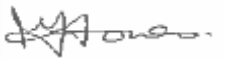
	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Enteral (GB) UK** **2. University Hospital Of North Midlands** **3. Nursing Times Publications Editor** **4. NHS England Small Bore Connector Clinical Advisory group (Supply Chain StakeholdersMHRA/NHS Supply Chain/British Standards and Industry Groups)** **5. ISO Standards Agency**
1	**CORONER** I am Margaret J Jones HM Assistant Coroner for Stoke-on-Trent & North Staffordshire Coroner's Court.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 21/12/2017 I commenced an investigation into the death of Peter John Hussey, aged 81, which concluded at the end of the inquest on 19th April 2021. The deceased was diagnosed with mid rectal cancer in 2016. He underwent anterior resection of the bowel with loop ileostomy on the 7th October 2016. He underwent elective reversal of the ileostomy on the 4th December 2017 at the University Hospital North Midlands. On the evening of the 5th December 2017 nursing staff noted he was vomiting. A nasogastric tube was passed at 03.20 hours on the 6th December 2017 but he continued to vomit despite the nasogastric tube being in place. A chest x-ray confirmed aspiration pneumonia and abdominal film reported an evolving adynamic ileus. He was transferred to the intensive care unit but continued to deteriorate and died at 20.00 hours on the 12th December 2017. The following probably contributed to his death:- The use of a nasogastric tube which was unsuitable when used for stomach decompression. A failure to recognise that the nasogastric tube was inadequately draining and to consider alternative methods of treatment and to escalate his deteriorating condition. The following possibly contributed to the death :- Miscommunication between Enteral, the manufacturer of the tube, and the Hospital Trust as to the correct usage of the carefeed 14F nasogastric tube. A failure by the Trust to adequately evaluate the nasogastric tube during the procurement process. The cause of death was 1a. Aspiration pneumonia 1b. Intestinal ileus. 1c. Reversal of ileostomy.- 2. Chronic obstructive pulmonary disease and pulmonary fibrosis combined. The conclusion of the inquest was: - The deceased died from post-surgical complications which included the use of a carefeed 14F nasogastric tube which inadequately drained the stomach allowing vomiting past the tube leading to aspiration pneumonia and death.
4	**CIRCUMSTANCES OF THE DEATH** See above
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion

there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

The **MATTERS OF CONCERN** are as follows. –

(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. Please see attached link to the Nursing Times. https://www.nursingtimes.net/clinical-archive/nutrition/selection-and-management-of-commonly-used-enteral-feeding-tubes-18-02-2019/
(7) This was a joint inquest into the deaths of two patients who died in quick succession as a result of the Enteral 14F 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.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe that you **1. Enteral (GB) UK** **2. University Hospital Of North Midlands** **3. Nursing Times Publications Editor** **4. NHS England Small Bore Connector Clinical Advisory group (Supply Chain StakeholdersMHRA/NHS Supply Chain/British Standards and Industry Groups)** **5. ISO Standards Agency** and/or your organisation have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 28th June 2021. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:- 1. [redacted], daughter of Mr Hussey 2. [redacted], son of Mr Hussey 3. [redacted], son of Mr Hussey 4. [redacted], son of Mr Hussey 5. [redacted] AVMA 6. I am also under a duty to send the Chief Coroner a copy of your response and all interested persons who in my opinion should receive it. I may also send a copy of your response to any other person who I believe may find it useful or of interest. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response.
9	19/04/2021 Signature:  Margaret J Jones HM Assistant Coroner **Stoke-on-Trent & North Staffordshire Coroner's Court**