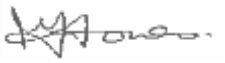
	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Enteral (GB) UK** **2. University Hospital Of North Midlands** **3. Nursing Times Publications Editor** **4. NHS England Small Bore Connector Clinical Advisory group (Supply Chain Stakeholders MHRA/NHS Supply Chain/British 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 11/11/2020 I commenced an investigation into the death of Stephen James Oakes, aged 59. The investigation concluded at the end of the inquest on 19th April 2021. The deceased had suffered with pain in his back and a cough since December 2014. He was seen by a number of doctors but the cause was not identified. In July 2016 he was diagnosed with carcinoma of the lung which had metastasised. On the evening of the 21st December 2017 he was admitted to the University Hospital North Midlands with a history of abdominal pain and vomiting. A CT scan suggested a remediable bowel obstruction due to the metastatic cancer and changes suspicious of existing left lower lobe infection. A nasogastric tube was placed to decompress the stomach. Conservative management was planned for 24 hours to see if the problem resolved, failing which surgery was a consideration. At 06.17 hours on the 23rd December 2017 he deteriorated significantly and was vomiting past the nasogastric tube. A chest film showed changes consistent with aspiration pneumonia. He died at the hospital at 20.30 hours on the 23rd December 2017. The following probably contributed to the death:- The use of an 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. 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 Small bowel obstruction secondary to metastatic carcinoma 1c Metastatic bronchial carcinoma The conclusion of the inquest was The deceased died from complications caused by the use of a carefeed 14F nasogastric tube which inadequately drained stomach contents allowing vomiting passed the tube leading to aspiration pneumonia on a background of significant natural disease.

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 NG 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 death of two patients who died in quick succession as a result of the Enteral 14F nasosgastric tube 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 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 Stakeholders MHRA/NHS Supply Chain/British Standards and Industry Groups)** 5. **ISO Standards** 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 Personswho may find it useful or of interest:- 1. [redacted] – widow of Mr Oakes 2. [redacted] AVMA 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**