Issue date
29 August 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Community Nursing Services
- Hospital in the Home (HITH) Services
- Aged Care Outreach Services
- Cancer Care
- Palliative Care
- Outpatient Clinics
- Pharmacy Departments

Drug & Therapeutics Committees
All other relevant clinicians and clinical departments where these devices are prescribed, stored and used.

Expert Reference Group
Content reviewed by:
Medication Safety Expert Advisory Committee
ACI Palliative Care and End of Life Network
CEC Critical Response Unit
HealthShare NSW

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

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Optimisation of elastomeric infusion devices

Situation

NSW Health facilities have reported that elastomeric infusion devices (EIDs) have been infusing slower than the expected rate resulting in significant residual volumes at the end of the prescribed infusion time.

Background

EIDs are self-powered pumps that use the force of a deflating balloon reservoir housed in a hard outer casing to infuse medication via an intravenous or subcutaneous route. These lightweight, single-use devices administer antimicrobials, cytotoxics and analgesics primarily in community settings. A number of compounded, saline-filled or empty devices are available from suppliers in various sizes with variable flow rates. Examples include the Nipro Mobifuser, Nipro Surefuser and Baxter Infusor.

Assessment

There is a potential for patient harm associated with incomplete administration which can result from delays in treatment, inaccurate dosing, and reduced therapeutic effect. Specific requirements to optimise the function of EIDs to ensure delivery of the required dose within the prescribed time, include:

- **Solution viscosity –** The infusion rate may vary due to changes in the viscosity and density of the solution compared to the calibrated diluent. Some diluents and antibiotic solutions (for example, piperacillin plus tazobactam, flucloxacillin and benzylpenicillin) are significantly more viscous, which may decrease the flow rate.
- **Access –** Use of subcutaneous cannula smaller than a 22 gauge may decrease the flow rate.
- **EID temperature and moisture –** The infusion rate is affected by variations in the temperature of the EID and should be minimised (higher the temperature, faster the flow rate; the lower the temperature, slower the flow rate). The EID must not be exposed to direct sunlight, extremes of temperature or moisture. Prior to infusion, the EID may be stored at room temperature or in the refrigerator. Storage conditions are determined by drug stability and should be clearly stated on the dispensing/product label.
- **Leveling –** The EID casing should remain at approximately the same level as the Luer Lock connector for the duration of the infusion and secured to the skin close to the catheter/port.
- **Body temperature and securement of flow restrictor and/or flow regulator –** To maintain a consistent flow rate, the flow restrictor and/or flow regulator must be secured against the skin with a semi-permeable film dressing for the duration of the infusion as it is activated and calibrated by skin temperature. If the patient is peripherally cool, the subcutaneous catheter or peripheral intravenous cannula may need to be re-sited.
- **Clamping and kinking of tubing –** The tubing must remain unclamped and should be regularly monitored for any twists or kinks during the infusion as EIDs have no occlusion alarms.

Note: Requirements may vary between devices. Refer to the instructions for use within the device's 'Clinician Guide' (or similar document) for further information.

Made obsolete 14 December 2023 - Replaced by SI:016/23

Recommendations

- The manufacturer's instructions for storage and use of the specific EID should be followed to ensure optimal functioning of the device.
- All staff responsible for preparing and administering medicines using EIDs should receive comprehensive education and training to understand the specific requirements to optimise functioning of the device. LHDs/SHNs should also consider initial and ongoing competency assessment.
- The appropriateness for use of EIDs should be assessed on a case-by-case basis considering specific patient factors, medicine compatibility and treatment requirements. The use of battery-operated syringe drivers may be considered as an alternative option for certain patient groups for example, palliative care.
- Patients and caregivers should be carefully assessed for their willingness and ability to manage the specific EID in the home setting.
- Patients and caregivers should receive appropriate education and training, including written information, to ensure they understand how to monitor the infusion and maintain the requirements for the duration of the infusion. The EID should be regularly monitored during the infusion to ensure the balloon is deflating and the medicine is continuing to infuse (noting that there is no alarm to indicate malfunctioning). The amount of medicine that has been infused can be monitored by lining up the volume indicator line with the measurement markings on the outer case.
- Patients and caregivers should be provided with the details of the clinician to direct any inquiries or concerns, including if the balloon does not appear to be deflating, if the volume indicator line is not moving down, if the tubing becomes disconnected or if any occlusions are identified.
- Clinicians should adhere to their local policy regarding safe and accurate medication administration, including independent second person checking procedures where applicable (see NSW Health Policy Directive Medication Handling [PD2022_032]).
- For larger doses of viscous medicines, consider dividing the dose between two EIDs (in consultation with external compounders, where applicable) to ensure optimisation of this mode of administration.
- Clinicians are encouraged to record any residual volumes in the medical record and notify the medical team.
- Report any incidents relating to EIDs to the supplier and the TGA, including the batch number where possible, as well as in the local incident management system (e.g., ims+). Person(s) responsible to report and escalate issues to be determined locally.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant clinicians and clinical departments where elastomeric infusion devices may be prescribed, stored or used.
2. Escalate any concerns to CEC-MedicationSafety@health.nsw.gov.au.
3. Report any incidents associated with elastomeric infusion devices via the local incident management system (e.g., ims+), to the supplier and TGA.

Made obsolete 14 December 2023 - Replaced by SI:016/23