Safe Administration of Liquid Medicines by Routes other than Injection

Summary This policy provides direction to minimise the risk of patient injury or death from inadvertent parenteral administration of liquid drug doses intended for other routes.

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Applies to Local Health Districts, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Hospitals
Distributed to Public Health System, Divisions of General Practice, Government Medical Officers, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes
Audience Administration;Clinical
SAFE ADMINISTRATION OF LIQUID MEDICINES BY ROUTES OTHER THAN INJECTION

PURPOSE

There have been a number of incidents resulting in serious injury where doses of oral liquid medicines have been administered parenterally.

These incidents have occurred through the use of parenteral syringes to prepare liquid medicine doses resulting in inadvertent administration of the dose via the incorrect route. The outcomes of this type of incident may be catastrophic and can be fatal.

This policy has been developed to minimise the risk of serious injury or death from the parenteral administration of liquid doses of medicines intended for other routes (principally oral or enteral).

MANDATORY REQUIREMENTS

• Oral/enteral dispensers (also called oral/enteral syringes) or graduated medicine cups are to be used to prepare, measure and administer all liquid doses intended for:
  - Oral and enteral use
  - Inhalational, intranasal, topical, or rectal use where measurement of volume is required
  - Injectable medicines intentionally prescribed for non-parenteral use

• Devices used for withdrawing liquid medicine doses intended for non-parenteral use from their container must have connections compatible with the oral/enteral dispensers

• Enteral feeding catheters, both nasogastric and percutaneous must have connections compatible with the oral/enteral dispensers in use.

• No device intended for access to the gastrointestinal tract should feature a female Luer® connector (Luer-Lok® or Luer-Slip®).

IMPLEMENTATION

Local Health District Chief Executives

• Assign responsibility for implementation of the standard and maintenance of the use of oral/enteral dispensers in line with mandatory requirements within the Local Health District.

Directors of Clinical Governance

• Ensure systems are in place to:
  - Implement the mandatory requirements and standards.
  - Monitor compliance with the policy and standards.
Hospital, facility, clinical stream and unit managers, Heads of Departments, Nurse/Midwife In Charge

- Ensure systems and practices prescribed in this policy are implemented and sustained successfully.
- Clearly identify and store oral/enteral dispensers separately from parenteral syringes.
- Ensure that oral/enteral dispensers and compatible connectors are available at the point-of-care.
- Monitor compliance and practices described in this policy.
- Ensure compliance of staff with use of the devices as described.

Directors of Pharmacy

- Liaise with relevant staff to ensure supply of oral/enteral dispensers and compatible connectors are maintained in all clinical areas.
- Ensure all clinical pharmacists and technicians are aware of this policy and ensure it is followed in all clinical areas.
- Ensure all dose measuring devices issued to outpatients and those transferring to the community comply with this policy.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
</tr>
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<tbody>
<tr>
<td>January 2012 (PD2012_006)</td>
<td>Director-General</td>
<td>New Policy</td>
</tr>
</tbody>
</table>

ATTACHMENTS

*Policy Standard – Safe Administration of Liquid Medicines by Routes Other Than Injection*
Safe administration of liquid medicines by routes other than injection.
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1. BACKGROUND

The policy statement and standards together provide direction to minimise the risk of patient injury or death from inadvertent parenteral administration of liquid drug doses intended for other routes.

This policy mandates use of oral/enteral dispensers to measure and administer liquid medication doses by routes other than injection. Oral/enteral dispensers allow accurate volume measurement and prevent connection with injectable access devices. Use of dedicated devices provides a check against a medicine dose being administered by the incorrect route.

This policy is relevant to all clinical staff involved in administration of medicines and applies to adults, children and neonates.

2. KEY DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration line</td>
<td>This includes all giving sets, administration lines and invasive monitoring lines through which medicines and fluids could be administered.</td>
</tr>
<tr>
<td>Barrel (of syringe)</td>
<td>The hollow cylinder of a syringe in which fluids are measured</td>
</tr>
<tr>
<td>Catheter</td>
<td>A flexible tubular device for removing fluids from, or delivering fluids to, a body cavity.</td>
</tr>
<tr>
<td>Calibration</td>
<td>(the scale of a measuring instrument) an instrument divided into marked intervals for optimal measuring so that it can be read in the desired units.</td>
</tr>
<tr>
<td>Dead space</td>
<td>The volume of fluid remaining in the tip of a syringe after the plunger of the syringe has been fully depressed into the barrel.</td>
</tr>
<tr>
<td>Enteral</td>
<td>Fluids (nutrition or medicine) given into the gastrointestinal tract.</td>
</tr>
<tr>
<td>Female (Luer) Connector</td>
<td>Describes the shape and size of the port which connects with a male Luer connector. The standard shape of devices designed to access the vascular system.</td>
</tr>
<tr>
<td>Hub/syringe adaptor</td>
<td>The proximal end of a needle which attaches to the syringe barrel by means of a press-fit mechanism (Luer) or a twist-on mechanism (Luer-Lok).</td>
</tr>
<tr>
<td>Injection</td>
<td>For the purposes of this policy includes intravenous, intramuscular, intra-arterial, epidural, subcutaneous routes of administration</td>
</tr>
<tr>
<td>Intravenous</td>
<td>Parenteral drug and fluid administration into or within a vein or veins.</td>
</tr>
<tr>
<td>Luer taper</td>
<td>A Luer taper is a standardised system of small-scale fluid fittings used for making leak-free connections between a male taper fitting and its mating female part on medical and laboratory instruments, including hypodermic syringe tips and needles. It originated as a 6% taper fitting for glass bottle stoppers. Key features of Luer taper connectors are defined in the ISO 594/1:1986 standard. (BS EN 20594-1:1994).</td>
</tr>
</tbody>
</table>
There are two varieties of Luer taper connections: Luer-Lok and Luer-Slip. Luer-Lok fittings are securely joined by means of a tabbed hub on the female fitting which screws into threads in a sleeve on the male fitting. Luer-Slip fittings simply conform to Luer taper dimensions and are pressed together and held by friction (they have no threads). Luer components are manufactured either from metal or plastic and are available from many companies worldwide.

"Luer-Lok" and "Luer-Slip" are registered trademarks of Becton Dickinson. In the literature a "Luer-Lok" style connector is often generically referred to as a "Luer lock connector" and it has since become an industry standard.

<table>
<thead>
<tr>
<th>Male (Luer) Connector</th>
<th>Describes the shape and size of the nozzle (tip) of a syringe that connects to a female Luer port. The standard shape of the tip of an intravenous syringe.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must</td>
<td>Indicates a mandatory action required by a NSW Health policy directive, law or industrial instrument.</td>
</tr>
<tr>
<td>Nasogastric tube</td>
<td>A flexible plastic tube passing into the stomach through the nostril and nasopharynx.</td>
</tr>
<tr>
<td>Oral/enteral dispenser</td>
<td>A device manufactured with a non-Luer taper male tip so that it cannot be fitted to a female Luer port. This device is used to measure and/or administer liquid doses of medicines for non-parenteral administration. Some products may be labelled as oral/enteral syringes.</td>
</tr>
<tr>
<td>Parenteral (Medicine)</td>
<td>Taken into the body or administered in a manner other than through the digestive tract. For the purposes of this policy, refers to administration by injection</td>
</tr>
</tbody>
</table>
| Public health organisation (PHO) | • A local health district  
 • A statutory health corporation that provides inpatient services, or  
 • An affiliated health organisation in respect of its recognised establishments that provide inpatient services. |
| Plunger               | The movable part of the syringe which is pushed down the barrel to expel its contents or pulled up within the barrel to fill the syringe.                                                              |
| Route of administration| The path by which a substance is taken into the body (i.e., by mouth, injection, inhalation, rectum, or by application).                                                                               |
| Should                | Indicates an action that should be followed unless there are sound reasons for taking a different course of action.                                                                                  |
| Straw                 | A length of plastic tubing that connects to an oral/enteral dispenser used to draw up liquids from a container                                                                                           |
| Syringe               | A device for injecting or withdrawing fluids. For the purposes of this policy a syringe is used to administer medication or fluid parenterally. Devices used to measure and/or administer liquid doses of medicines for non-parenteral administration are referred to as oral/enteral dispensers |
| Tip (of syringe)      | The point of the syringe which is connected to a needle or device and from which fluids are delivered.                                                                                                   |
3. ORAL/ENTERAL DISPENSERS - REQUIREMENTS

- Oral/enteral dispensers are manufactured with non-Luer connector geometry and in several coloured presentations. Requirements include:
  - must be designed with a tip which is unable to be connected to a Luer fitting on injectable systems. This lack of connectivity may be achieved by variation of the angle of the Luer taper e.g. reverse Luer taper, straight taper, non-Luer taper.
  - must be readily distinguishable from parenteral syringes by labelling (oral/enteral use only) and/or colour (of plunger or barrel).
  - must be available in a size range from one millilitre (1mL) to at least fifty millilitres (50mL) to accommodate the possible range of oral dose volumes.
  - must be provided clean, not necessarily sterile, but over-wrapped, individually or in small quantities to facilitate clean handling
  - must be single patient use devices.
  - must have minimal dead space to ensure accurate measurement.
  - must be calibrated in metric quantities and in millilitre increments.
  - must be compatible with administration sets used for enteral feeding purposes. These should be clearly differentiated from giving sets for parenteral use. There must be a mechanism or use of clear labelling to alert clinical staff that the device is in use for enteral feeds ONLY.
- Oral/enteral dispenser caps must be used for pre-packed doses e.g. from pharmacy, but must be kept out of reach of children due to potential choking hazard.
- Devices to assist withdrawal of doses from liquid containers (stoppers or straws) must be compatible with the oral/enteral dispensers.

4. ENTERAL FEEDING SYSTEMS

- All nasogastric and enteral feeding tubes chosen for use must have connections compatible with the oral/enteral dispensers in use and should not feature any in-line female Luer administration ports nor be able to be connected to the patient using a male Luer terminal connector.
- Only devices with non-Luer or catheter-tip connectors to fit catheter-tip ports on enteral feeding systems must be used.
- Three-way taps and syringe-tip adaptors should not be used in enteral feeding systems.
• A portal for administration of oral medicines via enteral feeding catheters must be available. Note: the oral medicines portal must not contain ports that can be connected to parenteral syringes or have (distal or proximal) end connectors which can be connected to parenteral lines.

• Enteral feeding tubes should be labelled to indicate route of administration.

• Oral/enteral dispensers must be used for expressed breast milk or formula, if administered via enteral catheter or by mouth to an infant except when cups or bottles are in use.

5. LIQUIDS FOR INHALATION, INTRANASAL, TOPICAL OR RECTAL ADMINISTRATION

• Liquids for inhalation, intranasal, topical or rectal administration
  o are to be purchased in ready to use units wherever possible.
  o parenteral syringes should not be used for measurement or administration of doses.

• If injectable solutions are prescribed for inhalation, intranasal, topical or rectal administration and there is no alternate product,
  o oral/enteral dispenser and compatible straw should be used where possible.
  o withdrawal of doses from vials may require the use of needles and luer-compatible syringes.
  o to reduce risk of inadvertent injection dose should be both drawn up and administered at the bedside. Where this is not possible the container must be labelled with the intended route of administration eg FOR INHALATION ONLY.
  o labelling of any dispensed product must include the intended route of administration.

• If a bulk pack of solution for inhalation must be used, a non-Luer dispenser must be used to withdraw doses and expel them into inhalation reservoirs.

• Where a sterile solution is prepared in a pharmacy, it must be dispensed in a container clearly labelled with the intended route of administration. Containers should be chosen that are not amenable to withdrawal of solution for injection17.

6. PROCEDURES

6.1 Obtain and stock oral/enteral dispensers which are:

• clearly differentiated from parenteral syringes through barrel or plunger colouring or through clearly distinguished packaging.

• readily available in clinical areas where liquid medicine doses for routes other than injection are prepared.
• clearly recognised through use of pre-printed labelling eg **FOR ORAL/ENTERAL USE ONLY.**
• stored separately from parenteral syringes and storage areas clearly identified.

**6.2 Prepare and administer doses as follows:**

- Oral/enteral dispensers should be used to prepare and administer liquid medication doses which are:
  - not readily measured by available calibrations using an oral medicine measure or cup
  - administered by the oral or the enteral route (whether by nasal or percutaneous entry)
  - given by inhalation, intranasal, topical or rectal administration where measurement of volume is required
  - injectable medicines intentionally prescribed for non-parenteral use.
- Shake containers of oral medicine in suspension form prior to withdrawal of doses, to ensure accurate dose delivery.
- Devices to assist measurement and withdrawal of medicine doses from liquid containers (stoppers or straws) must be compatible with oral/enteral dispensers.
- Oral/enteral dispensers are single patient use devices and must be discarded after use. If several liquid medicine doses are to be given to one patient at the same time of day, they should each be separately prepared and administered.
- For accurate dose measurement, align the widest part of the plunger with the calibrated markings on the barrel.
- Determine compatibility of the medicine with oral feeds and flush feed tubing between administration of doses.

**6.3 Labelling of non-parenteral liquid doses**

- Preparation of doses for immediate administration is preferred.
- If doses must be prepared in advance, these must be labelled at a minimum with the drug, dose, volume and intended route of administration eg **FOR ORAL/ENTERAL USE ONLY.** The label is to be affixed so that it does not obscure calibrations.
- If a single dose is prepared for immediate administration labelling is not required.
- All administration lines used for administration of non parenteral medication should be labelled and include route of administration with the label near the insertion point on the patient side. For paediatric patients where the label should be placed near the container to minimise dislodgement.
• If a dose of medicine is prepared for enteral administration via an infusion device, the dispenser must be labelled with drug, dose, volume, route and time of preparation, name of person preparing as well as patient identification.

6.4 Dispensing

• Where unusual drug doses are to be administered, professional judgement should be used to determine if pre-loaded doses in capped oral/enteral dispensers are to be be provided by the pharmacy service.

• Bulk pre-packing of oral doses in oral/enteral dispensers must not be routinely undertaken unless in exceptional cases and by an accredited pharmacy service using principles of Good Manufacturing Practice and adherence to Australian pharmacy manufacturing standards.

• Oral/enteral dispensers must be provided to outpatients or patients transferred to community care for all non-parenteral medicine doses of liquid medicines not readily measured in a calibrated oral medicine cup.

• Oral/enteral dispensers supplied as part of a commercial drug product pack must be used unless the dose to be given is unable to be accurately measured using the device or if a Luer fitting syringe has been provided.

7. PATIENT EDUCATION

When patients or carers are required to administer liquid medicines by routes other than injection, only oral/enteral dispensers are to be supplied.

Particular care is required to educate such patients or carers of patients where a long-term intravenous catheter is in situ as some medicines may need to be given by injection and others by the oral/enteral route. Interpreters are to be used for patients or carers of culturally and linguistically diverse backgrounds. Visual aids such as brochures may be provided.

8. REFERENCES


5. European Standard EN 1615:2000 Enteral feeding catheters and enteral giving sets for single use and their connectors. Design and testing. This European Standard specifies requirements for the
design and testing of single-use enteral feeding catheters, single-use enteral giving sets and their connection systems.


11. AS 1094-1993 Medical equipment – Single-use syringes (sterile) for general medical use.

12. Standards aligned with PIC/S: Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme), developed with the Therapeutic Goods Administration – Pharmacy Manufacturing Technical working group.


15. National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines. Australian Commission on Safety and Quality in Health Care, August 2010


17. NSW Health Policy Directive PD 2007_036 Infection Control Policy
### APPENDIX 1 – IMPLEMENTATION & COMPLIANCE CHECKLIST

<table>
<thead>
<tr>
<th>Assessed by:</th>
<th>Date of Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REQUIREMENTS</strong></td>
<td>Not commenced</td>
</tr>
<tr>
<td>1. Responsibility is assigned to personnel for implementation of Safe Administration of Liquid Medicines by Routes Other Than Injection</td>
<td>![ ]</td>
</tr>
<tr>
<td>2. Oral/enteral dispensers are present in all clinical areas where non-parenteral doses are prepared and administered.</td>
<td>![ ]</td>
</tr>
<tr>
<td>3. Oral/enteral dispensers are stored away from parenteral syringes and are accessible at the location used for preparation of doses.</td>
<td>![ ]</td>
</tr>
<tr>
<td>4. Only oral/enteral dispensers or a graduated medicine cup are used to prepare and administer non-parenteral liquid doses, including oral, enteral, topical intranasal, rectal and inhaled doses</td>
<td>![ ]</td>
</tr>
<tr>
<td>5. A pharmacy service, where available, pre-loads unusual medication doses into oral/enteral dispensers for accurate, ready-to-use administration.</td>
<td>![ ]</td>
</tr>
<tr>
<td>6. On transfer, patients are always provided with oral/enteral dispensers for all non-parenteral medicine liquid for medicines not readily measured in a calibrated oral medicine cup</td>
<td>![ ]</td>
</tr>
</tbody>
</table>