Aim

- Compliance with Operational Directive OD0647/16 National Standard for User-Applied Labelling of Injectable Medicines, Fluids and Lines

Key Points

1. The following minimum requirements are to be implemented at KEMH
   - All medicines and fluids removed from the manufacturers or hospital pharmacy’s original packaging must be identifiable.
   - All containers containing medicines leaving the hands of the person preparing the medicine must be labelled.
• Only one medicine at a time should be prepared and labelled before the preparation and labelling of subsequent medicines.
• Any medicine or container that cannot be identified should be considered unsafe and discarded immediately.

2. From 1st January 2016 this clinical guideline **does** include labelling injectable medicines / containers for use in the perioperative setting.

3. This guideline applies to injectable medicines defined as any medicine intended for administration by the following routes:

<table>
<thead>
<tr>
<th>Intravenous</th>
<th>Intramuscular</th>
<th>Intrathecal</th>
<th>Intra-arterial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous</td>
<td>Intradermal</td>
<td>Intraventricular</td>
<td>Epidural</td>
</tr>
<tr>
<td>Intravesicular</td>
<td>Intravitreal</td>
<td>Intrapleural</td>
<td>Intraocular</td>
</tr>
<tr>
<td>Oral</td>
<td>Enteral</td>
<td>Inhalation</td>
<td></td>
</tr>
</tbody>
</table>

• Labelling of non-injectable medicines and fluids prepared in the same area as injectable medicines

4. General considerations for labelling all containers of injectable medicines include:
• Expressing total amount, volume and concentration
• The total amount of active ingredient added to the bag or syringe must be identified including units e.g. mg
• The total volume of fluid contained in the bag or syringe must be identified in millilitres (mL)
• The concentration (units / mL) must be identified.
• Expressing medicine concentration as a ratio (e.g. 1:1000, 1:10,000) is associated with medication errors and discouraged.² Exception: Preprinted labels in closed-practice environments (e.g. theatre), may be printed with a ratio to be consistent with expression of strength on the original packaging.²

5. Any unlabelled syringe (or other container) containing a solution must be immediately discarded.

6. Any container where there is doubt over the contents, must be discarded.

7. Any medicine remaining in the container at the end of a procedure must be discarded.

8. Any syringe (or other container) where there is doubt regarding its content must be discarded.

9. Any medicine remaining in the syringe (or other container) at the end of the procedure must be discarded.

10. Labelling Standard Exclusions
• Injectable medicines and fluids prepared by the hospital pharmacy, 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, solution and chemicals

**Process of Medicine and Label Preparation – Bags with Additives**

- Bags and bottles only require user-applied labels when a medicine is added in the clinical/ward area.
- All bags and bottles shall be labelled immediately when an injectable medicine is added.
- Each injectable medicine drawn up in a bag or syringe shall be prepared and labelled as a single operation by the same person.
- Whenever possible, the pharmacy or manufacturer’s labelling of product name, batch number and expiry date must remain visible after the label has been applied. Place the label on the front, slightly off centre to ensure the graduations on one side of the bag remain visible.
- The diluent should be identified on the label if the base fluid is not easily identifiable from the original manufacturer’s label.
- A duplicate label should be applied to any over wrapper which does not allow clear visibility of the primary label attached to the bag or syringe e.g. TPN
- Bag additive labels shall be placed on the front of the bag in a way that ensures the name of the base fluid, batch number and expiry date remain visible.

**Labelling Syringes**

- Use prefilled syringes and premixed solutions in standard strengths whenever they are available, e.g. pre-filled 0.9% sodium chloride syringe.
- 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.
  - The syringe remains in the hands of the person who prepared it, and
  - The same person administers the medicine immediately.
- The label shall be placed on the long axis of the syringe barrel with the top edge flush with (but not covering) the graduations.
Labelling IV Flushes
- Label any fluid drawn up in a syringe for use as an IV flush (e.g. 0.9% sodium chloride) unless the preparation and bolus administration is one uninterrupted process.
- Use an abbreviated pre-printed 0.9% sodium chloride label

Labelling Lines and Catheters
- The label must not obscure the graduations.
- All administration lines shall be labelled to identify the route.
- The date and time that the line was commenced must be identified.
- Labels shall be colour coded according to the target tissue.
- Catheters (e.g. epidural, intrathecal) must be identified where there is a risk of wrong route administration (e.g. where the patient entry portal is distant from the administration site).
- Administration lines dedicated for continuous infusions must be labelled to identify the active ingredient within the line. Use pre-printed labels where possible or a generic medicine label.
- Lines for intermittent infusions do not need labelling for medicine. Any medicine label applied must be removed on completion of the infusion.
- Label placement (route): use a colour coded route label and label near the injection port on the patient side.
- The label shall be placed far enough from the injection port to prevent interference with the mechanics of administration
- Prevent the introduction of infection

Labelling Burettes
- Use ‘peel off’ labels reserved for use on burettes only
- Place the label so that the 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.

Monitoring Lines
- All lines must be identifiable including those where the primary purpose of the line is not for medicine administration.
- The date and time that the line was commenced must be identified.
- Labels shall be colour coded according to target tissue.
Catheter Lock (For central venous access devices that are locked with a medicine e.g. heparin).

- Label to partially cover the catheter dressing
- Remove the labels after removing the medicine from the lock.

Inhalation

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

Perioperative Environments - Closed Practice Environment

- Continue to label syringes containing drugs used during anaesthesia to comply with ISO26825:2008.
- Concentration is optional with the exception of adrenaline (when used as a single medicine) and when medicines are available in different concentrations in the perioperative environment.  
- Pre-printed labels should be used where possible; use a generic abbreviated container label when a preprinted label is unavailable.
- On perioperative sterile fields, pre-printed abbreviated container labels without patient identification details may be used.
- Any container holding medicines or fluids on the operative sterile field must be labelled when removed from their original containers in an area where injectable medicines are used.
- Labels must remain intact for the duration of the procedure.
- Labels must adhere for the duration of the procedure.
- Labels on reusable containers should be removed at the end of the procedure.
- 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.
- When the patient moves to an open-practice environment (e.g. Recovery), any containers and catheters remaining in place must be fully labelled, with patient
and user identifiers, according to the labelling standard. This may include lines for continued delivery of infusion fluids with additives, administration and monitoring lines and drugs prepared in syringes to accompany the patient on transfer to another clinical area.
Intravenous Medications: Labelling of Injectable Medicines and Fluids

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

**Label syringes** containing medicines used during anaesthesia

*For example:*
- Morphine
- Ephedrine
- Atropine
- Suxamethonium
- Ketamine
- Levosimendan

Use ISO 26825:2008 compliant labels.

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 containers** in the sterile field – for example:
- **Adrenaline** 1 in 1,000
- **Bupivacaine**
- **Morphine**
- Sodium Chloride 0.9%
- Povidone-Iodine

Use sterile labels and sterile marker pens.

**Label lines** to identify route

**Label lines** to identify medicine in a dedicated continuous infusion line – for example:
- **Morphine**
- Noradrenaline
### Target Tissue | Routes 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 nor specified above | Pink

### References

### Related policies

### Related WNHS policies, procedures and guidelines