



HEALTHCARE SAFETY
INVESTIGATION BRANCH

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Summary report

Placement of nasogastric tubes

Independent report by the
Healthcare Safety Investigation Branch I2019/006

December 2020



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INVESTIGATION BRANCH



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About HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The

safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

Considerations in light of coronavirus (COVID-19)

A number of national reports were in progress when the COVID-19 pandemic significantly affected the UK. Much of the work associated with developing the reports necessarily ceased as HSIB's response was redirected. For this national report, while the learning

described has not changed due to COVID-19, the processes by which HSIB engages with patients and families had to be adapted. These changes are acknowledged in this report and described further.

A note of acknowledgement

We are grateful to Fabian and his Father, whose experiences are central to this report, for their ongoing support and involvement.

We would also like to thank the Trust and members of staff who participated in this investigation process and openly shared their perceptions of the incident with us.

Our investigations

Our team of investigators and analysts have diverse experience working in healthcare and other safety critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider potential incidents or issues for investigation based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements through:

- ‘**Safety recommendations**’ made with the specific intention of preventing future, similar events; and
- ‘**Safety observations**’ with suggested actions for wider learning and improvement.

Our reports also identify ‘**safety actions**’ taken during an investigation to immediately improve patient safety.

We ask organisations subject to our safety recommendations to respond to us within 90 days. These responses are published on our website.

More information about our national investigations including in-depth explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our **website**.

Maternity investigations

From 1 April 2018, we have been responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the **Each Baby Counts programme** (Royal College of Obstetricians and Gynaecologists, 2015) and also maternal deaths (excluding suicide). The purpose of this programme is to achieve learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB’s investigation replaces the local investigation, although the trust remains responsible for meeting the

Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly back to the families and to the trust. Our safety recommendations are based on the information derived from the investigations and other sources such as audit and safety studies, made with the intention of preventing future, similar events. These are for actions to be taken directly by the trust, local maternity network and national bodies.

Our reports also identify good practice and actions taken by the Trust to immediately improve patient safety.

Since 1 April 2019 we have been operating in all NHS Trusts in England.

We aim to make safety recommendations to local and national organisations for system-level improvements in maternity services. These are based on common themes arising from our trust-level investigations and where appropriate these themes will be put forward for investigation in the National Programme. More information about our maternity investigations is available on our **website**.

Executive Summary

Background

This investigation examined patient safety issues related to the placement of nasogastric (NG) tubes. NG tubes are passed through the nose, down the back of the throat and through the oesophagus to the stomach. They are used to give medication, fluids, or liquid feed (known as enteral feed) to patients.

Patients may need NG feeding, typically in the short to medium term, because:

- critical illness or unconsciousness leaves them unable to swallow at all
- neurological conditions such as stroke leave them at risk of not being able to safely swallow food or drink normally by mouth
- they have conditions that mean they cannot take in enough food and drink by mouth to meet their nutritional needs.

The placement of an NG tube is checked initially by testing the pH (acidity or alkalinity) of fluid from the stomach that is sucked out of the NG tube using a syringe. This fluid is known as gastric aspirate. The pH tests are conducted using testing strips known as CE marked enteral testing strips for human gastric aspirate. 'CE marked' means that the strips have been certified by the manufacturer as meeting European standards. If the aspirate pH is in the 'safe range', this indicates that the NG tube is placed correctly in the gastrointestinal tract and can be used to give feed, fluid, or medications. If no

aspirate can be obtained, or if the pH of aspirate is not in the 'safe range', an X-ray should be undertaken to confirm the position of the NG tube.

A situation where an NG tube is positioned incorrectly, and this is not identified before the tube is used for feed, fluid or medications is a 'Never Event'. Never Events are defined by NHS Improvement as patient safety incidents that are considered preventable because there is national guidance or safety recommendations that provide strong systemic protective barriers which should have been implemented by healthcare providers.

This investigation used a specific incident of this type of Never Event, referred to in this report as the reference event, as an example to examine the patient safety issues associated with the placement of NG tubes.

The reference event

Fabian, a man aged 26 years, was admitted to an emergency department on 21 December 2018. He had fallen from his bicycle while swerving to avoid a motor vehicle and hit his head on a pavement. At the scene he was observed to be having seizures. Because of this, on arrival at hospital he was placed in an induced coma by an anaesthetic team prior to having a head-to-toe CT scan (which uses X-rays and computer technology to create detailed images of the inside of the body). The CT scan showed small intra-cranial bleeds (bleeding within the brain) and a small amount of bleeding around the

left kidney. Fabian was transferred to the critical care unit for ongoing care. While an inpatient on the critical care unit, Fabian had a nasogastric (NG) tube inserted. On 22 December 2018 during an attempted weaning from sedation, Fabian became agitated and removed his NG tube. Following further sedation, a new NG tube was inserted to ensure his nutritional needs were met. This NG tube was confirmed as correctly inserted via a pH test of gastric aspirate. It was subsequently found that the NG tube had inadvertently been inserted into Fabian's lungs and enteral feed had been delivered into his airways. Fabian received approximately 1,450ml of enteral feed into his lungs before the feed was stopped.

Once the misplaced NG tube was identified, the feed was removed from his lung using a special tube with a camera on (known as a bronchoscope). Saline fluid was used to wash out any feed and then syringed back out using the bronchoscope. The incident was immediately reported as a Never Event once the error was realised.

Following a stay on the critical care unit and subsequently on a ward, Fabian was discharged home on 8 January 2019.

National investigation

Data from NHS supply chain shows that each year at least 967,977 NG tubes are purchased in the NHS in hospitals and community settings (care home and home).

NG tubes have been the subject of numerous patient safety alerts in the last 15 years. There is a risk of serious

harm and risk to life if NG tubes are incorrectly placed into the lungs rather than the stomach and fluid, medicine or feed is passed through them. Such incidents are classified as a Never Event (NHS Improvement, 2018a).

The safety risk of misplaced NG tubes was referred to the Healthcare Safety Investigation Branch (HSIB) as a potential national investigation due to the persistence of harm despite several patient safety alerts. The referrer reported concerns that both pH testing and use of X-ray are prone to error; these concerns are supported by previous patient safety alerts and literature. The referrer believed that opportunities for error existed for all levels of staff, and that seniority did not necessarily reduce the risk.

A 2016 patient safety alert (NHS Improvement, 2016a) stated that misinterpretation of X-rays by medical staff was the most common cause of placement errors. Other causes included misinterpretation of pH testing of gastric aspirate, use of outdated checking methods, and communication issues between medical and nursing staff to confirm if tube placement was checked.

The HSIB investigation reviewed NG tube insertion and placement verification in the context of local and national practice and guidelines. The national investigation applied a human factors approach to understanding the processes, practices, interactions among people, and other elements of system performance involved with the insertion of NG tubes and confirmation of their position. The investigation

considered existing guidance as well as the procurement and implementation of the equipment required for NG tube insertion and confirmation, and how staff acquire the competencies to do this safely. The factors that contributed to the reference event have been grouped under two key processes which were the focus of analysis in this investigation:

- 1 Confirmation of NG tube placement using pH testing.
- 2 Interpretation of chest X-rays for clinical deterioration and identification of NG tube position.

Findings

Given the serious and ongoing safety risks, HSIB's initial national findings were published in an interim bulletin on 5 February 2020 and early safety observations were made. The findings listed below encompass the overall findings of the national investigation, including those from the **interim bulletin**. The investigation found:

General findings

- 1 The placement of NG tubes into the lungs rather than the stomach and fluid, medicine or feed being passed through them is defined as a Never Event in the NHS. However, there are no systemic barriers to preventing feeding into an NG tube that has been accidentally placed in the lung.
- 2 There is ongoing research to find a reliable design solution to reduce the risk of misplaced NG tubes.

However, these projects will not be completed for a few years. As such, a new technological solution is not imminent.

- 3 Local trust policies generally reflect national guidance. However, there are limitations in their use because of their length. Staff told the investigation they know the guidance is there, but such guidance is too long to read.
- 4 There is significant variation in how existing safety standards are implemented and continually monitored.
- 5 Reporting NG medical device related incidents to the Medicines and Healthcare products Regulatory Agency (MHRA) via its Yellow Card scheme is less frequently done in comparison to NG tube related incidents reported on the National Reporting and Learning System or Strategic Executive Information System (national systems for reporting patient safety incidents).
- 6 New ways of working, and specifically extending the role of the radiographer to improve patient safety in NG tube position confirmation, have been effectively implemented and successfully evaluated in some organisations.
- 7 The introduction of measures to manage COVID-19 resulted in increased challenges for NG tube insertion and confirmation of tube placement.

Findings related to pH testing

- 8 The process of confirmation of correct NG tube placement using pH testing strips is potentially unreliable and its complexity underestimated. The pH test cannot be used if stomach contents cannot be aspirated and will be inconclusive in patients with altered stomach pH. The investigation also identified concerns around the reliability and usability of pH strips.
- 9 There is a risk that organisations that insert NG tubes may have multiple types of pH strip in circulation, both CE marked, and non-CE marked.
- 10 Testing strips are 'read' by checking the colour on the strip against a colour chart on the container the strips are kept in. CE marked enteral pH testing strips from different manufacturers have different pH colour coding scales which are inconsistent. If a healthcare provider has more than one type of enteral pH testing strip in circulation at the same time, there is a risk of error when comparing the strips from one product against a container with a different pH scale. Therefore, having two or more types of CE marked strips in circulation could result in inaccurate readings.
- 11 The multiple types of strip present in the Trust where the reference event took place highlights the need for trusts to have reliable processes in place to implement changes that are required by national guidance – in this case, the removal of non-CE marked pH testing strips for testing human gastric aspirate.
- 12 There is no standard process on how to read a pH strip. A standard process needs to be defined.
- 13 Training on NG tube placement is available albeit variable in terms of delivery and content. The cascade model of training (where one group of staff is trained, then each trained staff member trains another group, and so on) has led to some staff 'teaching' the incorrect method for testing pH.
- 14 There is no consistent process for assessing and recording competency in NG tube placement and confirmation using pH testing.
- 15 There are clinical guidelines on the 'safe range' for pH and some trusts use a lower pH due to a perception that a lower pH is safer. Although a range of research has been carried out, there is no consistent research conclusion to guide what the best cut-off pH is to exclude placement in the respiratory tract. There is concern about use of 'safe range', and there have been no accredited clinical guidelines or research that would change the 'safe range'.
- 16 The environment within which pH testing strips are being interpreted can increase the risk of error. In the reference event, this was particularly noted with the poorly lit environment.

Findings related to X-ray

- 17 X-ray confirmation of NG tube placement is thought to be the most accurate method if a standard process is consistently followed

(Metheny et al, 2019). However, incorrect X-ray confirmation and interpretation is the most common cause of NG tube incidents.

- 18** There is no consistent process for assessing and recording competency in NG tube placement and confirmation using X-ray. People described different ways of interpreting an X-ray. Even when staff are trained, they may still not follow the algorithm for interpretation and may still not identify NG tube misplacement.
- 19** All NG tubes are radio-opaque (which means they can be detected on an X-ray). However, it is important that when an X-ray is requested a specific requirement is given. The policy at the reference event Trust and other organisational policies refer to chest X-ray as opposed to NG X-ray. A specific NG X-ray will ensure more visibility below the diaphragm than a standard chest X-ray and therefore the language and choice of image request matters.
- 20** Whatever the reason for carrying it out, a chest X-ray will enable a clinician to spot incidental findings and is an opportunity to check NG tube position. However, in Fabian's case, the rationale for chest X-ray was clinical deterioration and the NG tube position was not observed and was not being considered as a causal factor for his clinical deterioration. Therefore, there were missed opportunities in the reference event to identify the misplaced NG tube associated with inattentive blindness (people's tendency to miss things that are visible because their attention is elsewhere) when interpreting X-rays.
- 21** There was not a formal radiology interpretation (report) of the X-ray. The responsibility for undertaking a clinical evaluation was delegated to the specialist critical care staff and underpinned by local policy (under the Ionising Radiation (Medical Exposure) Regulations (IR(ME) R) 2017 employer's procedures). This is not uncommon and is an accepted practice (Care Quality Commission, 2018b).
- 22** Limited availability and detectability of vital information about NG tube displacement and re-insertion may adversely influence clinical assessment and decision making. This is further confounded by difficulties in the detectability of NG tubes on X-ray, and inattentive blindness when interpreting X-rays.
- 23** The context within which staff are interpreting X-rays influences their ability to accurately identify abnormalities. This includes factors such as the viewing environment, technical aspects such as display screen resolution, time pressures associated with the software, and the quality of X-ray images.
- 24** While workload was not a definitive causal factor in the reference event, it is recognised that workload, distractions, and concurrent task requirements will influence staff's levels of attention. This may mean that protocols for X-ray interpretation are not followed.

25 While it is acknowledged that competency-based training is not a strong systemic barrier to improve safety, there was no standardised competency framework and delivery model for training and assessment in NG tube placement and undertaking placement checks. The potential to use specifically trained experts, such as radiographers, was considered but would need to be trialled. Any training would need to be defined, developed, and tested using a human factors approach prior to any widespread implementation.

HSIB makes the following safety recommendations

Safety recommendation R/2020/106:

It is recommended that **Health Education England** coordinates the development and publication of a national standardised competency-based training programme for nasogastric tube placement and confirmation by pH testing. The model may include simulation, observed practical assessment and ongoing competency assessment. The competency-based training programme would need to be defined, developed, and tested using a human factors approach prior to any widespread implementation. The competency-based training programme will lead to a recognised accreditation which will be transferable across the NHS care providers in England.

Safety recommendation R/2020/107:

It is recommended that **NHS England and NHS Improvement** works with the Department of Health and Social Care

and others, to identify the process by which the NHS can identify and commission necessary research to support improvements in patient safety. This would include research to confirm nasogastric tube placement.

Safety recommendation R/2020/108:

It is recommended that **NHS Supply Chain and the British Standards Institution** work together (engaging other system leaders as appropriate, such as the Medicines and Healthcare products Regulatory Agency and NHS England and NHS Improvement), to develop and publish an agreed standard to minimise the risks relating to human errors in the use of pH strips designed for testing human gastric aspirate at the bedside. The standard should consider product design, regulatory standards, procurement practices and human factors engineering to provide a consistent approach that can be embedded within NHS Supply Chain product specifications.

Safety recommendation R/2020/109:

It is recommended that **NHS Supply Chain** develops essential specifications to support the clinically-led procurement of devices to include devices to confirm nasogastric tube placement, for example, pH testing strips. The essential specifications should set out a range of factors critical to inform the selection by NHS Supply Chain of a product including, but not limited to: clinical output requirements; design and ergonomics; human factors and intended use; and limitations on use and usability. Critically, these specifications should

ideally be established in partnership across the healthcare system with clinicians, healthcare professionals and safety leads, while maximising best practice.

While not directly relevant to the reference event, the following safety recommendation has been made given the continued risk of NG tube Never Events following incorrect X-ray interpretation.

Safety recommendation R/2020/110:

It is recommended that the **British Society of Gastrointestinal and Abdominal Radiologists**, working with **Health Education England and the Society and College of Radiographers**, develops and publishes a national standardised competency-based training programme for X-ray interpretation to confirm nasogastric tube placement. The competency-based training programme will include the referral process for X-ray to confirm nasogastric tube position and the subsequent reviewing, recording and communication of the clinical evaluation of the X-ray findings prior to initiation of feed. The standards must meet the Ionising Radiation (Medical Exposure) Regulations IR(ME)R requirements. The competency-based training programme will lead to a recognised accreditation for those qualified to clinically evaluate and record their findings, for example doctors, radiographers and advanced care practitioners. The accreditation certificate will be transferable across NHS care providers in England.

HSIB makes the following safety observations

Safety observation O/2020/086:

It would be beneficial if chest X-rays for acutely ill patients were reported by a radiologist, or a radiographer who has undertaken training, to enable them to report on examinations at an appropriate time. The report should include the position of a nasogastric tube if one is present on a chest X-ray.

Safety observation O/2020/087:

It may be beneficial if national organisations including the Medicines and Healthcare products Regulatory Agency, NHS Supply Chain and NHS England and NHS Improvement review arrangements for ensuring all medical device related incidents, Yellow Card reports, or other device safety related information, including any involving concerns with pH or X-ray in the context of nasogastric tubes, are shared between the relevant organisations to inform their respective patient safety responsibilities.

Safety observation O/2020/088:

It would be beneficial for the Department of Health and Social Care to consider post-Brexit arrangements for sharing patient safety incident data with Europe.

Safety observation O/2020/089:

It would be beneficial if the (recommended) national standardised competency-based training programme for nasogastric X-ray interpretation to confirm nasogastric tube placement will be made a

contractual and/or regulatory requirement for all healthcare providers to implement and evidence ongoing compliance with.

Safety observation O/2020/090:

It may be beneficial if accreditation for reviewing, recording and communication of the clinical evaluation of the X-ray findings, prior to initiation of feed, is limited to specific staff groups trained in confirming nasogastric tube placement, for example reporting radiographers or radiologists.

Safety observation O/2020/056 (previously shared in interim bulletin):

It is important that organisations are aware that there is not a standard scale/colour scheme across the different manufacturers of CE marked enteral testing strips and they vary in scale (pH of 1-12, 0-6, 2-9 or 3-7). If organisations have CE marked enteral pH testing strips from more than one manufacturer in use at the same time, there is still a potential for error if a pH testing strip is compared against the incorrect box.

Safety observation O/2020/057 (previously shared in interim bulletin):

It is important when transitioning between any types of bedside testing equipment (not just pH strips) the potential for confusion between old and new stock is considered, and the transition managed to reduce that risk and to ensure that staff understand any difference between techniques needed with past and future brands of bedside tests.

HSIB notes the following safety actions

Safety action A/2020/034:

The Trust where the reference event happened, amended the timing of its daily aspirate check from midnight to 10:00 hours.

Safety action A/2020/035:

The Trust where the reference event happened checked the hospital clinical areas to confirm there were no other areas holding non-CE marked pH testing strips for human gastric aspirate.

Safety action A/2020/036:

The Trust where the reference event happened implemented and recorded training and competency assessments for all nursing staff prior to allowing them to insert and confirm placement of nasogastric tubes.



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