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

December 2015

WA Health

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

* To be read in conjunction with:
National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, August 2010

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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
- Labelling is often not done or incomplete, omitting information such as:
  - name of medicine
  - medicine dose
  - patient name
  - time of preparation.
- Incomplete/omitted labelling is a source of medication error

Medicine administration errors

Medicine administration errors related to absent or inadequate labelling include:

- Wrong medicine
- Wrong route
- Wrong patient

Labelling errors are particularly associated with:

- Patient transfer between clinical areas
- Perioperative 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(unpublished)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

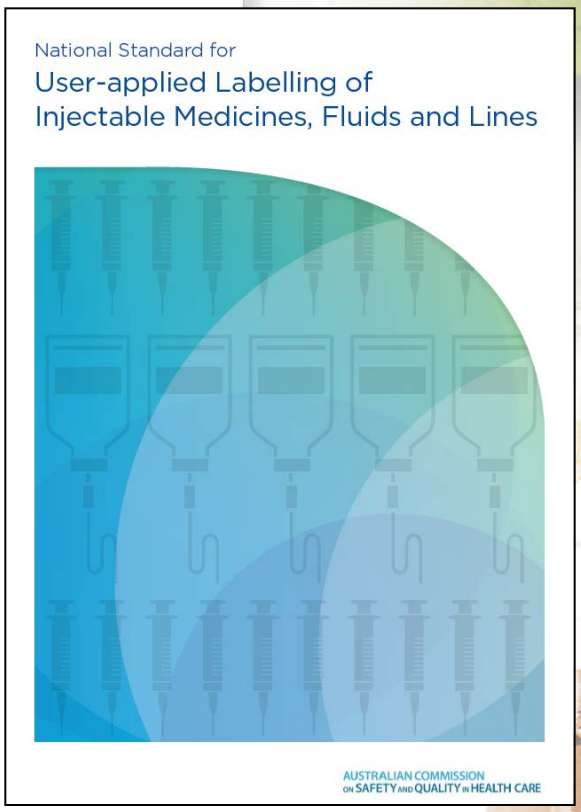
A patient was given intravenous (IV) lignocaine with adrenaline solution intended for local anaesthetic infiltration.

This syringe had been drawn up and placed in a kidney dish alongside IV morphine and midazolam for procedural sedation.

(unpublished)

The Labelling Standard

- Draft recommendations were 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
- Version 2 released February 2012
- National Standard released September 2015



The Labelling Standard

- A national standard for clinical practice in Australia
- Identifies medicines and fluids removed from manufacturer's original 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

- Based on:
  - International literature/recommendations
  - Australian Standard AS4940: 2002 User-applied identification labels for use on fluid bags, syringes and drug administration lines.
  - International Standard ISO 26825:2008 Anaesthetic and respiratory equipment – user-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance
  - Expert opinion
  - Pilot testing
  - Reported medicine administration incidents

Labelling Standard
Minimum requirements

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

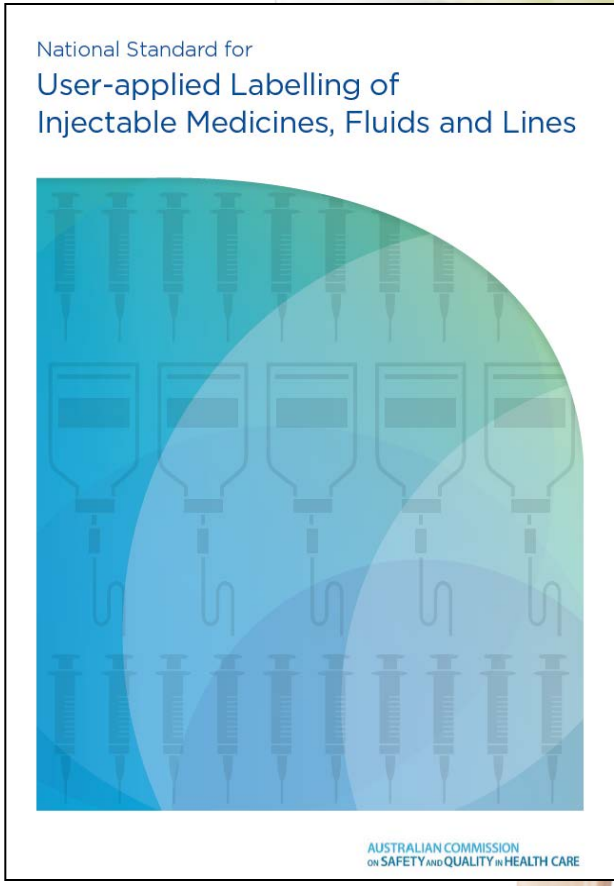
Labelling Standard Consultation

Labelling Standard development since 2009 has involved:

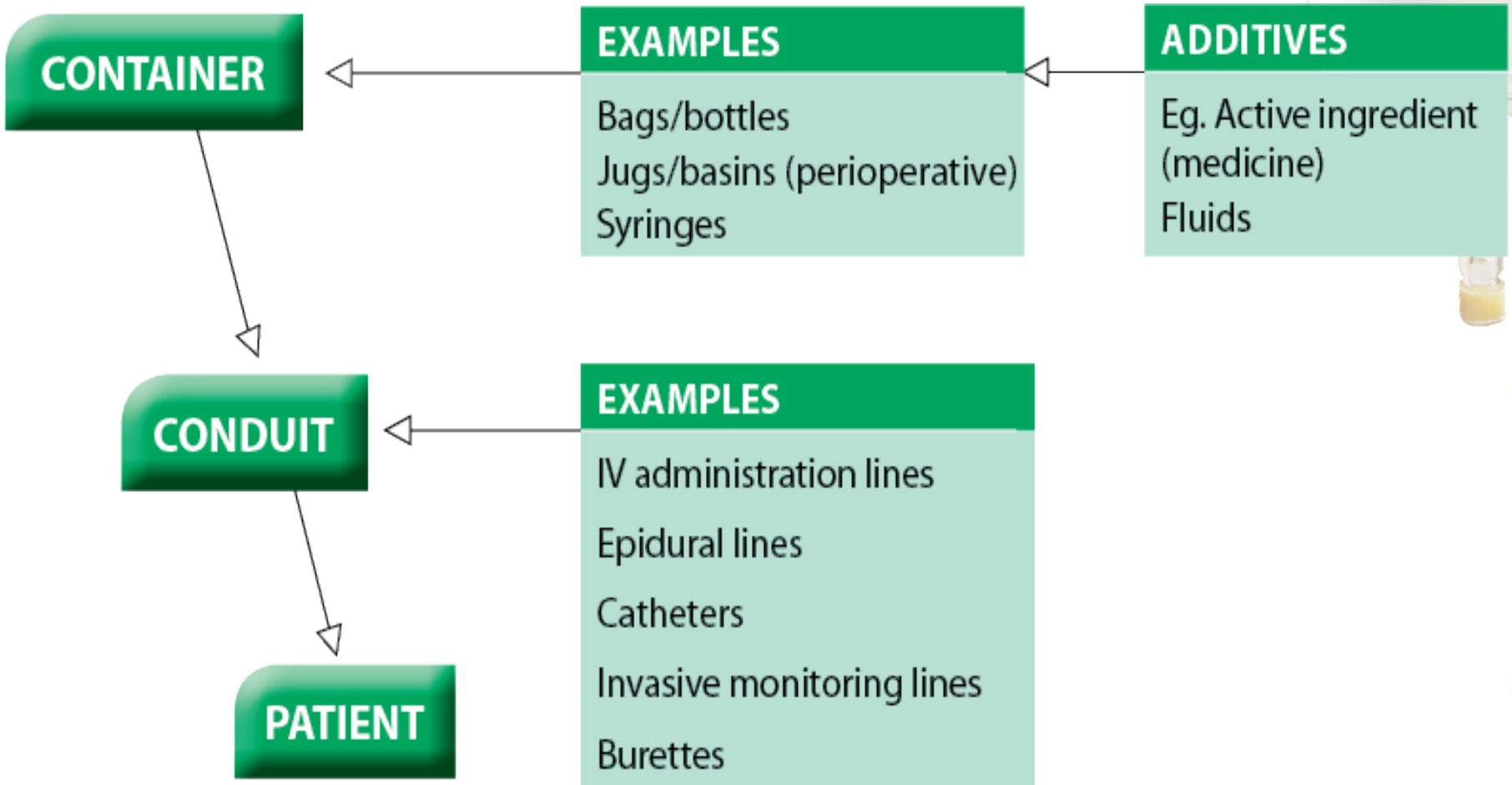
- State and territory health departments
- State and territory safer medicines groups
- Australian Association of Nuclear Medicine Specialists
- Australian College of Critical Care Nurses
- Australian College of Nursing
- Australian College of Operating Room Nurses
- Australian and New Zealand College 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 Outline

- What should be labelled
- What should be included on the label
- Where the label should be placed
- Where the Labelling Standard applies



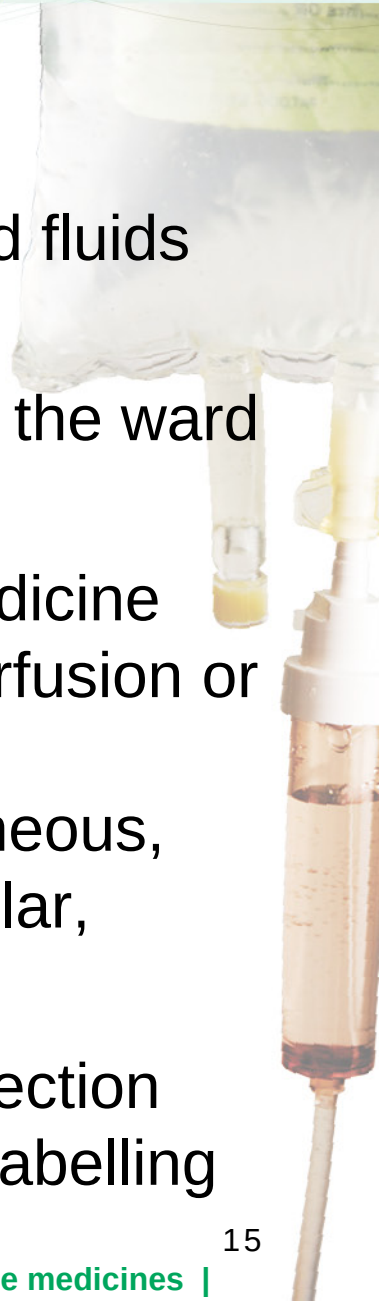
Labelling Standard Scope



Labelling Standard Scope

- **all clinical areas** where injectable medicines and fluids are administered
- **all injectable medicines and fluids** prepared in the ward or clinical area
- **injectable medicines**, defined as any sterile medicine intended for administration by bolus injection, perfusion or infusion by the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intra-ocular.

  This list is not exhaustive, and other routes of injection should also be considered in the context of the Labelling Standard (e.g. intraosseous and intraperitoneal)



Labelling Standard Extended Scope

- Labelling of containers in perioperative settings (including cardiac catheter and interventional radiology units). The Anaesthetic Labelling Standard (ISO 26825:2008) applies to syringes containing medicines used during anaesthesia
- Colour coded pre-printed medicine labels for use on dedicated continuous infusion lines
- Liquid medicines for oral, enteral and inhalational use
- Labelling of non-injectable medicines and fluids prepared in the same area as injectable medicines.

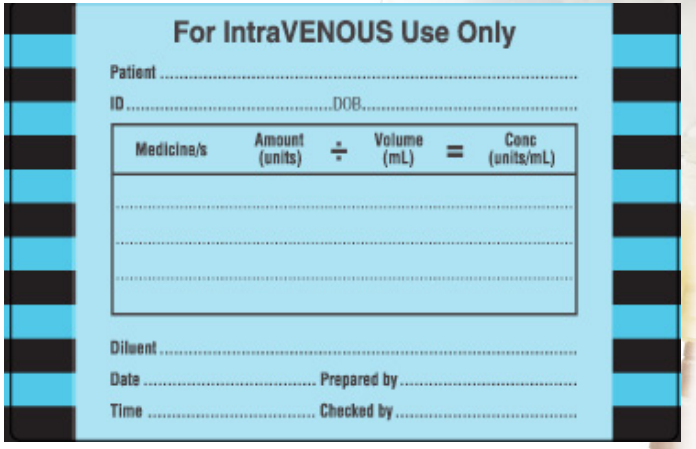
Labelling Standard Exclusions

- 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
- Topical products prepared when injectable medicines are not present; however, the same principles of identification translate to topical use of medicines, solutions, chemicals
- extemporaneously dispensed radiopharmaceuticals and reagents

Application in clinical practice

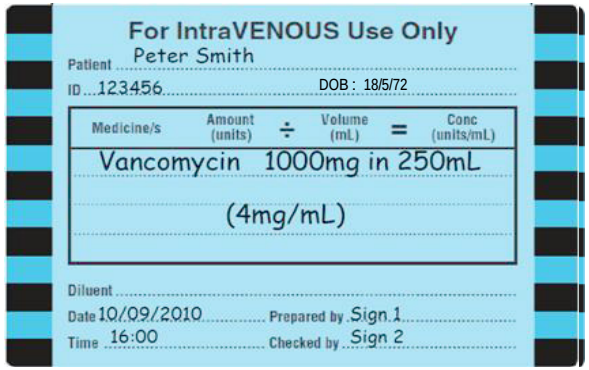
All Containers: Label content

- **Patient:** Write the patient's given name and family name
- **Identifier (ID):** This is the URN or MRN or other local unique identifier for the patient
- Date of Birth (DOB): This is a third patient identifier on the label
- For each medicine added to the container specify:
  - Medicine name (active ingredient)
  - Amount (total added to the container), including units
  - Volume (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



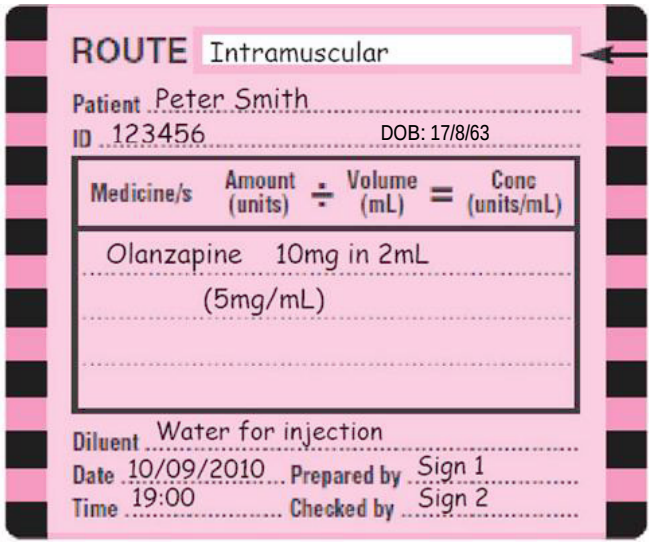
All Containers: Label content
(continued)

- Diluent - complete for all syringes
- ‘Date’ and ‘Time’ the medicine is prepared
- ‘Prepared by’ and ‘Checked by’ to be signed by responsible personnel



Example of intravenous bag additive label

All Containers: Label content
(continued)



Example of intramuscular route syringe label

Example of subcutaneous route syringe label

Identifying target tissue/ route of administration

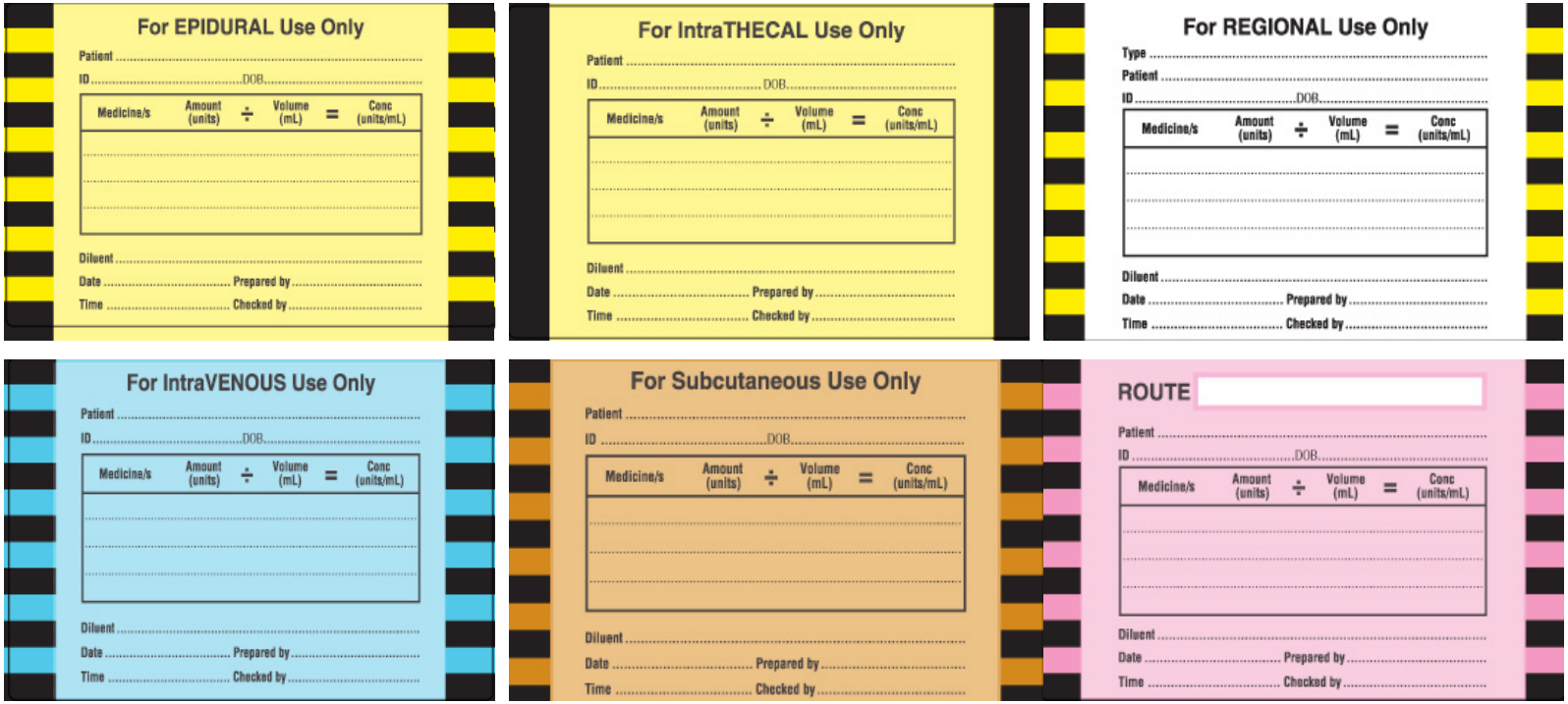
A standard colour system is used to identify the target tissue/intended route of administration*

Target tissue	Route of administration	Colour
Intra-arterial	Intra-arterial	Red
Intravenous	Intravenous	Blue
Neural	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

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.
- Place slightly off centre to ensure graduations on one side of the bag remain visible

Syringes
For bolus or infusion

- Label all injectable medicines drawn up in syringes that leave the hand of the operator **IMMEDIATELY**.
- Prepare multiple syringes by preparing and labelling one syringe in an independent operation before preparing a subsequent medicine
- Labelling is NOT required when
  - preparation and bolus administration of a SINGLE medicine from a SINGLE syringe are one uninterrupted process, and
  - the syringe remains in the hand of the person who prepared it, and
  - the same person administers the medicine IMMEDIATELY

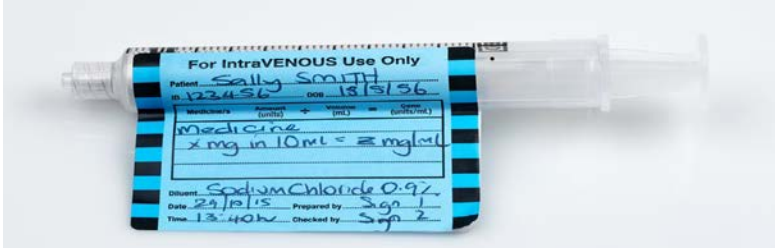
Syringes
For bolus or infusion (continued)

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
- Use an abbreviated preprinted 0.9% sodium chloride label
- Use full container labels for all other medicines and fluids

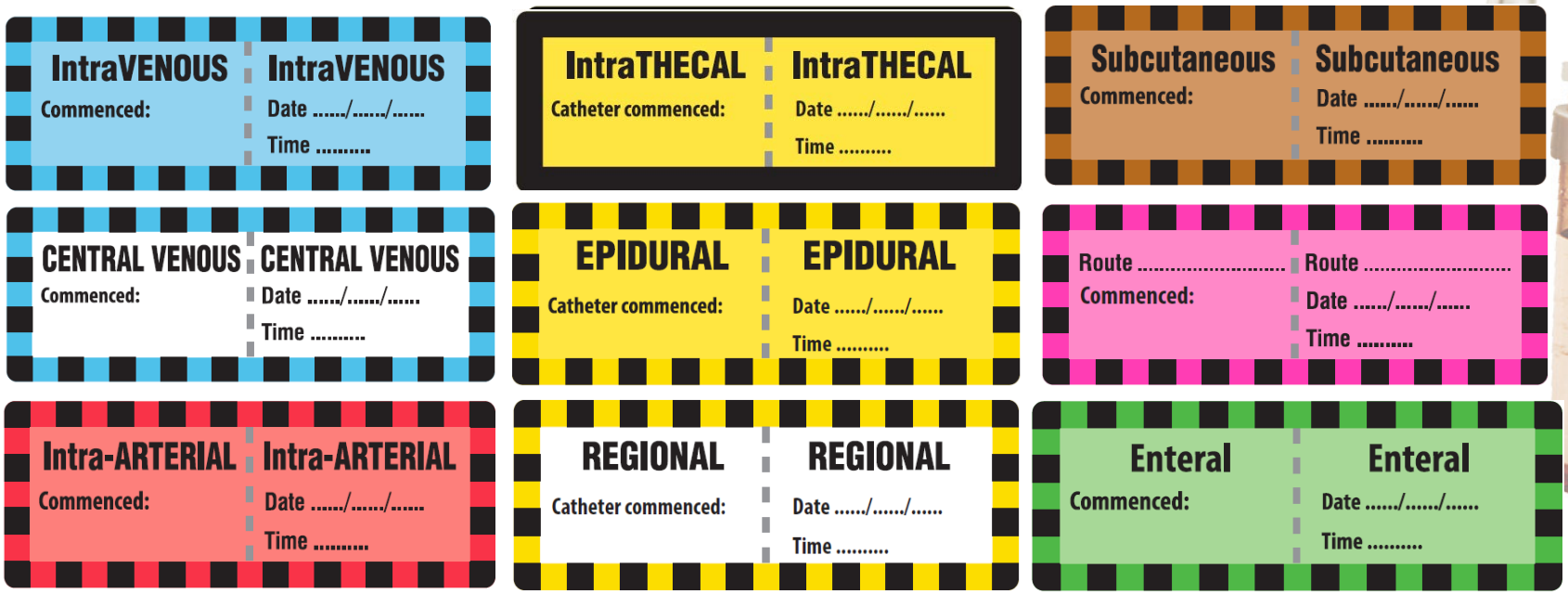
Sodium Chloride 0.9%

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

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 was commenced
  - 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 medicine (active ingredient) within administration lines for dedicated continuous infusions
- Use preprinted labels where possible.
- Colour should comply with Anaesthetic Labelling Standard (and its extension)

Potassium Chloride

- Lines for intermittent infusions do not need labelling for medicine. Any medicine label applied must be removed on completion of infusion

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

Pre-printed medicine line label guide

The following **examples** of medicine line labels for dedicated continuous infusion lines represent the majority of medicine line labels. For details on selection and application please refer to details on reverse.

Adrenaline
Vasopressor, Adrenaline
Violet bold reverse plate letters in a black bar on upper half of the label. Violet on lower half of label
PMS 256 **RGB** 222.191.217

amINOPHYLLIne
Miscellaneous
B/W, Tall Man lettering

amIODARONe
Miscellaneous
B/W, Tall Man lettering

Atropine
Anticholinergic
Green label with black font
PMS 367 **RGB** 163.217.99

Cisatracurium
Muscle relaxant
Fluorescent red with black font. Note (d)
PMS 811 **RGB** 253.121.86

Clonidine
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Dexmedetomidine
Miscellaneous
B/W

Diazepam
Benzodiazepine
Orange label with black font, Tall Man lettering
PMS 151 **RGB** 255.102.0

Dobutamine
Vasopressor
Violet label with black font
PMS 256 **RGB** 222.191.217

Dopamine
Vasopressor
Violet label with black font
PMS 256 **RGB** 222.191.217

Fentanyl
Opioid
Blue label with black font
PMS 297 **RGB** 133.199.227

Frusemide
Miscellaneous
B/W

Glyceryl trinitrate
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Heparin
Anticoagulant
Teal green label with a 1 to 2mm solid black border
PMS 3255 **RGB** 71.214.199

Insulin
Miscellaneous /High risk
White label with red font

Isoprenaline
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Ketamine
Induction agent
Yellow label with black font
PMS Process yellow C
RGB 255.255.0

Levosimendan
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Lignocaine
Local anaesthetic
Grey label with black font
PMS 401 **RGB** 194.184.171

Magnesium
Miscellaneous
B/W

Metaraminol
Vasopressor
Violet label with black font
PMS 256 **RGB** 222.191.217

Midazolam
Benzodiazepine
Orange label with black font
PMS 151 **RGB** 255.102.0

Milrinone
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Morphine
Opioid
Blue label with black font
PMS 297 **RGB** 133.199.227

Naloxone
Opioid antagonist
Blue with white diagonal stripe border
PMS 297 **RGB** 133.199.227

niMODIPine
Hypotensive
Violet with white diagonal stripe border, Tall Man Lettering
PMS 256 **RGB** 222.191.217

Noradrenaline
Vasopressor
Violet label with black font
PMS 256 **RGB** 222.191.217

Octreotide
Miscellaneous
B/W

Oxycodone
Opioid
Blue label with black font
PMS 297 **RGB** 133.199.227

Pancuronium
Muscle relaxant
Fluorescent red with black font. Note (d)
PMS 811 **RGB** 253.121.86

Potassium chloride
Miscellaneous/High risk
White label with red font

propOFol
Induction agent
Yellow label with black font, Tall Man lettering
PMS Process yellow C
RGB 255.255.0

Protamine
Anticoagulant antagonist
Teal green label with a 1 to 2mm diagonal stripe black border
PMS 3255 **RGB** 71.214.199

Rocuronium
Muscle relaxant
Fluorescent red with black font. Note (d)
PMS 811 **RGB** 253.121.86

Ropivacaine
Local anaesthetic
Grey label with black font
PMS 401 **RGB** 194.184.171

Salbutamol
Miscellaneous
B/W

Sodium chloride 0.9%
Miscellaneous
B/W

Sodium chloride 20%
Miscellaneous/High risk
White label with red font

Sodium nitroprusside
Hypotensive
Violet with white diagonal stripe border
PMS 256 **RGB** 222.191.217

Suxamethonium
Muscle relaxant, Suxamethonium
Fluorescent red bold reverse plate letters in a black bar on upper half of label. Fluorescent red on lower half of label. Note (d)
PMS 811 **RGB** 253.121.86

Thiopentone
Induction agent
Yellow label with black font
PMS Process yellow
RGB C 255.255.0

Urokinase
Anticoagulant
Teal green label with black font
PMS 3255 **RGB** 71.214.199

Vasopressin
Vasopressor
Violet label with black font
PMS 256 **RGB** 222.191.217

Vecuronium
Muscle relaxant
Fluorescent red with black font. Note (d)
PMS 811 **RGB** 253.121.86

NOTES:

a) Colours are a guide only and will digitally print according to software used.

b) Refer to PMS and RGB code for printed label colour.

c) B/W = Black text on white background.

d) Use Warm Red or 245.64.41 if printing is difficult.

** To be read in conjunction with National Standard for User-applied Labelling of Medicines, Fluids and Lines (Feb 2014). Copyright the Australian Commission for Safety and Quality in Health Care 2014*

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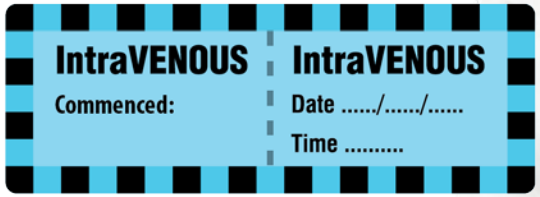
Lines:



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)

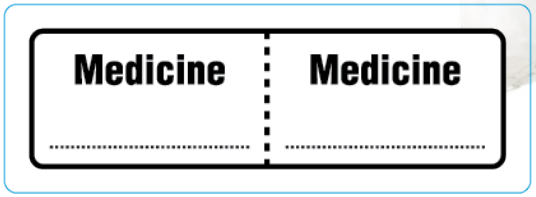
Potassium Chloride

Label Placement

- Medicine (Active ingredient):
  - Use pre-printed medicine label if available
  - Use generic medicine label
  - Label close to patient entry portal adjacent to route label

**Exception where there is a possibility of tampering*

(e.g. paediatric patients)



Special circumstances

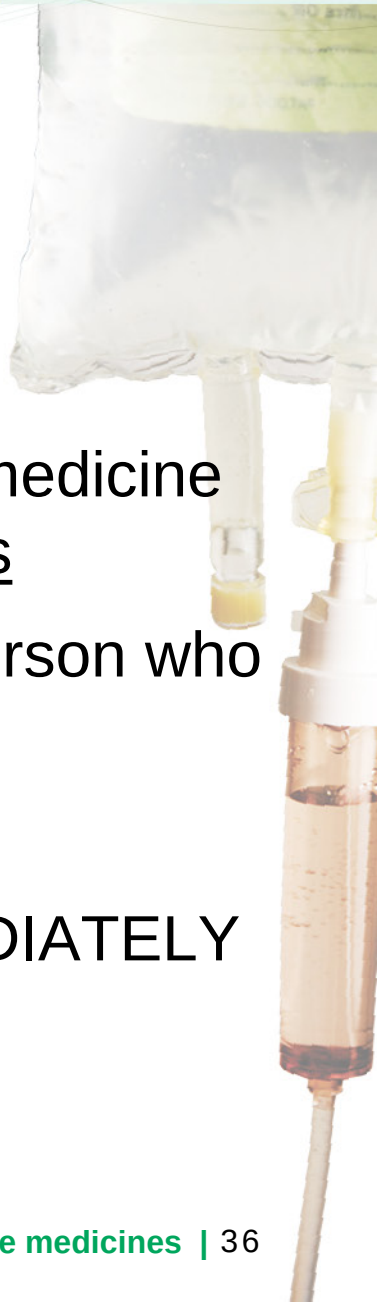
No label required if:

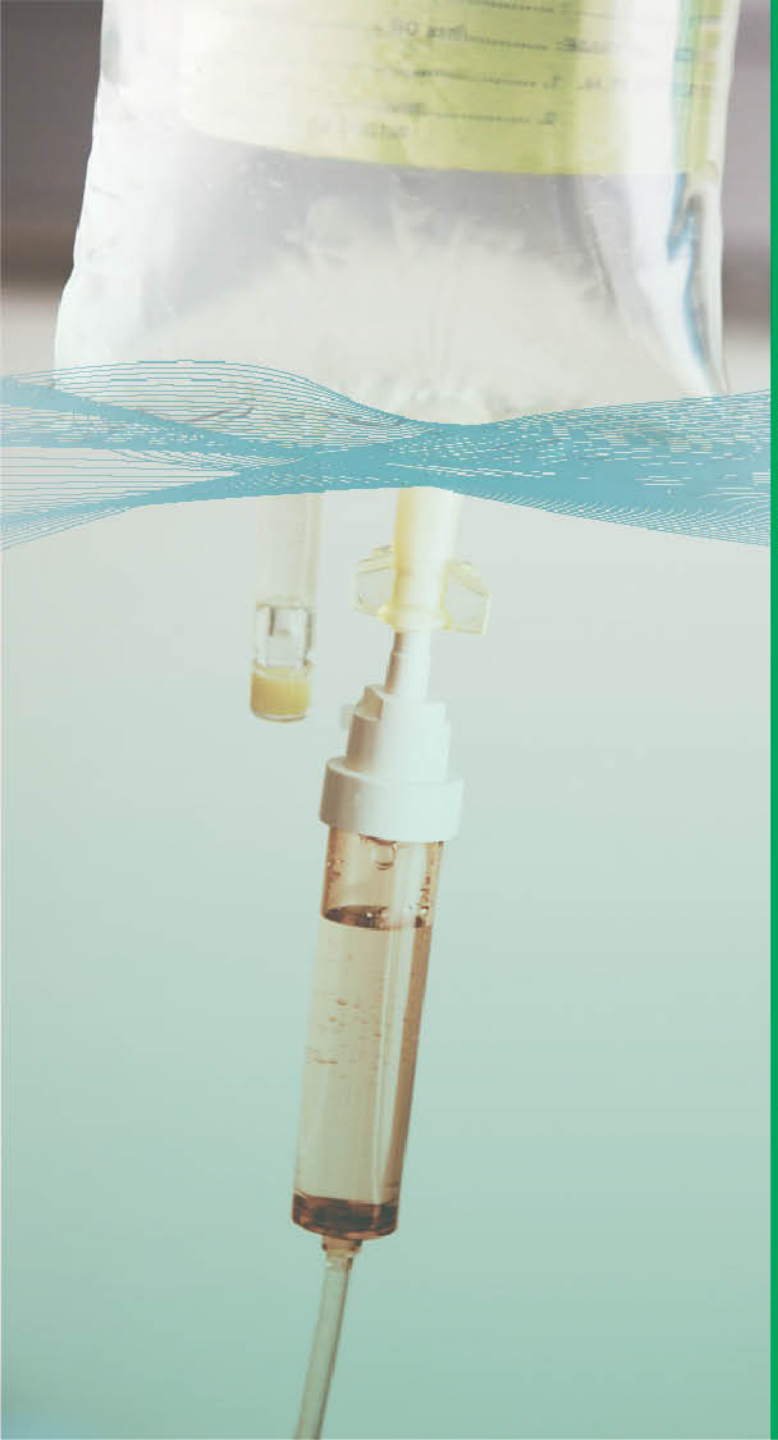
Preparation and bolus administration of a SINGLE medicine from a SINGLE syringe is one uninterrupted process

- the syringe DOES NOT leave the hands of the person who prepared it,

and

- that same person administers the medicine IMMEDIATELY

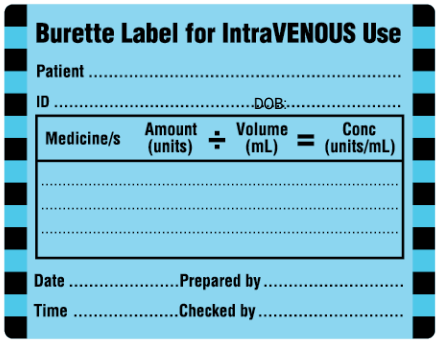




Burettes

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

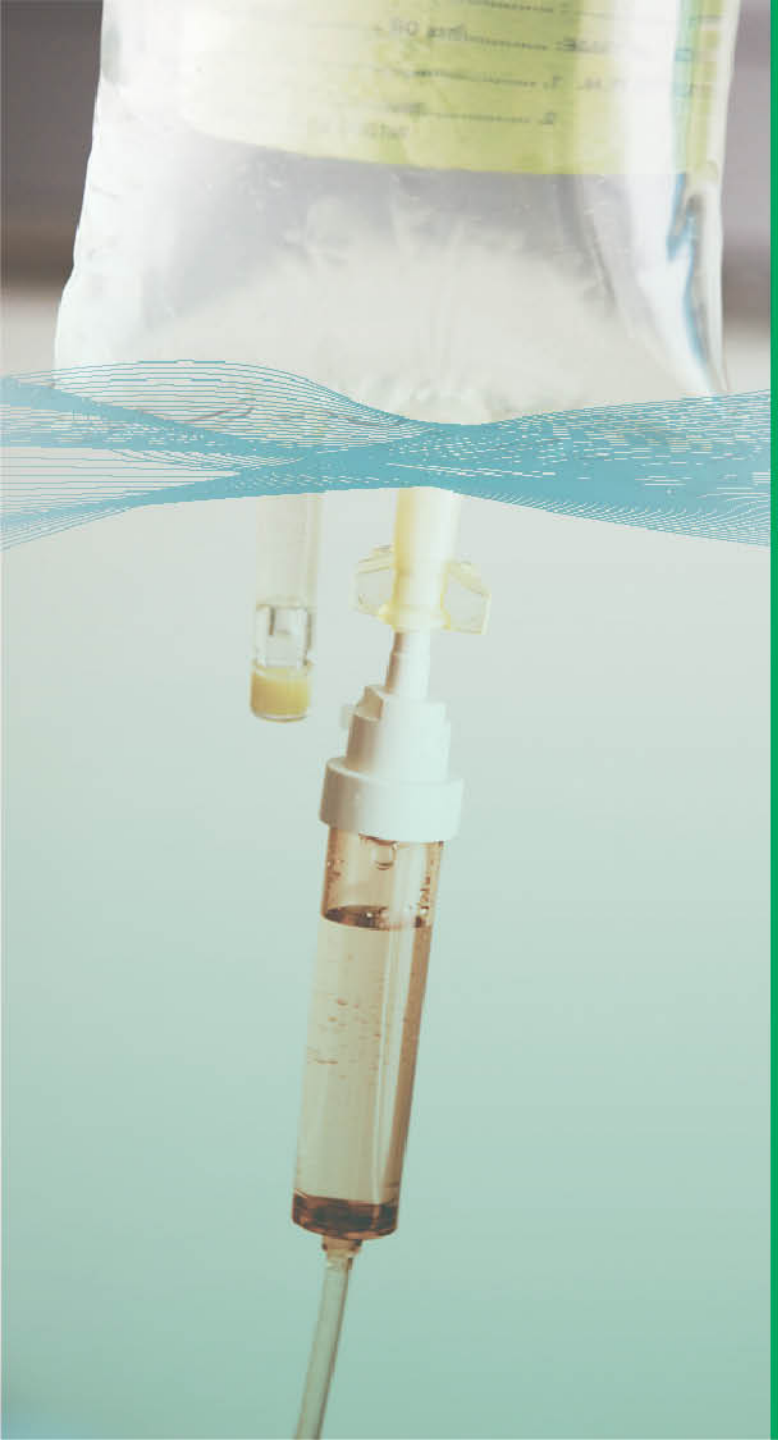
Patient .....

ID .....DOB:.....

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

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

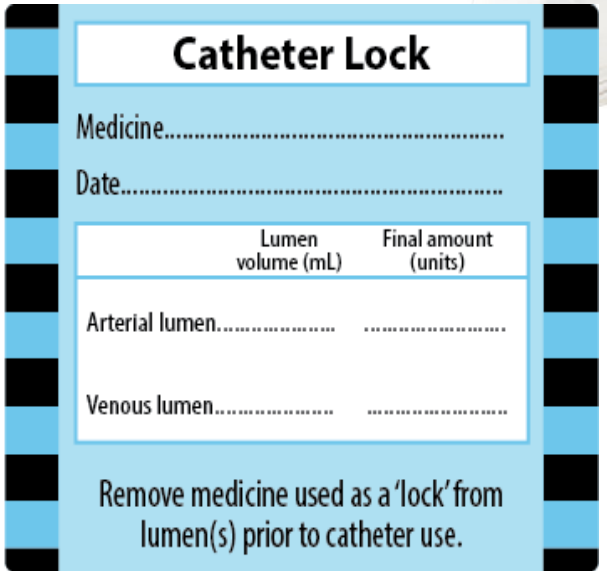
Time .....Checked by .....

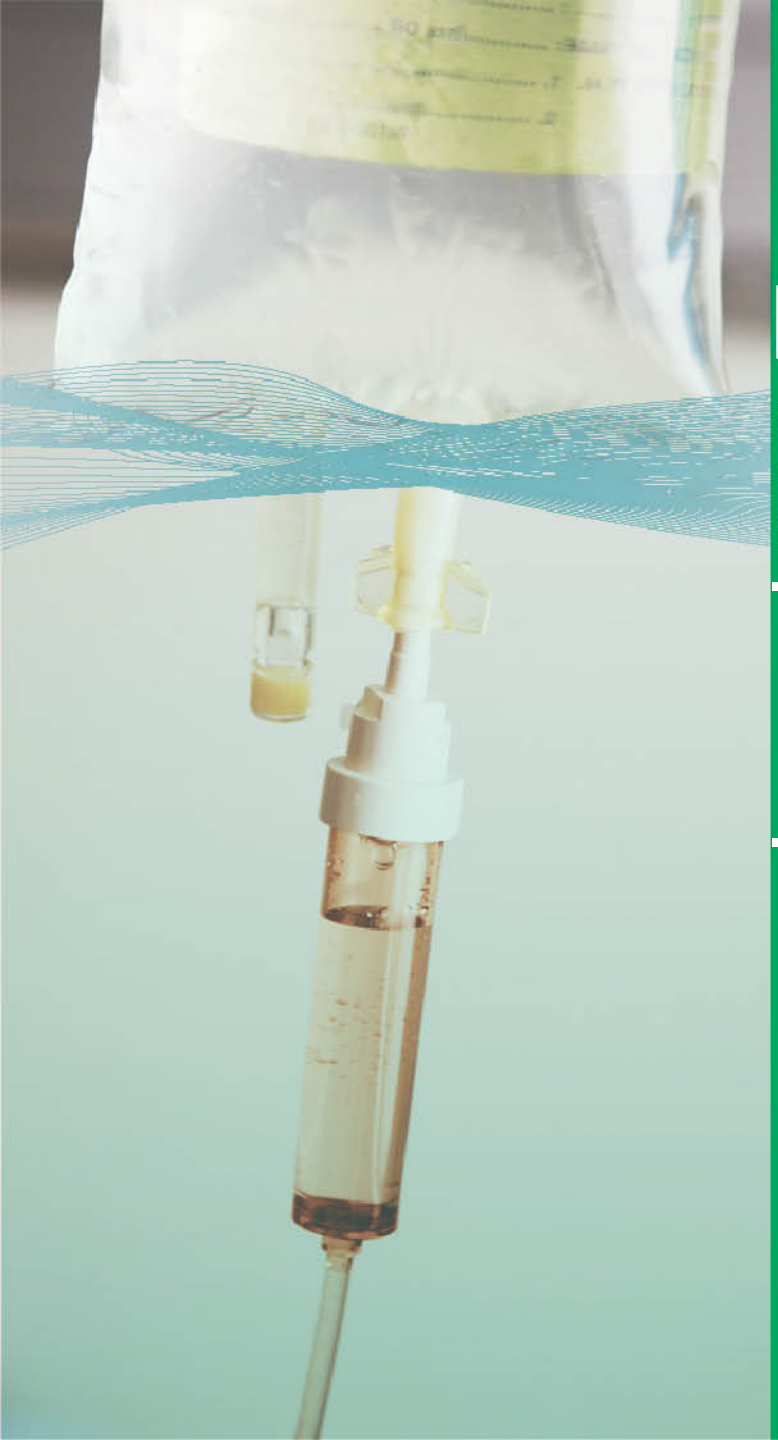


Catheter Lock

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
- Label to have a 'peel off' adhesive strength to ensure dressing remains in place





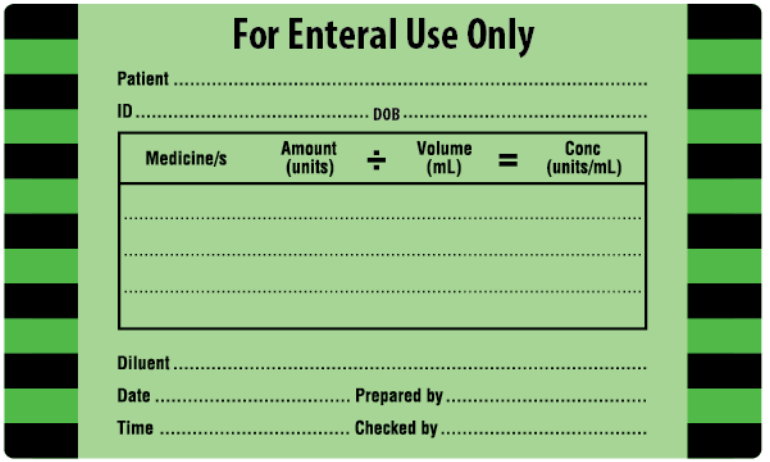
Non-Injectable Medicine

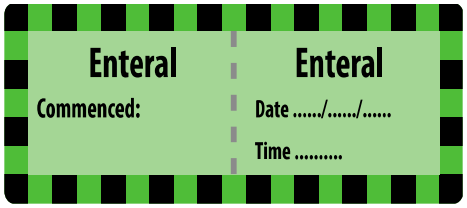
- ENTERAL ROUTE

- INHALATION

Non-Injectable Medicine – Enteral Route

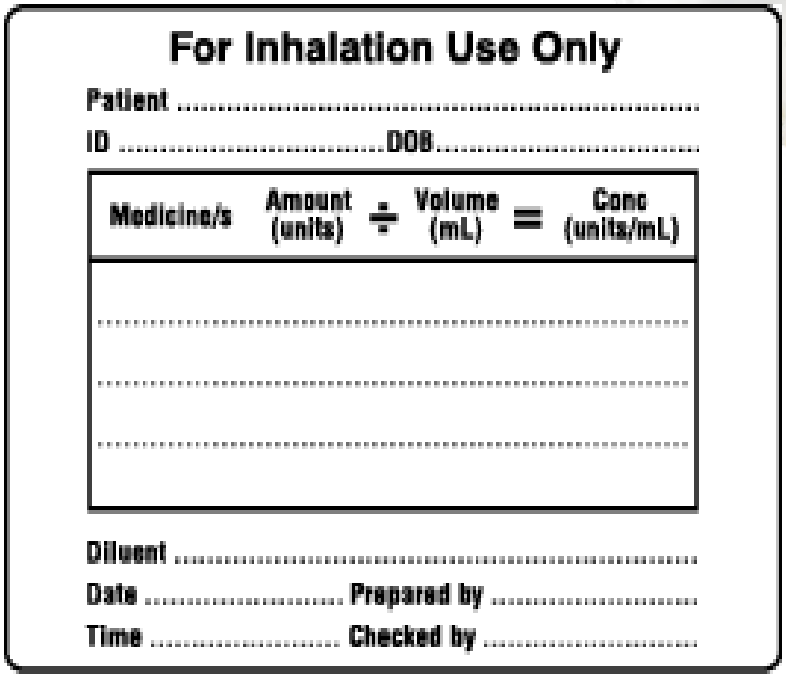
- Container and line labels available
- Syringes for non-injectable solutions must not be compatible with parenteral entry portals





Non-Injectable Medicine – INHalation

- Nebules are preferred source of solutions for inhalation
- If nebuliser solutions must be measured with a syringe then label the syringe



For Inhalation Use Only

Patient .....

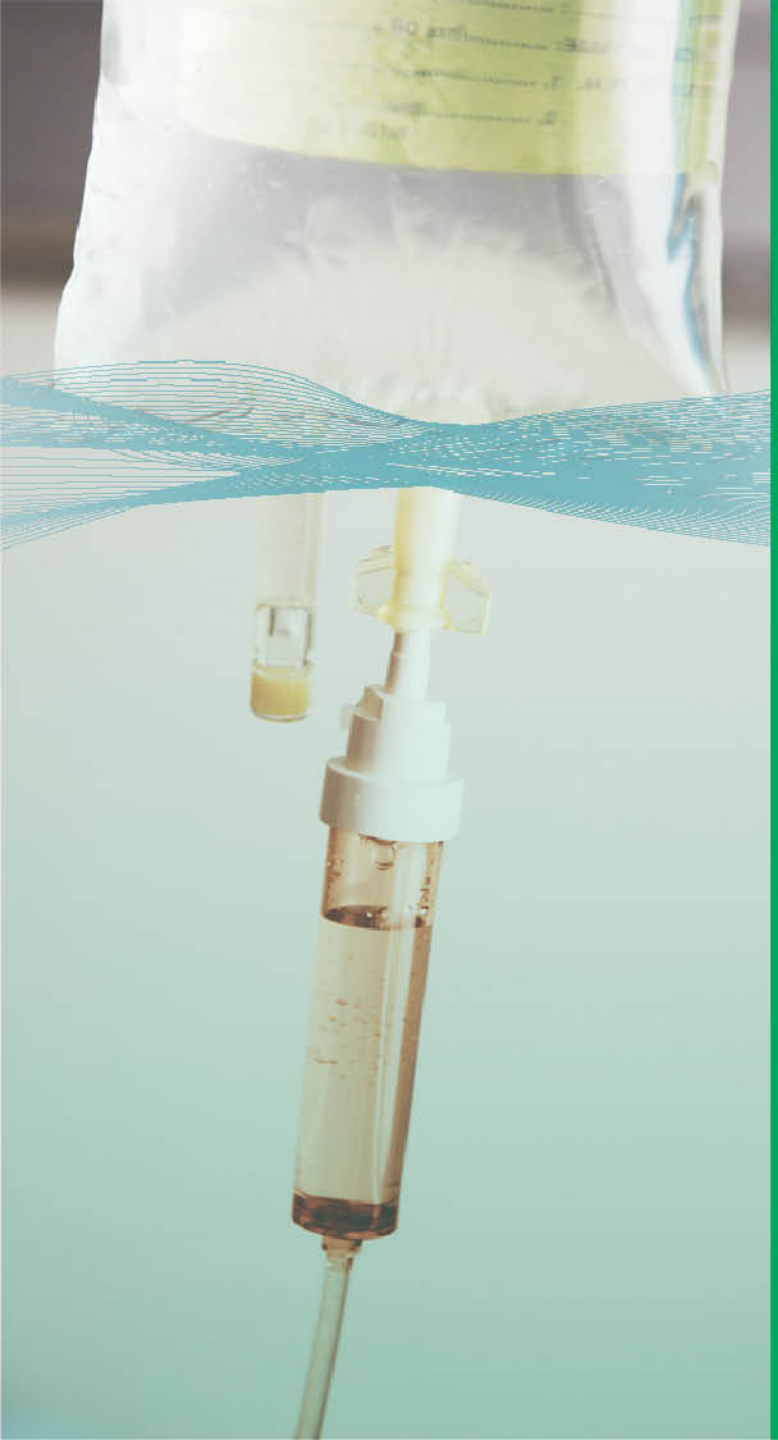
ID .....DOB.....

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

Diluent .....

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

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

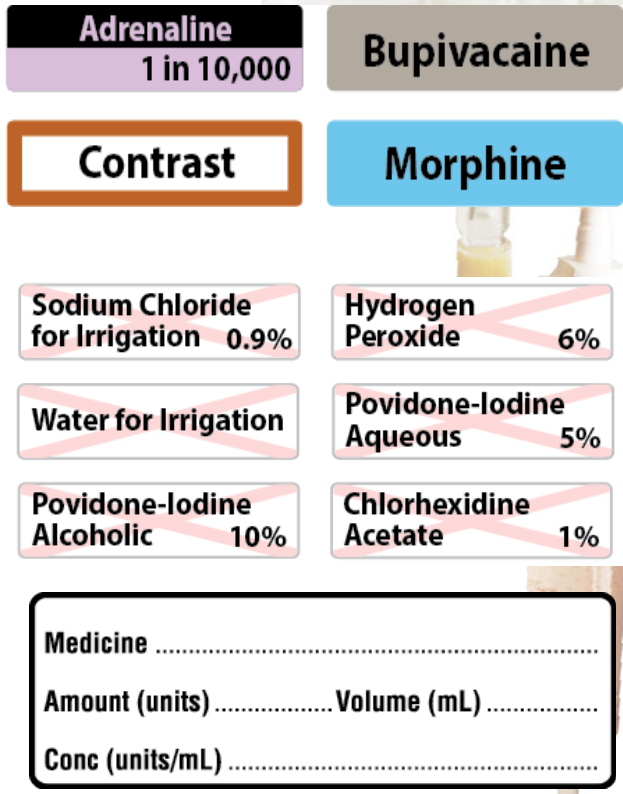


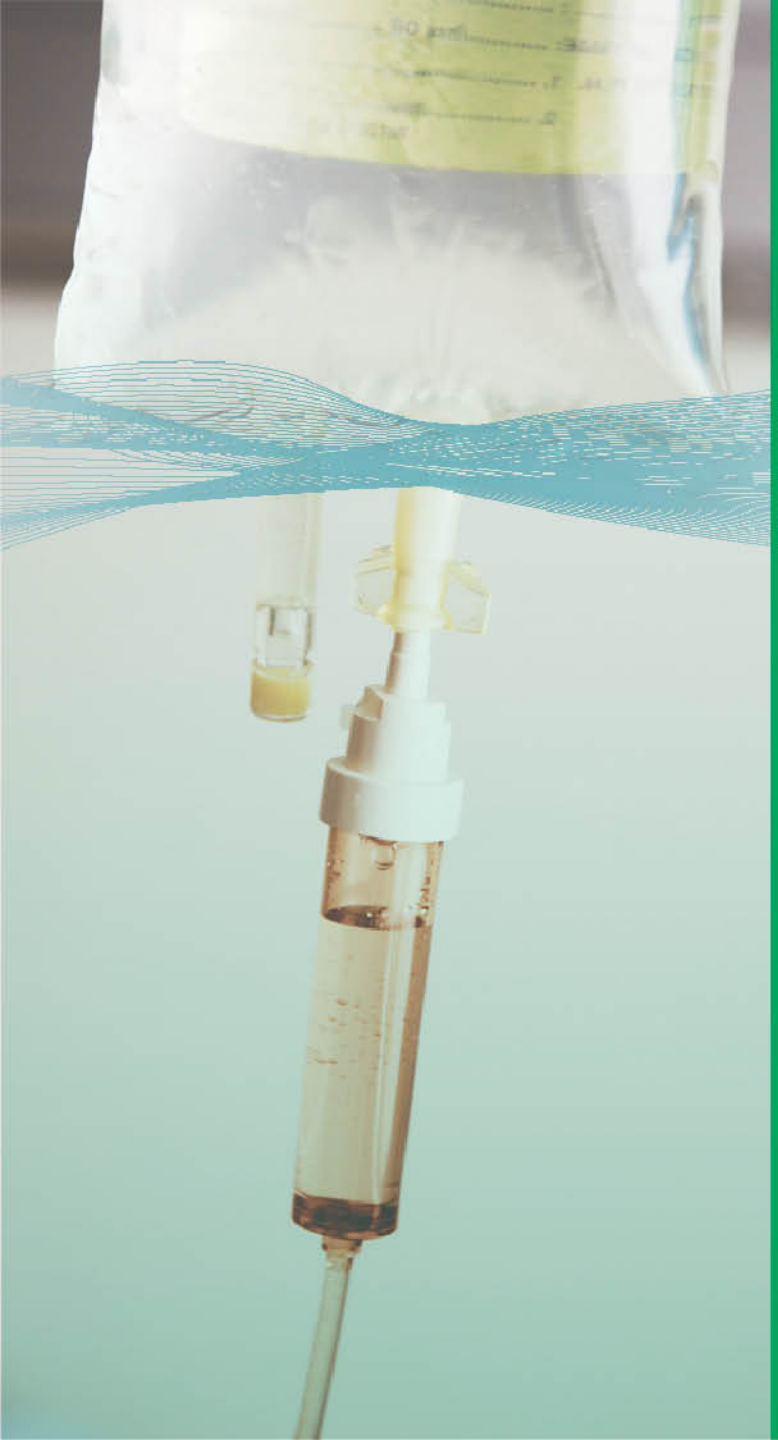
Closed –Practice Environments

- Perioperative Sterile Field
- Interventional Cardiology
- Radiology

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
- 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 for use in the sterile field.

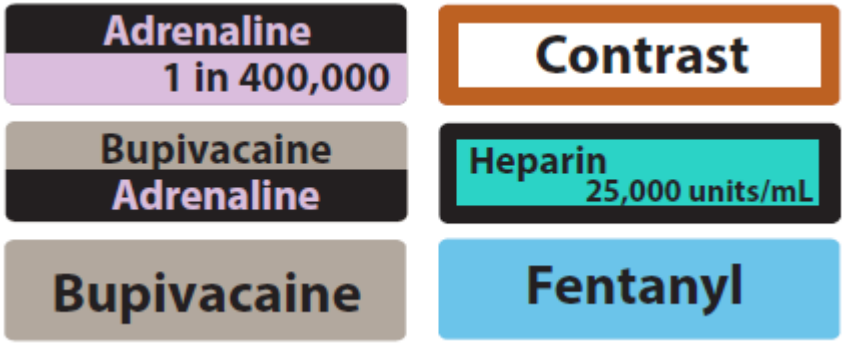




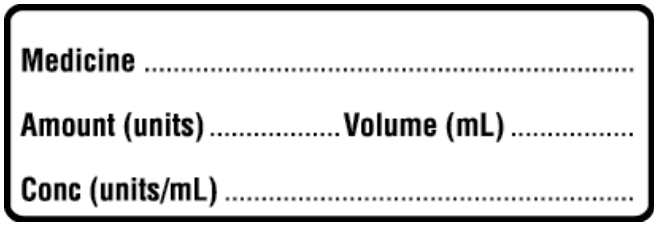
Perioperative environments

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.

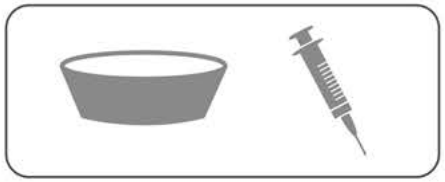
Label containers in the sterile field – for example:

Medicine.....
Conc (units/mL).....

Sodium Chloride 0.9% | ~~Povidone-Iodine~~

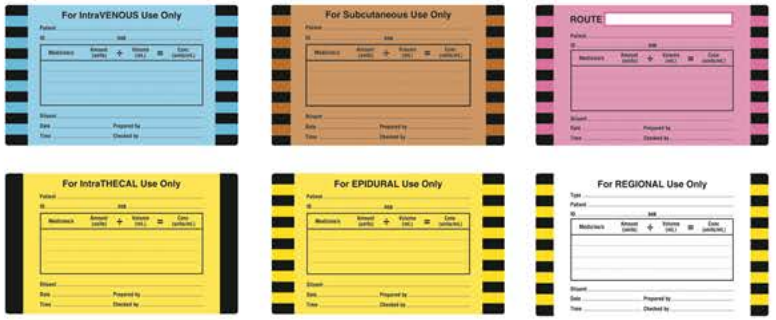
Adrenaline 1 in 1,000 | Bupivacaine | Morphine

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



Label lines to identify route

+

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

Medicine	Medicine .....

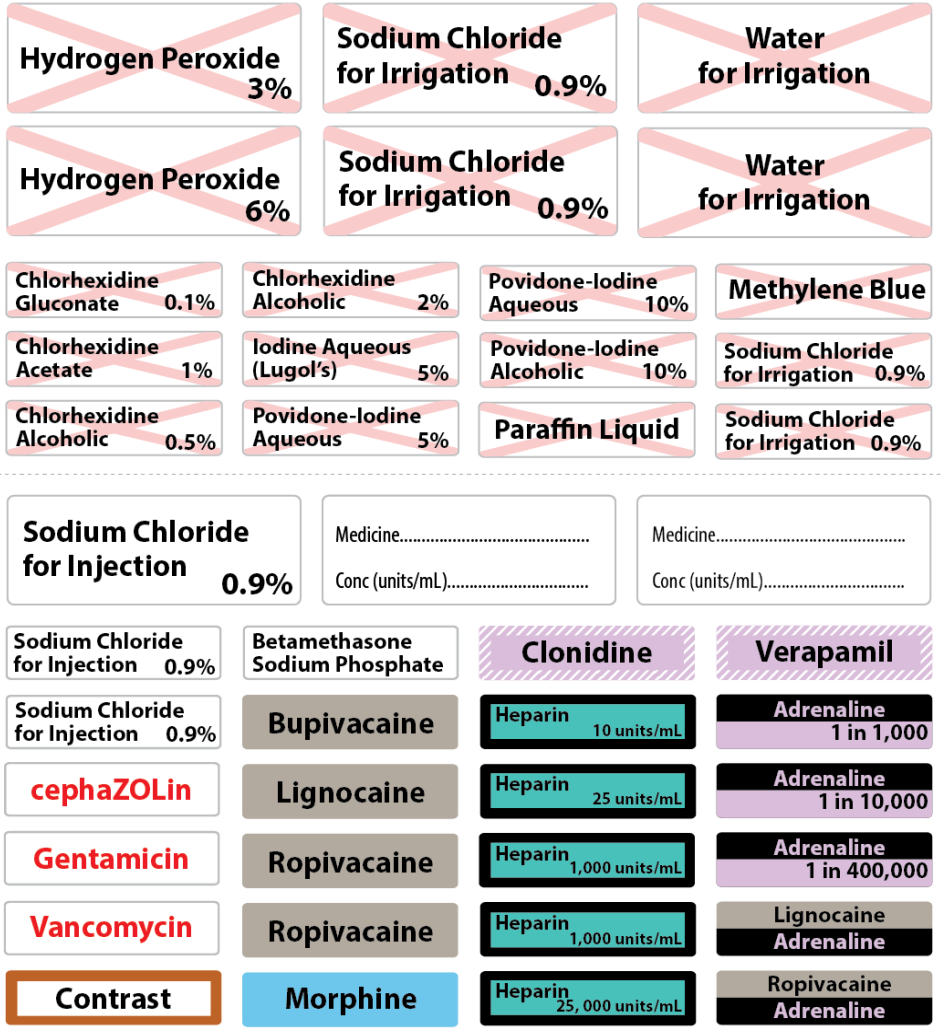
Morphine | Noradrenaline

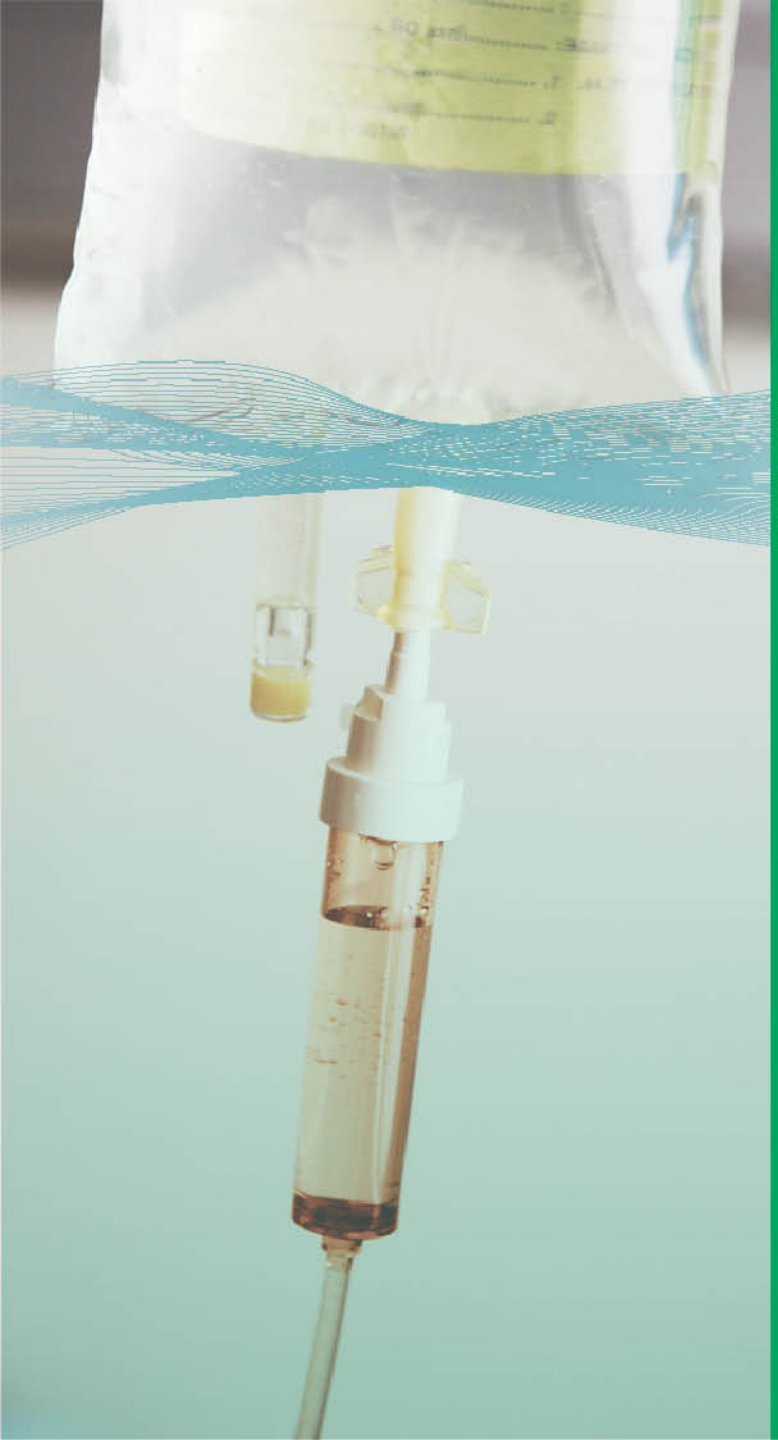
Perioperative sterile field

- 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 are clearly separated on the sheet

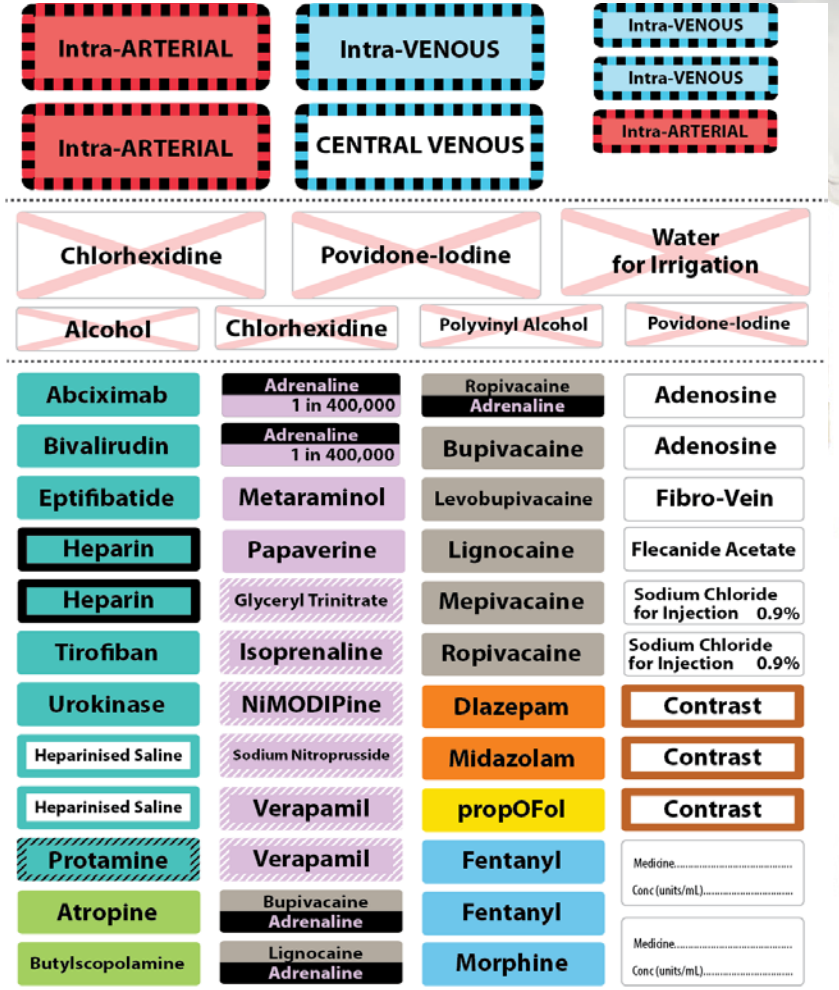


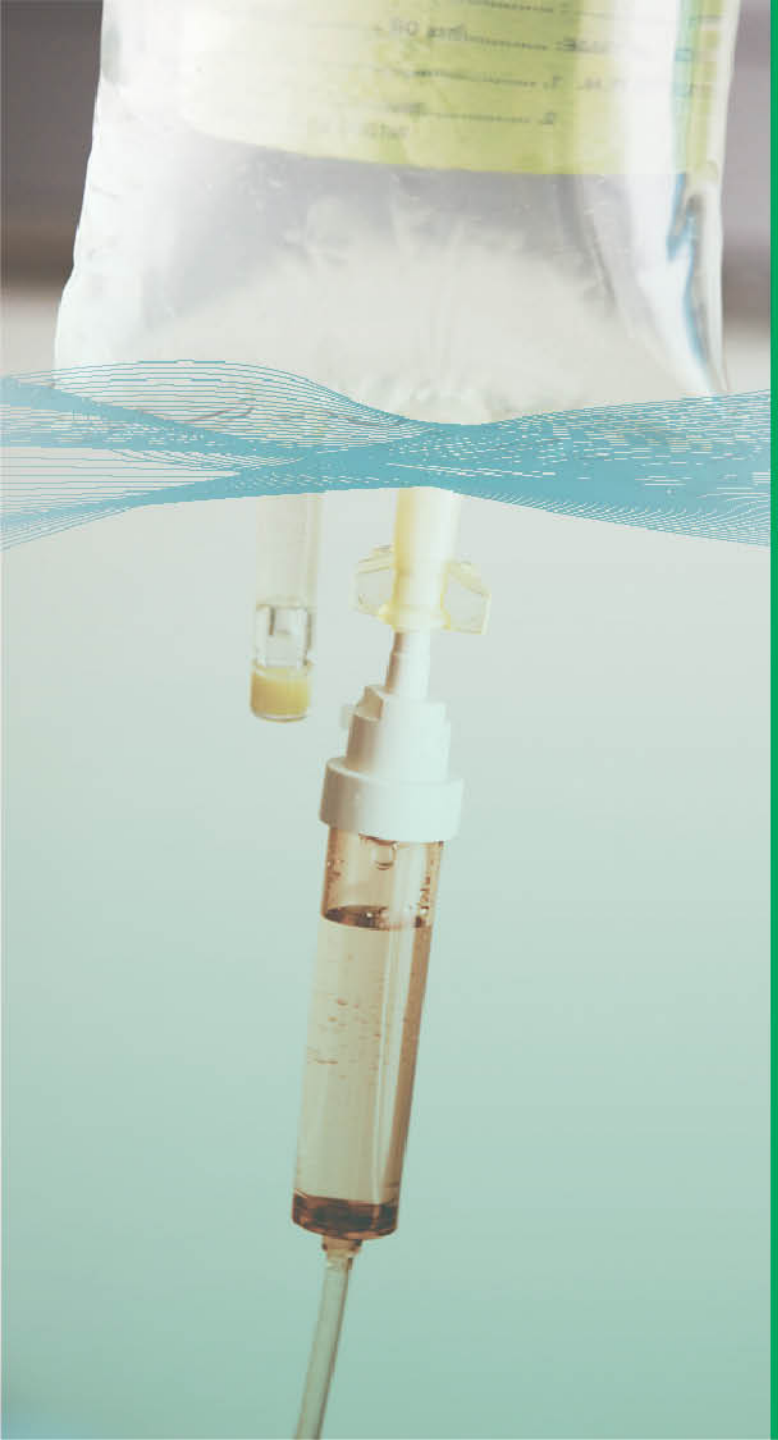


Interventional cardiology, radiology and other low-light procedure areas

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





Further information:

Go to the Australian Commission on Safety and Quality in Health Care website

www.safetyandquality.gov.au