatories

Medicine
Conc (units/mL)

Perioperative environments



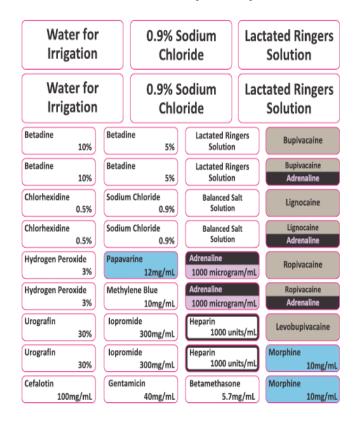
Perioperative sterile field

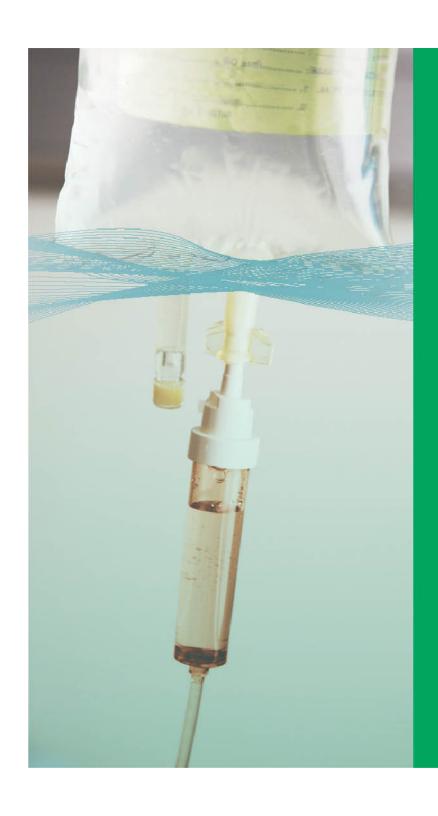
- Use pre-printed labels with medicine name and concentration.
 Colour-coding to follow ISO26825:2008 (anaesthetic labelling standard)
- > For example of pre-printed label sheet see next slide (44)
- Use abbreviated container label where pre-printed labels unavailable
- > Labels must remain intact for duration of procedure
- Label must adhere for duration of procedure
- Label should be removed at the end of the procedure for reusable hollowware containers

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Perioperative sterile field

Example of pre-printed label sheet for perioperative sterile field





Further information:

Australian Commission on Safety and Quality in Health Care website www.safetyandquality.gov.au