Safety Alert 001/19

enFlow Fluid Warmers – Risk of Aluminium Toxicity

13 March 2019

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Surgery
- Operating Suite Managers and Staff
- Biomedical Engineers
- Directors and Managers of Intensive Care Units
- Directors and Managers of Emergency Departments
- Clinicians who may use fluid warmers

Deadline for completion of action

14 March 2019

Expert Reference Group

Content reviewed by:

- Agency of Clinical Innovation
- Office of the Chief Health Officer
- HealthShare NSW
- Poisons Information Centre
- Director Patient Safety

Clinical Excellence Commission

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Review date

March 2020

Situation

A journal research article published in Anaesthesia, identified that the enFlow fluid warming device which uses an uncoated disposable aluminium heating plate can leak high concentrations of aluminium into intravenous infusion fluids. This could potentially lead to a risk of administering potentially harmful concentrations of aluminium with balanced salt crystalloid solutions (e.g. Hartmann's and PlasmaLyte) are used.

Background

Fluid warmers are used to warm blood, blood products and intravenous solutions during administration to prevent and manage hypothermia. The most common clinical areas these devices are used are in Operating Theatres, Intensive Care Units and Emergency Departments, however, may be used in other clinical areas.

Clinical experts have advised that high aluminium levels may not be adequately excreted via renal system, and can have a long half-life if deposited in tissues. The true effects of aluminium toxicity is difficult to quantify, however, is associated with a large range of diseases, including microcytic anaemia and encephalopathy.

enFlow Fluid Warmers are used throughout NSW Hospitals.

This device has been recalled in the United Kingdom, United States and Australia.

Assessment

It is acknowledged that patients are at risk of developing hypothermia if fluid warmers are not used when clinically indicated.

It has been determined that it is a clinical risk for patients to receive crystalloid fluids, blood or blood products via enFlow fluid warmers, or other fluid warmers with uncoated aluminium plates or cartridges.

If an alternative fluid warmer is not available, clinicians should undertake an individual patient risk assessment to establish a need for warming of parenteral fluids.

Patients at highest risk of aluminium toxicity are patients; with renal impairment, elderly, children, or who have repeated exposure.

Clinical recommendations

- Use an alternative fluid warming device if available.
- Consider other methods of warming patients at risk of hypothermia, e.g., use of forced air warmers
- Whilst the product has been recalled, and individualised risk approach should be used in the event of an emergency in the effort to maintain patient safety. Where there is no alternative available, and there is an established need for warming of parenteral fluids, a local risk assessment should be undertaken and documented prior to use of this warmer. It appears that where a crystalloid fluid is to be administered, normal saline may pose less risk than other crystalloids.

References

Perl, T; Kunze-Szikszay, N; Brauer, A; Quintel, M; Rohrig, A. L; Kerpen, K; Telgheder, U (2019) 'Aluminium release by coated and uncoated fluid-warming devices' *Anaesthesia,* doi:10.111/anae. 14601.

Actions required by Local Health Districts/Networks

1. Acknowledge receipt of this Safety Alert
2. Distribute this Safety Alert to all relevant managerial, clinical and biomedical engineering staff.
3. Each LHD/SHN and NSW Ambulance is to undertake a stocktake audit of enFlow fluid warmers, and provide a copy of collated local risk to CEC- Recalls@health.nsw.gov.au **by 12pm on Thursday 14 March 2019.**
4. Quarantine all affected devices
5. Escalate concerns that are not able to be managed locally to CEC-Recalls
6. Report all issues in the Incident Information Management System (IIMS)