Death of a child associated with hypothermia from malfunction and use error of a heater on a haemofiltration machine

An incident has been reported to the National Reporting and Learning System (NRLS) relating to a heater on a haemofiltration machine. The incident relates to a child, who was commenced on haemofiltration for Acute Kidney Injury on a paediatric intensive care unit. The haemofiltration machine heater alarm alarmed repeatedly. Advice was sought from the manufacturer but the company was not asked to attend as it was a weekend. The issue was not escalated to the technicians. An attempt was made to turn the heater down but the device continued to show a heater error alarm. Measures were taken to warm the patient but the patient did not achieve a core temperature within normal range; the child’s temperature was between 34.5-35.3 degrees C. The child died after the weekend.

The incident has been investigated locally and it was found that staff at the time did not fully understand what the heater alarm was indicating (described as ‘overheating’, but it actually indicates a difference between the target temperature set on the device and the measured temperature). They also did not fully understand the software upgrades performed (e.g. increased sensitivity of heater error alarm parameters) and there was a lack of clarity regarding out of hours escalation of medical device problems.

It is assumed that the staff did not want any further interruption of haemofiltration and for that reason believed it might be better for the child to continue with the therapy and to turn the heater off. It appears that they did not fully understand the risks and the fatal consequences that could result.

An alert may be issued by NHS England or MHRA following further investigation.

Action

- We would be grateful for information from Renal Units or Intensive Care Units to whether they have had similar incidents of malfunction of heaters or heater alarms on haemofiltration machines, and if so which make of machine.
- Haemofiltration machines (or any other equipment or devices) that malfunction should be reported to the manufacturer and should be taken out of service.
- Failure or use error of equipment and devices must be reported as incidents through hospital reporting systems and also to the MHRA.
- Renal Units and Intensive Care Units should ensure that all staff are trained in the use of all equipment and are aware of the action to be taken in the event of equipment or device malfunction or failure.

Please submit comments, solutions, and personal experience to:

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