Issue date
23 December 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:

- Ambulatory Care Units
- Anaesthetics
- Biomedical Engineers
- Cardiology
- Community Services
- Emergency
- Intensive Care
- Obstetrics
- Oncology
- Operating Theatres
- Paediatrics
- Pharmacy

Expert Reference Group
Content reviewed by:
Agency for Clinical Innovation
HealthShare NSW
System Preparedness and Response Unit

Clinical Excellence Commission
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Internet Website
Intranet Website

December 2023

DEFECT ALERT: Computerised Ambulatory Delivery Device (CADD) Infusion pump disposables

Situation

The Therapeutic Goods Administration (TGA) has recently advised NSW Health of a product defect alert regarding two potential issues with certain Smiths Medical CADD Infusion System sets. This is not a current product recall, however services are asked to follow the clinical recommendations below.

Multiple lot numbers are affected. Smiths Medical has advised that they will replace potentially affected stock when new unaffected stock becomes available.

The two issues are:

Issue 1: Lack of delivery or under delivery related to tubing occlusion. Manufacturing variations may cause the green CADD Flow Stop arm to compress and partially occlude the tubing before clinical use. This may result in under delivery, despite the pump displaying that the infusion is running properly. This issue effects specific medication cassette reservoirs with flow stop and administration sets used with all CADD pumps.

Issue 2: False "No Disposable Attached (NDA)" Alarms

There is a potential that CADD-Legacy pumps may not detect 50 mL and 100 mL CADD Medication Cassette Reservoirs with Flow Stop attached to the pump when the cassettes are properly attached. In this case, the pump will issue a No Disposable Attached (NDA) double-beep audible warning. The user must clear the alarm and resolve the cause of the NDA event before using the pump, resulting in a delay or interruption of therapy.

Background

Smiths Medical is an international company, and this issue has affected products nationally and internationally. CADD Infusion System Sets provide a multi-therapy infusion solution for medication delivery. They are used across NSW Health in adult and paediatric patients in hospital and in community settings.

The company has received reports of serious injuries and two deaths potentially related to this issue. Smiths Medical is unable to confirm whether the deaths were directly caused by the affected product or where they occurred.

Assessment

These issues potentially affect multiple public and private health services across NSW.

There have been two incidents reported in NSW Health facilities relating to the "No Disposable" alarm (Issue 2). Neither of these incidents resulted in patient harm. No incidents have been reported in relation to Issue 1.

Additional precautions

Issue 1: Prime the set using the pump. If the fluid doesn't flow properly or takes an abnormally long time to prime, or if the pump displays a higher than expected priming volume, replace the reservoir or set. The priming volume is listed on the packaging for each administration set.

Issue 2: If a pump displays an NDA alarm, the user can attempt to resolve the alarm by:

a) repositioning the CADD Medication Cassette Reservoir while connected to the pump;
b) repositioning the reservoir by disconnecting from the pump and reattaching it to the pump; or
c) replacing the reservoir.

Clinical Recommendations

1. Institute appropriate alternative administration strategies or techniques for life sustaining medications for hospital inpatients. If any issues are identified, escalate in line with local escalation protocols.
2. Investigate appropriate alternative administration strategies or techniques for non-life sustaining medications for hospital inpatients
3. Where the CADD pump is continued to be used for non-life sustaining medications, ensure the additional precautions described above are used and:
   a) Patient observation and monitoring for evidence of underdosing is increased.
   b) Visual inspection of medication in the device occurs frequently.
4. For patients in the community where no alternative device is available (e.g. patients with pulmonary hypertension), undertake an assessment to determine the level of risk. Where patients remain at home, ensure they understand the signs and symptoms of underdosing or lack of administration.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Alert to all relevant clinicians and clinical departments where CADD pumps are used.
2. Include this Safety Alert in relevant handovers and safety huddles.
3. Follow the clinical recommendations.
4. Escalate any concerns to local Executive On-Call.
5. Report any incidents associated with these [devices] into ims+ and TGA.
6. Confirm receipt and distribution of this Safety Alert within 24 hours to cec-recalls@health.nsw.gov.au