

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

June 2016



AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Presentation summary

- Labelling for safety
- Labelling Standard
 - Aims
 - Minimum requirements
 - Outline and content
- Application in clinical practice

Labelling for safety

- Labelling of injectable medicines, fluids and delivery devices is a major patient safety issue
- Medicines removed from original manufacturer's packaging must be identifiable
- Incomplete/omitted labelling is a source of medication error

Medicine administration errors

Errors relating to absent or inadequate labelling include:

- Wrong medicine
- Wrong route
- Wrong patient

Errors attributable to labelling have been associated with:

- Patient transfer
- Perioperative sterile field
- 0.9% sodium chloride flush
- Line misconnections

Medicine administration errors: case reports

- 10 mg 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 The unlabelled syringe had a 0.9% sodium chloride ampoule attached (unpublished)
- 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This syringe had been drawn up and placed in a kidney dish alongside IV morphine and midazolam for procedural sedation (unpublished)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 Standard

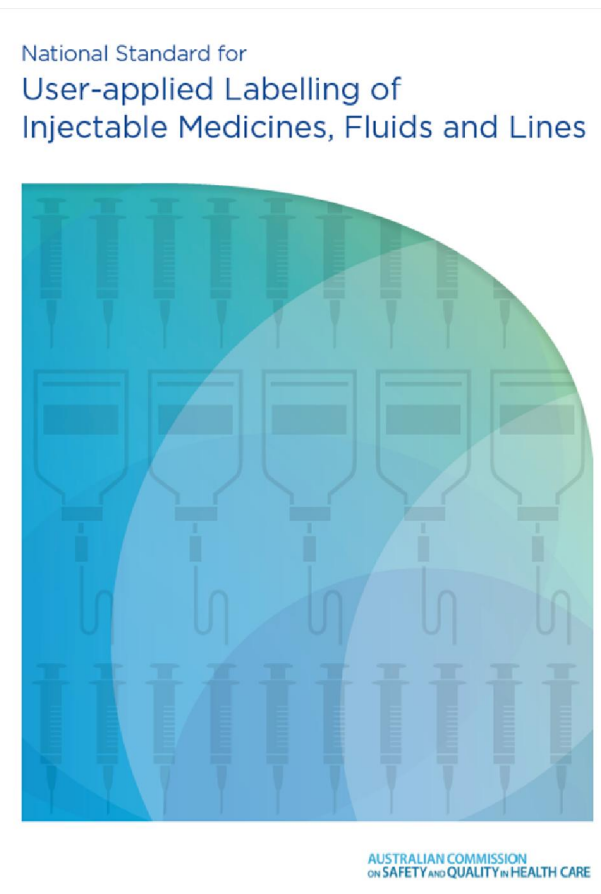
National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines, September 2015

Replaces the previous Labelling Recommendations (2012) and Issues Register



The Labelling Standard

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



Labelling Standard 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 Standard 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
- Labelling Recommendations endorsed by Australian Health Ministers in November 2010
- Further evaluation, particularly in perioperative areas and interventional procedure rooms
- Labelling Standard published September 2015

Labelling Standard 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 and consultation
 - Pilot testing
 - Reported medicine administration incidents

Labelling Standard consultation

Labelling Standard development since 2009 has involved:

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

Labelling Standard: 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 Standard: outline

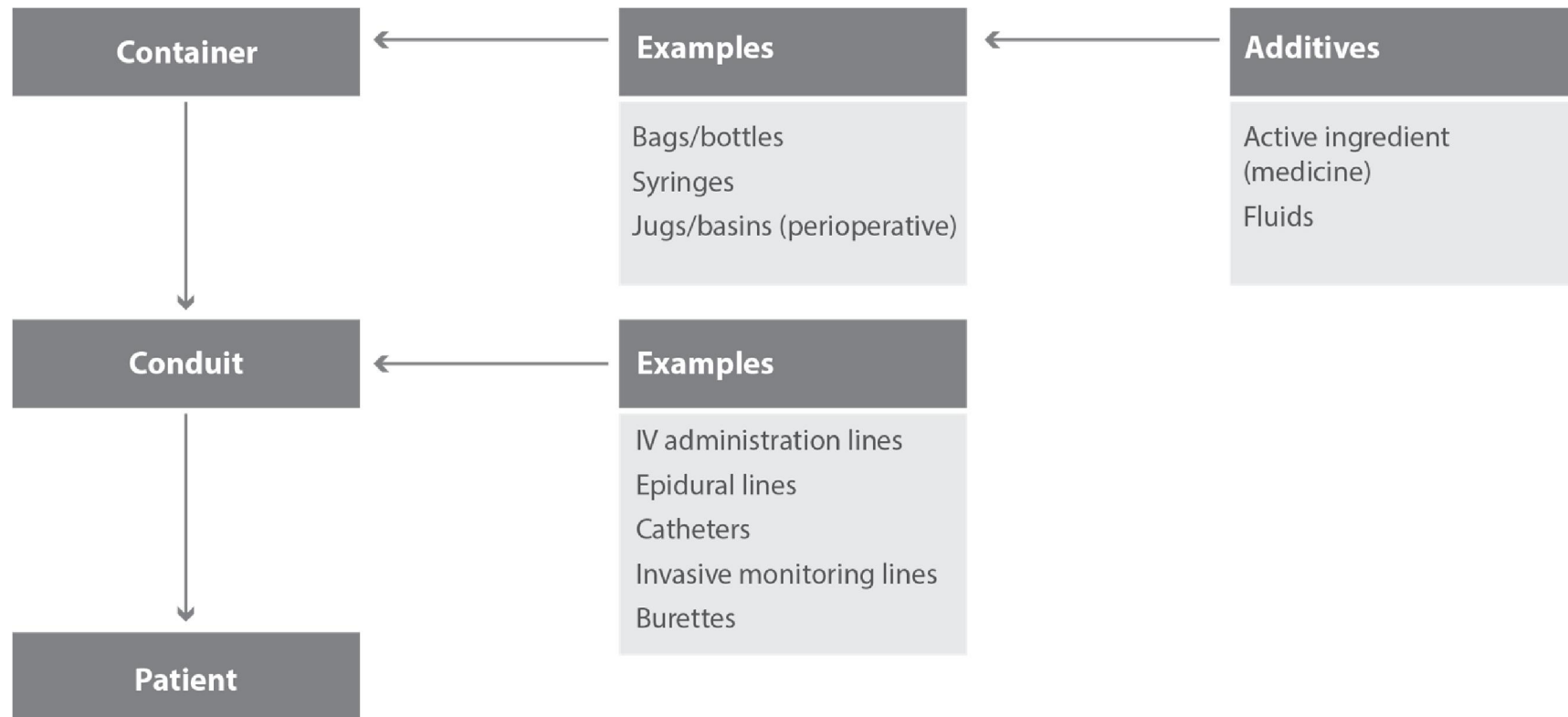
- What should be labelled
- What should be included on the label
- Where the label should be placed

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



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Labelling Standard: scope



Labelling Standard: 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**
- **Syringe drivers and pumps**

Application in clinical practice

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 (units/mL)
 - Diluent (syringes only)
 - Date and time of preparation
 - Signed by personnel preparing and checking medicine

For IntraVENOUS Use Only				
Patient				
ID		DOB		
Medicine/s	Amount (units)	÷	Volume (mL)	= Conc (units/mL)
.....
.....
Diluent				
Date		Prepared by		
Time		Checked by		

All containers: label content

Example of miscellaneous route syringe label

ROUTE Intramuscular

Patient Peter Smith
 ID 123456 DOB 1/1/1980

Medicine/s	Amount (units)	÷	Volume (mL)	=	Conc (units/mL)
Olanzapine	10mg in 2mL				(5mg/mL)

Diluent Water for injection
 Date 10/09/2015 Prepared by Sign 1
 Time 19:00 Checked by Sign 2

Example of subcutaneous route syringe label

For Subcutaneous Use Only

Patient Peter Smith
 ID 123456 DOB 1/1/1980

Medicine/s	Amount (units)	÷	Volume (mL)	=	Conc (units/mL)
Morphine	60mg in 10mL				(6mg/mL)
Metoclopramide	30mg in 10mL				(3mg/mL)

Diluent Water for injection
 Date 10/09/2015 Prepared by Sign 1
 Time 19:00 Checked by Sign 2

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	Epidural / Intrathecal / Regional	Yellow
Subcutaneous	Subcutaneous	Beige
Intragastric	Enteral	Green
Respiratory	Inhalational	White
Miscellaneous	Any other route not specified above	Pink

*Modified from Australian Standard AS4940

Bag and syringe labels: 2 sizes

For EPIDURAL Use Only

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

For IntraTHECAL Use Only

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

For REGIONAL Use Only

Type
 Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

For IntraVENOUS Use Only

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

For Subcutaneous Use Only

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

ROUTE []

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

For Intra-ARTERIAL Use Only

Patient
 ID DOB

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

Diluent
 Date Prepared by
 Time Checked by

Bags with additives

- Bags (and bottles) require labelling when a medicine is added in the clinical/ward area
- Label IMMEDIATELY when an injectable medicine is added
- The 'diluent' should be identified on the label if the base fluid is not easily identifiable from the original manufacturer's 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
- Place slightly off centre to ensure graduations on one side of the bag remain visible



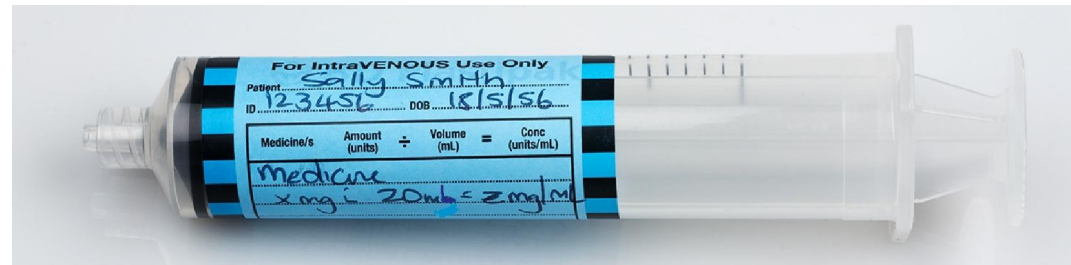
Syringes for bolus or infusion

- Label IMMEDIATELY all injectable medicines drawn up in syringes that leave the hand of the operator
- Prepare and label multiple syringes sequentially in independent operations
- Exception: Labelling is not required when
 - preparation and bolus administration of a SINGLE medicine from a SINGLE syringe are one uninterrupted process, and
 - the syringe DOES NOT leave the hands of the person who prepared it, and
 - the same person administers the medicine IMMEDIATELY

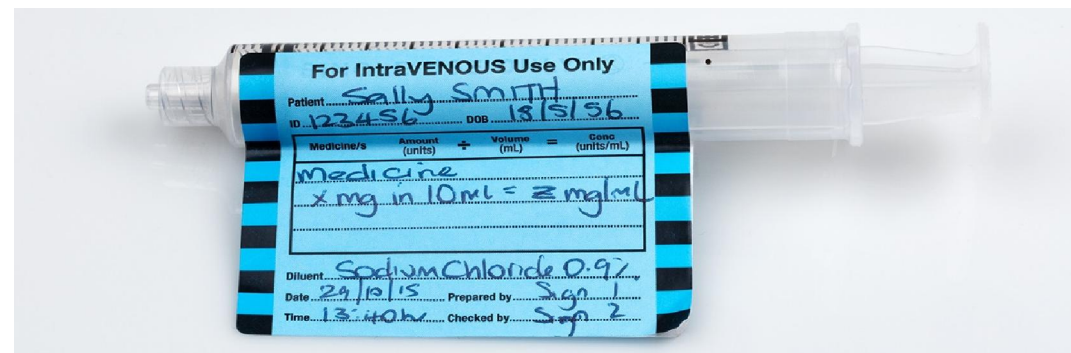
Syringes for bolus or infusion (continued)

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



- Apply label as a 'flag' for small syringes



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.

Sodium Chloride 0.9%

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

IntraVENOUS	IntraVENOUS
Commenced:	Date/...../.....
	Time

IntraTHECAL	IntraTHECAL
Catheter commenced:	Date/...../.....
	Time

Subcutaneous	Subcutaneous
Commenced:	Date/...../.....
	Time

CENTRAL VENOUS	CENTRAL VENOUS
Commenced:	Date/...../.....
	Time

EPIDURAL	EPIDURAL
Catheter commenced:	Date/...../.....
	Time

Route	Route
Commenced:	Date/...../.....
	Time

Intra-ARTERIAL	Intra-ARTERIAL
Commenced:	Date/...../.....
	Time

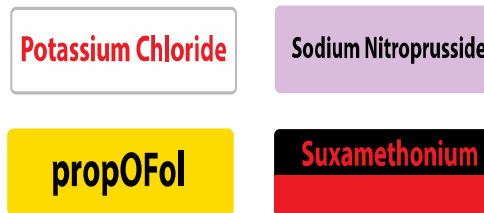
REGIONAL	REGIONAL
Catheter commenced:	Date/...../.....
	Time

Lines and catheters: route of administration (continued)

- Labelling administration lines and catheters
 - Label all lines to identify route
 - Add date and time the line was commenced
 - Identify catheters where there is a risk of wrong route administration (e.g. where 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 in administration lines for dedicated continuous infusions.
- Labels may be preprinted. Colour should comply with ISO26825:2008. For example



- The pre-printed medicine line label guide has more examples
- Lines for intermittent infusions may be labelled for medicine content, but ensure label is removed on completion of infusion

Pre-printed medicine line label guide

Medicine line	Label
<i>Vasopressor, adrenaline</i> Violet, bold, reverse plate letters in a black bar on upper half of label. Violet on lower half of label	Adrenaline
<i>Miscellaneous</i> B/W, Tall Man lettering	amiNOPHYLLine
<i>Miscellaneous</i> B/W, Tall Man lettering	amiODAROne
<i>Anticholinergic</i> Green label with black font	Atropine
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Clonidine
<i>Benzodiazepine</i> Orange label with black font, Tall Man lettering	Diazepam
<i>Vasopressor</i> Violet label with black font	Dobutamine
<i>Vasopressor</i> Violet label with black font	Dopamine
<i>Opioid</i> Blue label with black font	Fentanyl
<i>Miscellaneous</i> B/W	Frusemide
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Glyceryl Trinitrate
<i>Anticoagulant</i> Teal green label with 1–2 mm solid black border	Heparin
<i>Miscellaneous/high risk</i> White label with red font	Insulin
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Isoprenaline
<i>Induction agent</i> Yellow label with black font	Ketamine
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Levosimendan
<i>Local anaesthetic</i> Grey label with black font	Lignocaine
<i>Miscellaneous</i> B/W	Magnesium
<i>Vasopressor</i> Violet label with black font	Metaraminol
<i>Benzodiazepine</i> Orange label with black font	Midazolam
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Milrinone
<i>Opioid</i> Blue label with black font	Morphine
<i>Opioid antagonist</i> Blue label with white diagonal-stripe border	Naloxone
<i>Hypotensive</i> Violet label with white diagonal-stripe border, Tall Man lettering	niMODIPine
<i>Vasopressor</i> Violet label with black font	Noradrenaline
<i>Opioid</i> Blue label with black font	Oxycodone
<i>Muscle relaxant</i> Fluorescent red label with black font	Pancuronium
<i>Miscellaneous/high risk</i> White label with red font	Potassium Chloride
<i>Induction agent</i> Yellow label with black font, Tall Man lettering	propOFol
<i>Anticoagulant antagonist</i> Teal green label with 1–2 mm diagonal-stripe black border	Protamine
<i>Muscle relaxant</i> Fluorescent red label with black font	Rocuronium
<i>Local anaesthetic</i> Grey label with black font	Ropivacaine
<i>Miscellaneous</i> B/W	Salbutamol
<i>Miscellaneous</i> B/W	Sodium Chloride 0.9%
<i>Miscellaneous/high risk</i> White label with red font	Sodium Chloride 20%
<i>Hypotensive</i> Violet label with white diagonal-stripe border	Sodium Nitropruside
<i>Muscle relaxant, suxamethonium</i> Fluorescent red, bold, reverse plate letters in a black bar on upper half of label. Fluorescent red on lower half of label	Suxamethonium
<i>Induction agent</i> Yellow label with black font	Thiopentone
<i>Anticoagulant</i> Teal green label with black font	Urokinase
<i>Muscle relaxant</i> Fluorescent red with black font	Vecuronium

B/W = black font on white background

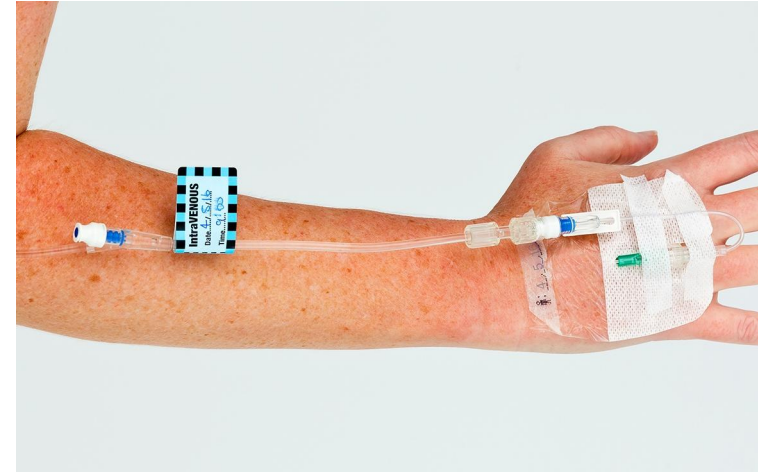
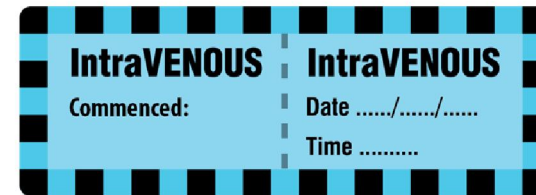
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Lines

Label placement

- Route:
 - Use colour coded route label
 - Label near the injection port on the patient side*

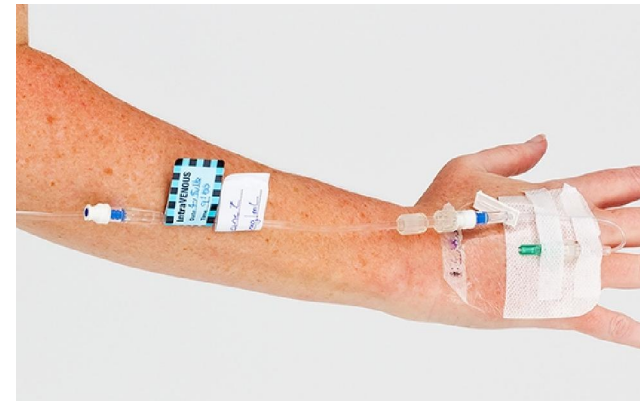
*Exception where there is a possibility of tampering (e.g. paediatric patients)



Lines (continued)

Label placement

- Active ingredient:
 - Use medicine line label (preprinted where possible)
 - Label adjacent to route label
 - Label close to patient entry portal*



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

Catheter lock

- For central venous access devices that are locked with a medicine (e.g. heparin)
- Label to partially cover the catheter dressing
- Remove label after removing medicine from the lock
- **ADD PHOTOGRAPH**

Catheter Lock

Medicine.....

Date.....

	Lumen volume (mL)	Final amount (units)
Arterial lumen.....
Venous lumen.....

Remove medicine used as a 'lock' from lumen(s) prior to catheter use.

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

Patient

ID DOB

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

Date Prepared by

Time Checked by



Non-injectable medicines: enteral route

- Syringe and line labels
- Syringes for non-injectable solutions must not be compatible with parenteral entry points

For Enteral Use Only

Patient

ID DOB

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

Diluent

Date Prepared by

Time Checked by

Enteral	Enteral
Commenced:	Date/...../.....
	Time

Non-injectable medicines: inhalation route

- Label syringes used to measure nebuliser solutions

For Inhalation Use Only					
Patient					
ID		DOB			
Medicine/s	Amount (units)	÷	Volume (mL)	=	Conc (units/mL)
.....
.....
.....
Diluent					
Date		Prepared by			
Time		Checked by			

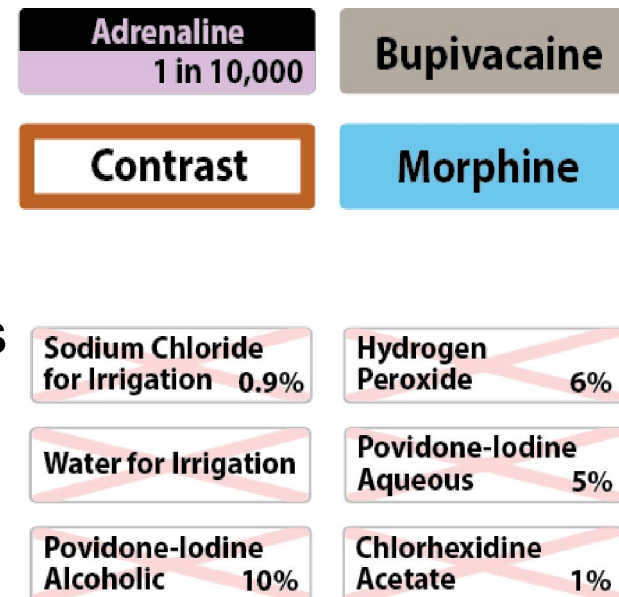
Closed-practice environments

Sterile field (i.e. aseptic conditions)

- Closed-practice environment: where patient identification is established and other means of recording labelling and preparation signatories are available
- Examples: perioperative sterile field, interventional cardiology and radiology procedure rooms

Sterile field (continued)

- Any container holding medicines or fluids on the perioperative sterile field must be identifiable
- Preprinted abbreviated container labels can be used
- Non-injectable medicines and fluids are identified with a red St Andrew's Cross watermark
- Sterile markers must be available to complete generic labels



Perioperative environments

Perioperative environments

- Continue to label syringes containing drugs used during anaesthesia to comply with ISO26825:2008
- Use preprinted labels or the ‘peel off’ abbreviated container label where patient identity is established and there are other means of recording labelling and preparation signatories

Perioperative environments

Closed-practice environment (a single patient with established identity)

Label syringes containing medicines used during anaesthesia

For example:

Morphine	Ephedrine	Atropine
Ketamine	Levosimendan	Suxamethonium



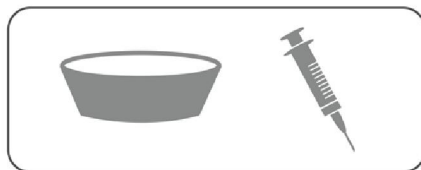
Use ISO 26825:2008 compliant labels.



Label containers in the sterile field – for example:

Medicine.....	Sodium Chloride 0.9%	Povidone-Iodine
Conc (units/mL).....	Bupivacaine	Morphine
Adrenaline 1 in 1,000		

Use sterile labels and sterile marker pens



Open-practice environment (more than one patient in the same area)

Label all containers (including syringes) containing medicines to continue beyond the operating room

For IntraVENOUS Use Only	For Subcutaneous Use Only	ROUTE
For IntraTHECAL Use Only	For EPIDURAL Use Only	For REGIONAL Use Only

Label lines to identify route

IntraVENOUS / IntraVENOUS	Subcutaneous / Subcutaneous	ROUTE / ROUTE	CENTRAL VENOUS / CENTRAL VENOUS
EPIDURAL / EPIDURAL	REGIONAL / REGIONAL	IntraTHECAL / IntraTHECAL	Intra-ARTERIAL / Intra-ARTERIAL



Label lines to identify medicine in a dedicated continuous infusion line – for example:

Medicine	Medicine	Morphine	Noradrenaline
----------	----------	-----------------	----------------------

Perioperative sterile field

- Use preprinted label sheets with medicine name and concentration. Colour coding to follow ISO26825:2008 (Anaesthetic Labelling Standard)
- Use abbreviated container label where preprinted labels unavailable
- Labels must remain intact for duration of procedure
- Labels must adhere for duration of procedure
- Labels should be removed at the end of the procedure for reusable hollowware containers

Perioperative sterile field

- Example of preprinted label sheet for perioperative sterile field
- Note that labels for non-injectable fluids (with the St Andrew's Cross) are in a separate section on the sheet

Hydrogen Peroxide 3%	Sodium Chloride for Irrigation 0.9%	Water for Irrigation	
Hydrogen Peroxide 6%	Sodium Chloride for Irrigation 0.9%	Water for Irrigation	
Chlorhexidine Gluconate 0.1%	Chlorhexidine Alcoholic 2%	Povidone-Iodine Aqueous 10%	Methylene Blue
Chlorhexidine Acetate 1%	Iodine Aqueous (Lugol's) 5%	Povidone-Iodine Alcoholic 10%	Sodium Chloride for Irrigation 0.9%
Chlorhexidine Alcoholic 0.5%	Povidone-Iodine Aqueous 5%	Paraffin Liquid	Sodium Chloride for Irrigation 0.9%

Sodium Chloride for Injection 0.9%	Medicine..... Conc (units/mL).....	Medicine..... Conc (units/mL).....
---------------------------------------	---------------------------------------	---------------------------------------

Sodium Chloride for Injection 0.9%	Betamethasone Sodium Phosphate	Clonidine	Verapamil
Sodium Chloride for Injection 0.9%	Bupivacaine	Heparin 10 units/mL	Adrenaline 1 in 1,000
cephaZOLin	Lignocaine	Heparin 25 units/mL	Adrenaline 1 in 10,000
Gentamicin	Ropivacaine	Heparin 1,000 units/mL	Adrenaline 1 in 400,000
Vancomycin	Ropivacaine	Heparin 1,000 units/mL	Lignocaine Adrenaline
Contrast	Morphine	Heparin 25,000 units/mL	Ropivacaine Adrenaline

Interventional cardiology, radiology and other low-light procedure areas

Low-light procedure areas

- Use preprinted label sheets with medicine name
- Colour coding to follow ISO26825:2008 (Anaesthetic Labelling Standard)
- Example preprinted label sheet for cardiac catheter laboratory

The image displays a grid of preprinted labels for cardiac catheter laboratory use, organized into several sections:

- Top Section:** Labels for routes of administration: Intra-ARTERIAL (red/black checkered), Intra-VENOUS (blue/black checkered), and CENTRAL VENOUS (blue/black checkered).
- Second Section:** Labels for irrigation and disinfection: Chlorhexidine, Povidone-Iodine, and Water for Irrigation (all crossed out with a red 'X').
- Third Section:** Labels for disinfection: Alcohol, Chlorhexidine, Polyvinyl Alcohol, and Povidone-Iodine.
- Bottom Section:** A grid of medicine labels with color coding:
 - Teal:** Abciximab, Bivalirudin, Eptifibatide, Tirofiban, Urokinase, Heparinised Saline, Heparinised Saline.
 - Black:** Adrenaline 1 in 400,000, Adrenaline 1 in 400,000, Ropivacaine Adrenaline, Bupivacaine Adrenaline, Bupivacaine, Lignocaine Adrenaline, Lignocaine Adrenaline.
 - Purple:** Metaraminol, Papaverine, Glyceryl Trinitrate, Verapamil, Verapamil.
 - Grey:** Levobupivacaine, Mepivacaine, Ropivacaine, Bupivacaine, Fentanyl, Fentanyl, Morphine.
 - Orange:** Diazepam, Midazolam, Contrast, Contrast, Contrast.
 - Yellow:** propOFol.
 - White:** Adenosine, Adenosine, Fibro-Vein, Flecanide Acetate, Sodium Chloride for Injection 0.9%, Sodium Chloride for Injection 0.9%, Medicine....., Conc (units/mL)....., Medicine....., Conc (units/mL).....

Further information:

Australian Commission on Safety
and Quality in Health Care

www.safetyandquality.gov.au