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

June 2016
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 The unlabelled syringe had a 0.9% sodium chloride ampoule attached (unpublished)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This syringe had been drawn up and placed in a kidney dish alongside IV morphine and midazolam for procedural sedation (unpublished)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
Labelling Standard: scope

- **Container**
  - Examples:
    - Bags/bottles
    - Syringes
    - Jugs/basins (perioperative)

- **Conduit**
  - Examples:
    - IV administration lines
    - Epidural lines
    - Catheters
    - Invasive monitoring lines
    - Burettes

- **Patient**
  - Additives:
    - Active ingredient (medicine)
    - Fluids
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
All containers: label content

Example of miscellaneous 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*

<table>
<thead>
<tr>
<th>Target tissue</th>
<th>Route of administration</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-arterial</td>
<td>Intra-arterial</td>
<td>Red</td>
</tr>
<tr>
<td>Intravenous</td>
<td>Intravenous</td>
<td>Blue</td>
</tr>
<tr>
<td>Neural</td>
<td>Epidural / Intrathecal / Regional</td>
<td>Yellow</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>Subcutaneous</td>
<td>Beige</td>
</tr>
<tr>
<td>Intragastric</td>
<td>Enteral</td>
<td>Green</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Inhalational</td>
<td>White</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>Any other route not specified above</td>
<td>Pink</td>
</tr>
</tbody>
</table>

*Modified from Australian Standard AS4940
Bag and syringe labels: 2 sizes
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
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

- IntraVENOUS
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

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

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

- Subcutaneous
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

- Subcutaneous
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

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

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

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

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

- Route: _______________________
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

- Route: _______________________
  - Commenced: _______________________
  - Date: ......./......./......
  - Time: ...........

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

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

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

- 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

<table>
<thead>
<tr>
<th>Medicine line</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasopressor, adrenaline</td>
<td>Adrenaline</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>ProMoxine</td>
</tr>
<tr>
<td>BIV, Tail flaps</td>
<td>Furosemide</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Clonidine</td>
</tr>
<tr>
<td>Muscle relaxant</td>
<td>Diazepam</td>
</tr>
<tr>
<td>Vasopressor</td>
<td>Dobutamine</td>
</tr>
<tr>
<td>Muscle relaxant</td>
<td>Dopamine</td>
</tr>
<tr>
<td>Opaloid</td>
<td>Fentanyl</td>
</tr>
<tr>
<td>Vasopressor</td>
<td>Frusemide</td>
</tr>
<tr>
<td>Vasopressor</td>
<td>Glyceryl Trinitrate</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Heparin</td>
</tr>
<tr>
<td>Vasopressor/Fixed risk</td>
<td>Insulin</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Ketamine</td>
</tr>
<tr>
<td>Vasopressor/Fixed risk</td>
<td>Isoprenaline</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Lignocaine</td>
</tr>
<tr>
<td>Vasopressor/Fixed risk</td>
<td>Magnesium</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Metaraminol</td>
</tr>
<tr>
<td>Vasopressor/Fixed risk</td>
<td>Midazolam</td>
</tr>
</tbody>
</table>

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

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
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)
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
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
Non-injectable medicines: enteral route

- Syringe and line labels
- Syringes for non-injectable solutions must not be compatible with parenteral entry points
Non-injectable medicines: inhalation route

• Label syringes used to measure nebuliser solutions
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

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline</td>
<td>1 in 10,000</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td></td>
</tr>
<tr>
<td>Contrast</td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.9%</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>6%</td>
</tr>
<tr>
<td>Water for Irrigation</td>
<td></td>
</tr>
<tr>
<td>Povidone-Iodine</td>
<td>5%</td>
</tr>
<tr>
<td>Aqueous</td>
<td></td>
</tr>
<tr>
<td>Povidone-Iodine</td>
<td>10%</td>
</tr>
<tr>
<td>Acetate</td>
<td>1%</td>
</tr>
</tbody>
</table>
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
- Gonc (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:

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