National Medical Director
NHS England & NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

Margaret Jones, HM Assistant Coroner
HM Coroner's Court & Chambers
Stoke Town Hall
Kingsway
Stoke-on-Trent
ST4 1HH

29th June 2021

[redacted]

Dear Ms Jones,

Re: Regulation 28 Report to Prevent Future Deaths – Stephen James Oakes

Thank you for your Regulation 28 Report (hereafter 'report') dated 19 April 2021 concerning the death of Mr Stephen James Oakes on 23 December 2017. Firstly, I would like to express my deep condolences to Mr Oakes's family.

The report concludes Mr Oakes's death was a result of "complications caused by the use of a carefeed 14F nasogastric tube which inadequately drained stomach contents allowing vomiting passed (sic) the tube leading to aspiration pneumonia on a background of significant natural disease and death".

Following the inquest you raised concerns in your report to NHS England and NHS Improvement (NHSE/I) 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.
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. 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.

Further to the email sent on 10 June 2021 from [redacted], Business Manager in my Quality Strategy Team, I am conscious that the majority of your concerns would be better placed with the Local Trust, to whom you have sent the report, and colleagues at the Medicines and Healthcare products Regulatory Agency (MHRA). The Small Bore Connector Group, which you refer to in the addressees of the report was discontinued some time ago. On that basis I have shared the report with colleagues at MHRA who I understand will address the concerns relevant to their area of work.

In terms of wider patient safety, NHSE/I's Patient Safety Team have discussed this issue and are currently undertaking a review of the National Reporting and Learning System (NRLS) to see if they can identify any reported incidents since January 2018; when GBUK issued a Field Safety Notice in respect of this issue. Pending the outcome of this review, Patient Safety colleagues will work with MHRA to determine if any further action is required.

In relation to concern 5, around Root Cause Analysis training, it is important to note that all NHS trusts are required to comply with the Serious Incident Framework (2015) when conducting patient safety incident investigations into incidents such as the tragic events described. The Framework states that;

"The investigation must be conducted using a recognised systems-based investigation methodology that identifies:

- The problems (the what?);
- The contributory factors that led to the problems (the how?), taking into account the environmental and human factors; and
- The fundamental issues/root cause (the why?) that need to be addressed.

Within the NHS, the recognised approach is commonly termed Root Cause Analysis (RCA) investigation. The investigation must be undertaken by those with appropriate skills, training and capacity." (p23, Serious Incident Framework)

It further states that investigation team members must have "knowledge of what constitutes an effective systems investigation process, and the skills/ competencies to lead and deliver this" (p37).

Recognising that there are well identified and publicised issues with the quality of patient safety investigations in the NHS, there is ongoing work, as part of the NHS Patient Safety Strategy, to pilot a new framework for incident response: the Patient Safety Incident Response Framework (PSIRF). This framework focusses on the importance of conducting a system-based patient safety incident investigation. Much like the Serious Incident Framework, the PSIRF, and the Patient Safety Incident Investigation Standards which sit alongside it, require investigators to be appropriately trained.

NHS England and NHS Improvement are working with the Healthcare Safety Investigation Branch (HSIB); who are testing and introducing national patient safety incident investigation training. In addition, a patient safety incident investigation training procurement framework is also being developed to support healthcare providers and commissioners to access quality assured investigation training.

Thank you for bringing this important patient safety issue to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

Professor [redacted]
National Medical Director