Medicines & Healthcare products Regulatory Agency

MHRA

Mrs M Jones
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19 July 2021

Dear Mrs Jones

Regulation 28 request relating to the death of Mr Stephen Oakes [redacted], Nasogastric tubes

I write with reference to your Regulation 28 report (dated 19 April 2021) concerning the death of Mr Stephen Oakes. Mr Oakes suffered post-surgical complications, which included the use of a Carefeed 14Fr nasogastric tube that inadequately drained his stomach contents, allowing vomiting past the tube leading to aspiration pneumonia, against a background of significant natural disease.

Your report was received by MHRA on the 10 June 2021 via NHS England and Improvement. Both organisations agreed to provide a separate response to address concerns relevant to each organisation, as the NHS England Small Bore Connector Clinical Advisory group (Supply Chain Stakeholders/MHRA/NHS Supply Chain/British Standards and Industry Groups) to which it was addressed has been disbanded.

We have previously provided a report to the Coroner on 5 March 2021 to assist with the inquest. Following the inquest you raised the matters of concern below:

(1) The product description used by Enteral was insufficient to enable the end user to clearly identify that the tube marketed as a Carefeed size 14Fr feeding and drainage tube would not operate as a 14Fr tube due to the restricting en-fit connector.
(2) Enteral sales marketing staff were not trained to recognise the new restriction in the bore of the tube and were consequently unable to advise the end user of the change.
(3) The Hospital Trust did not fully evaluate the size 14Fr tube prior to replacing all previous drainage tubes (Ryles) with the Carefeed 14Fr feeding and drainage tube. Feedback was generally difficult to obtain.
(4) Nursing staff did not consider alternative action when the nasogastric tubes were not adequately draining. There was no general recognition of the need to aspirate the tube.
(5) There is no compulsory training of clinicians required to undertake root cause analysis.
(6) Despite reports to the MHRA and issue of amended instructions for use and a field safety notice the product continues to be promoted as suitable to feeding and drainage.
(7) This was a joint inquest into the deaths of two patients who died in quick succession as a result of the Enteral 14Ff nasogastric tubes being used for decompression in an emergency situation. Four similar (non-fatal) incidents followed. It was not clear to the hospital that the Enteral connector reduced the bore of the size 14Fr tube. The inquest was aware that other Hospital Trusts had also needed to change the tubes. I am concerned that the product labelling problem identified

during these inquests may not be limited to the University Hospital North Midlands but is in fact a much wider problem that merits wider industry investigation and changes.

We would like to address the highlighted concerns 1, 2, 6 and 7 relevant to our regulatory role. The manufacturer, GBUK, has informed us that they have updated the product labelling for the Carefeed devices to remove the secondary intended use of drainage. The primary intended use is clearly stated as 'Feeding Tube'. We understand GBUK has recently communicated this to you. We continue to engage with GBUK on the outstanding issue regarding update to their website for the instructions for Use (IFU) on Carefeed devices. They are currently reviewing their website and aim to complete this action within the next 2 months. The above addresses concern 1.

In relation to concerns 2, 6 and 7, we will continue to collaborate with NHS England and Improvement on the best way to address this issue, such as raising awareness on the Medical Devices Safety Officers' (MDSO) network. We will write to UK manufacturers of nasogastric tubes to advise them of the risk associated with the use of the ISO standard ENFit connector in aspiration/decompression situations and ask them to update their risk assessment if not already done. We will advise that where applicable, they should conduct a Field Safety Corrective Action (FSCA) and update their IFU, ensuring that their staff are fully trained in the changes so that they can provide advice to clinicians where necessary. This action will be completed within 1 month.

In addition, we have contacted the British Association for Parenteral and Enteral Nutrition (BAPEN) and the National Nurses Nutrition Group (NNNG) to raise further awareness of this issue.

We have not received any similar reports to date.

We understand from NHS England and Improvement that a separate response has been provided to yourself covering points 3, 4 and 5.

I hope this information is reassuring to you.

Thank you for bringing this important patient safety issue (Regulation 28 report) to our attention and please contact me should you need any further information.

Yours sincerely,

[redacted]

Director of Devices
MHRA