Operational Directive

Enquiries to: Senior Policy Officer - Medication Safety
Phone number: 9222 4008
Supersedes: OD 0647/16

OD number: 0647/16
Date: 11/7/2016
File No: FAA - 04459

Subject: NATIONAL STANDARD FOR USER-APPLIED LABELLING OF INJECTABLE MEDICINES, FLUIDS AND LINES

AMENDMENT TO OD0647/16: Change to compliance date.

Hospitals are required to comply with the National Standard for User-Applied Labelling of Injectable Medicines, Fluids and Lines (including the WA modification identified in this Operational Directive) by October 31, 2016.

The Australian Commission on Safety and Quality in Healthcare has released the National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines (the Labelling Standard) in September 2015.

The Labelling Standard expands on the Labelling Recommendations (OD 0284/12) to include:

- Labelling of containers in perioperative settings (including theatre, cardiac catheter and interventional radiology units)
- Colour-coded preprinted 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.

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. 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 Standard.

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

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incomplete, omitting information such as name of medicine, dose, patient name or time of preparation. 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, and that medicines in well labelled syringes are more likely to have been prepared correctly.

THE LABELLING STANDARD

This National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines (the Labelling Standard) has been developed as a national solution to the risks posed by erroneous administration of injectable medicines. It replaces the 2012 National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (the Labelling Recommendations) which 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.

Adherence to the Labelling Standard 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 Labelling Standard is based on the following practice principles:

1. All medicines and fluids removed from the manufacturer's 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 should be prepared at a time 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) is considered unsafe and should be discarded.

ACCESSING THE LABELLING STANDARD

The Labelling Standard is attached and can be accessed at:

IMPLEMENTATION RESOURCES

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

- **Powerpoint education:**

- **Label specifications for specialist clinical areas (Perioperative, interventional cardiology and radiology, and intensive care units)**

- **A series of posters:**

PRINTING SPECIFICATIONS

The recommended labels can be accessed in EPS (for professional printing) format here:

WA health services and hospitals must follow these specifications, including WA modifications identified below, and advise their printing services accordingly.

WESTERN AUSTRALIAN MODIFICATION TO THE LABELLING STANDARD

**Stippling to Beige, Blue and Red Labels**

The Labelling Standard specifies 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 Standard.
AUDIT AND EVALUATION

It is highly recommended that compliance with the Labelling Standard be audited, including pre- and post-implementation audits.

Please visit the website below for suggested audit tools:

ISSUES REGISTER

The Quality Improvement and Change Management Unit will maintain an issues register regarding the Labelling Standard.

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

Attachment:

1. Australian Commission on Safety and Quality in Health Care National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines.

Dr DJ Russell-Weisz
DIRECTOR GENERAL
DEPARTMENT OF HEALTH WA

This information is available in alternative formats for a person with a disability.
National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines*

December 2015
WA Health

*To be read in conjunction with:
National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, August 2010
Copyright – Australian Commission on Safety and Quality in Health Care 2010
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

<table>
<thead>
<tr>
<th>CONTAINER</th>
<th>EXAMPLES</th>
<th>ADDITIVES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bags/bottles</td>
<td>Eg. Active ingredient (medicine)</td>
<td></td>
</tr>
<tr>
<td>Jugs/basins (perioperative)</td>
<td>Fluids</td>
<td></td>
</tr>
<tr>
<td>Syringes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONDUIT</th>
<th>EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV administration lines</td>
<td></td>
</tr>
<tr>
<td>Epidural lines</td>
<td></td>
</tr>
<tr>
<td>Catheters</td>
<td></td>
</tr>
<tr>
<td>Invasive monitoring lines</td>
<td></td>
</tr>
<tr>
<td>Burettes</td>
<td></td>
</tr>
</tbody>
</table>
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*

<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

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
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
- Sodium Nitroprusside
- propOFol
- Suxamethonium

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

- **Fentanyl**
  - Opioid
  - Blue label with black font
  - PMS 256 RLG 222.191.217

- **Metaraminol**
  - Vasopressor
  - Blue label with black font
  - PMS 256 RLG 222.191.217

- **Potassium chloride**
  - White label with red font
  - PMS 256 RLG 222.191.217

- **Sodium nitroprusside**
  - Hypotensive
  - White label with white diagonal stripe border
  - PMS 256 RLG 222.191.217

- **PropOFol**
  - Induction agent
  - Yellow label with black font, Tall Man lettering
  - PMS 256 RLG 222.191.217

- **Protamine**
  - Anticoagulant antagonist
  - Teal green label with a 1 to 2mm diagonal stripe border
  - PMS 256 RLG 222.191.217

- **Rocuronium**
  - Muscle relaxant
  - Fluorescent red label with black font, Note (a)
  - PMS 256 RLG 222.191.217

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

- **Sodium chloride 0.9%**
  - Miscellaneous
  - B/W

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

**NOTES:**
(a) Colours are a guide only and will digitally print according to software usage.
(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.
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

- 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
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

<table>
<thead>
<tr>
<th>Catheter Lock</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine: ..............................................................</td>
</tr>
<tr>
<td>Date: .................................................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lumen</th>
<th>Final amount (units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial lumen: ...................... ..............................</td>
<td></td>
</tr>
<tr>
<td>Venous lumen: ......................... ..............................</td>
<td></td>
</tr>
</tbody>
</table>

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

![Medication cards](image)

> 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:
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