



Department
of Health

*Philip Dunne MP
Minister of State for Health*

*Richmond House
79 Whitehall
London
SW1A 2NS*

Tel: 020 7210 4850

David LI. Roberts
HM Senior Coroner County of Cumbria
Fairfield
Station Road
Cockermouth
Cumbria
CA13 9PT

21 APR 2017

Dear Coroner Roberts,

Thank you for your letter of 18 January 2017 to the Secretary of State for Health about the deaths of Mrs Amanda Coulthard and Mr Michael Parke. I am responding as the Minister with responsibility for patient safety at the Department of Health.

I was saddened to read of the circumstances surrounding both Mrs Coulthard's and Mr Parke's death. Please pass my condolences to their families and loved ones.

My officials have worked closely with NHS England, NHS Improvement and the Care Quality Commission to ensure thorough examination of the concerns you have identified. I am grateful for the extra time you allowed to enable this work to take place.

Your Report asks that action be taken to ensure the failures identified at Inquest are addressed nationally, and that the 2011 Patient safety Alert is properly implemented.

We recognise your concerns that patient safety requirements around nasogastric tubes are not being consistently implemented by all NHS providers.

While the incidence of death resulting from the insertion of liquid into the respiratory tract as a result of nasogastric tube misplacement is rare, it should be wholly preventable with national guidance and safety recommendations available that, if correctly applied, provide a strong systemic protective barrier. Between September 2011 and March 2016, 95 'Never Event' incidents were reported

nationally where fluids were introduced into the respiratory tract via a misplaced nasogastric tube. While this should be considered in the context that over 3 million nasogastric or orogastric tubes were used by the NHS within that period, it is clear that a risk to patient safety persists.

Your Report refers to the 2011 Patient Safety Alert issued by the National Patient Safety Agency (NPSA). In addition to this, further communications were issued in 2012 and 2103 by the NPSA and NHS England respectively addressing relatively rare types of error in nasogastric tube confirmation.

However, the most recent major initiative to address continued concerns on implementation of safe practice for confirming initial nasogastric tube placement is the Patient Safety Alert and accompanying resource set issued by NHS Improvement in July 2016 (<https://improvement.nhs.uk/news-alerts/nasogastric-tube-misplacement-continuing-risk-of-death-severe-harm/>).

I am advised that the actions set out in the Alert are very relevant to the concerns identified at Inquest, and that the circumstances of Mrs Coulthard's and Mr Parke's deaths indicate that future deaths could be prevented if trusts take the systematic actions required by the 2016 Alert.

The focus of the Alert is on ensuring that the importance of a systematic approach to implementation of competency-based training, safe equipment, appropriate policy, bedside documentation and audit are recognised at Board level. To achieve compliance with the Alert, Boards were asked to assess and address compliance issues by 21 April 2017.

The Alert is informed by an analysis of the common findings of reported incidents relating to the misplacement of nasogastric tubes and NHS Improvement is confident that conscientious implementation of the actions required will have a substantial impact on preventing future deaths.

Alert compliance is an important area of assurance. Already, NHS Improvement collects and publishes data on Never Event occurrence and Alert compliance. This data provides a key tool in alerting commissioners and regulators to fundamental failings in quality, care and safety processes within an NHS provider.

The current system is based on self-declaration, and so regulatory oversight that declared compliance represents true compliance is also key. I am advised that the Care Quality Commission is looking to develop a tool that will assist inspectors to assess how well a service responds to safety alerts as part of formal inspections.



Department of Health

This work is at an early stage. However, it is an important development that has obvious benefits to strengthening patient safety.

The 2016 Patient Safety Alert is the key response to addressing the concerns around misplaced nasogastric tubes. I am advised that NHS Improvement is taking additional actions to ensure its effectiveness. For example, NHS Improvement is working with 'Sign up to Safety' to provide a series of webinars to support sharing of local nasogastric resources and training materials. A video is also being developed for promotion on social media designed to empower frontline staff who have not been provided with relevant training by April 2017 to challenge their managers and ask why this has not occurred.

You also addressed your recommendations to NHS England and my officials have worked with them to understand what more can be done across the health system. I am aware that Sir Bruce Keogh, NHS England Medical Director, has written to you to outline the actions they are taking forward following discussion at Regional Medical Director and Chief Nurse level. I hope this offers further assurance that the concerns you have raised are taken very seriously and efforts are being made to strengthen patient safety in this area. Particularly important is maintaining awareness of the patient safety dangers at a high level and I am encouraged to see that consideration is being given to highlighting this issue through professional and commissioning routes via medical and nursing directors.

Further work with Health Education England and the Medicines and Healthcare Products Regulation Authority will also be undertaken to explore if training and product messaging can be strengthened.

Turning to your recommendation that we take steps to ensure research is undertaken to identify a superior method of ensuring correct nasogastric tube placement. The National Institute for Health Research (NIHR), funded by the Department of Health, funds health and care research and translates discoveries into practical products, treatments, devices and procedures, involving patients and the public at every step. The NIHR ensures that the NHS is able to support research funded by all public, charity and industry research funders, which in turn encourages economic growth. The NIHR has, and continues to fund research into methods of ensuring correct nasogastric tube placement.

For example, in November 2016, NIHR published the conclusion of a cost analysis study into placement checks for nasogastric tubes:

<https://discover.dc.nihr.ac.uk/portal/article/4000491/simple-bedside-check-for-nasogastric-tube-positioning-is-cost-effective-and-prevents-deaths>. The study confirmed current guidance on nasogastric placement checks. However, the study did conclude that while pH testing may be the most cost effective and comparable to chest x-ray in terms of patient outcome, there remain some questions surrounding the correct interpretation of test results. The study emphasised the need to ensure that healthcare professionals have adequate support and training to help minimise the risk of error regardless of the method of checking employed.

Further detail on this and other recent projects is enclosed with this letter which I hope you will find helpful.

You will appreciate that there are challenges around demonstrating that any new method is superior given the relative rarity in which there is a failure with current methods. There are agreed routes through which NHS England can request further research from the Department of Health and the NIHR in areas of identified priorities.

In conclusion, I am advised that the challenge around improving patient safety in this area is not the availability or appropriateness of national guidance, or the effectiveness of current placement checks but rather their implementation. By ensuring medical and nursing staff have the right competencies to undertake procedures relating to nasogastric tube placement, NHS Trusts can ensure that patient harm and deaths are avoided.

More broadly, it is essential that providers learn from all deaths due to problems in care. In response to the CQC report, *Learning, Candour and Accountability: A review of the way NHS trusts review and investigate the deaths of patients in England*, the NHS National Quality Board has published the first edition of National Guidance on Learning from Deaths. This provides guidance for healthcare providers on reviewing and learning from the care provided to people who die and introduces a requirement for Trusts to publish on a quarterly basis from 2017-18 specified information on deaths, including estimates of how many could have been prevented. We are also amending regulations to require Trusts to summarise the published information in Quality Accounts from June 2018, including evidence of learning and action as a result of that information and an assessment of the impact of actions that a Trust has taken.

Finally, with regard to the North Cumbria University Hospitals NHS Trust, I am advised that the Trust, under the leadership of the Medical Director, has developed



Department of Health

an action plan to respond to your specific recommendations, as well as the requirements for wider organisational learning it has identified as a result of its review of the general matters of concern.

The Trust's response and the actions it puts in place will be monitored by NHS Improvement.

You will know the Trust came out of Special Measures on 29 March as a result of the findings of a CQC inspection conducted in December 2016. This found that the Trust had made a number of improvements, including to the Safe care domain.

The challenges facing the Trust in recent years are well known, including around patient safety and care. However, the removal from Special Measures demonstrates the progress the Trust has made to improve services and the quality of care. There is more to do and improvements need to be embedded but there is some confidence that the Trust is moving in the right direction.

Thank you for bringing the circumstances of Mrs Coulthard's and Mr Parke's death to our attention. I hope this information is useful.

PHILIP DUNNE



Department
of Health

RESEARCH – METHODS FOR CONFIRMING NASOGASTRIC TUBE PLACEMENT

Simple bedside check for nasogastric tube positioning is cost effective and prevents deaths - A study on bedside checks for tube placement covered recently by the NIHR Dissemination Centre – November 2016.

The study reviewed evidence on the effectiveness and cost effectiveness of methods of tube placement. This cost utility analysis utilised three sources of evidence to populate a decision tree model. Effectiveness data was gathered from a systematic review and meta-analysis. Three studies were included on chest X-rays, three on pH testing and three on the probability of obtaining a sample for the pH test.

Quality of life patient outcomes were not covered in the literature, so were calculated by asking 23 adult surgical patients to rate the imagined impact of different nasogastric tube scenarios. These ranged from no complications to serious complications. Cost information was obtained from current NHS prices and staff costs.

The study was conducted with reference to healthcare in Scotland, but should be applicable to the rest of the UK.

The study found that in adults who need a nasogastric tube for a short time, pH testing was the best initial approach followed by X-ray confirmation if pH testing wasn't successful. pH testing was four times less expensive than X-ray confirmation and when used in sequence both were cost effective uses of NHS resources.

For further reading access the link below:

<https://discover.dc.nihr.ac.uk/portal/article/4000491/simple-bedside-check-for-nasogastric-tube-positioning-is-cost-effective-and-prevents-deaths>

A NIHR Horizon Scanning Centre report on a technology to help prevent incorrect placement of tubes

The NIHR Horizon Scanning Centre examined the potential impact for a new technology. The Kangaroo™ feeding tube with IRIS technology was being

developed by Covidien Commercial Ltd, to help with nasogastric tube placement. The tube is a small-opening single use, disposable feeding tube which has an integrated real-time imaging system (IRIS) in the form of a 3mm camera to visually aid its placement. It was launched in the UK for research use in 2014, followed by a full NHS clinical launch in 2015.

For further reading access the link below:

<http://www.io.nihr.ac.uk/topics/kangaroo-feeding-tube-with-iris-technology-for-aid-in-nasogastric-tube-placement/>

NIHR Diagnostic Evidence Cooperative London (DEC) - a new test for tube placement (in conjunction with a Biomedical Catalyst Award)

The NIHR DEC based at Imperial College, London and Scottish SME Ingenza are collaborating to study and design a novel enzyme-based test for the accurate positioning of nasogastric tubes. The evidence generation and assessment of the new enzymatic test is being carried out using diagnostic toolkit methodology developed at the DEC. Multi-modality and systemic approach will guide evidence generation. The DEC London is providing the infrastructure for the study with NIHR health economists performing the required economic analysis.

For further reading (p.70) access the link below:

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwiX296xgqnSAhXLIIsAKHd7_C8QFgg1MAO&url=https%3A%2F%2Ffoxford.dec.nihr.ac.uk%2Freports-and-resources%2Fdec-workshop-2015-presentations%2Fravi-chana-funding-for-diagnostic-test-development.pdf&usq=AFQjCNFGTQ54wt0fKRPd5Ohg7Ozyj6hyjA

NIHR Invention for Innovation Grant funding for Location-Indicating Naso-gastric Tube (NGT) University of Hull (£667,542 Contract ended 2016)

Feeding through a tube passed through the nose into the stomach is very widely used. Most doctors and nurses think it is the best method of feeding patients of all ages who cannot feed normally and the procedure may be taught to patients and carers. Tubes currently used cannot indicate the position in which they have been placed and up to 1 in 5 of are incorrectly placed. Tubes wrongly placed in the gullet can cause irritation and prevent absorption and if placed in the windpipe or lungs there can be serious complications. The University of Hull are developing a new tube which is reliable, sensitive and effective in 'telling' the doctor, nurse or carer where they placed the tube ensuring greater safety and reduced distress to patients and carers.



Department of Health

Currently, finding where a tube has been placed involves sampling stomach contents to make a measurement. The new Hull tube can give a measurement at any time without doing this and is quicker, easier, safer and cheaper than present methods.

Prototypes have shown that the new tube works. It has a 'stripe' on the tip which is chemically sensitive to stomach contents. The 'stripe', sends a signal to an indicator outside the body which tells the carer that the tube is or is not in the stomach. If approved by the regulators, the Hull tube will be sold to the NHS and worldwide. It will take away the distress and harm of wrongly placed tubes.

