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NHS
Milton Keynes
University Hospital
NHS Foundation Trust

Mr Tom Osborne
HM Senior Coroner
Milton Keynes Council
[redacted]

06 September 2023

Dear Mr Osborne

Regulation 28 Report following an Inquest into the death of Mr Harry Stobie

I am writing following receipt of a regulation 28 Report dated 04 August, following on from the Inquest concluded on 20 July 2023. Mr Stobie died because of haemoperitoneum after insertion of a PEG tube. As you note in the regulation 28 report, this was a recognised complication of a necessary medical procedure.

In the regulation 28 report, you assert that Mr Stobie's *deteriorating condition was not monitored closely enough even though he was complaining of abdominal pain soon after the procedure was completed. His concerns were not escalated to a senior doctor for consideration of a possible bleed.* You state therefore that *the procedures and protocols following PEG insertion should be reviewed.*

I was disappointed to have received the regulation 28 report in the context of members of the Trust's staff not having been called to give oral evidence at Inquest. The written statements of [redacted] have been reviewed after the inquest and are all felt to be comprehensive and thorough. I do not believe that the Trust was offered the opportunity to respond to your emerging concerns during the inquest – which I would have thought might have been preferable for all parties.

By way of a summary of Mr Stobie's care on the day of PEG insertion:

- There was a clear indication for PEG insertion following the ischaemic stroke for which he was being treated (and dysphagia was improving more slowly than other symptoms). Mr Stobie had undergone video fluoroscopy prior to insertion.

- The procedure itself was straightforward and he was transferred back to the ward. Three sets of observations were undertaken over the first four and a half hours back on the ward. Whilst the frequency of observation should ideally have been higher over the first two hours, the observations recorded were not significantly deranged. It was noted that Mr Stobie did report some pain and vomiting. A ward doctor was involved in his assessment at this stage, and fluids and analgesia were administered. The quantification, recording and monitoring of his pain may have benefited from being more objective / standardised – see below.

- Five hours following return to the ward, Mr Stobie appeared less well, and observations were promptly repeated. He was hypotensive and this was escalated to our rapid response nursing team and the on-call medical team.

- At this point, Mr Stobie was found to have a tender abdomen. Within half an hour, a working diagnosis of bowel perforation was made, and a plan for an urgent CT scan was made. His antibiotics (broad spectrum antibiotics having been administered earlier) were continued. He was already on intravenous fluids following the earlier episode of vomiting.

- Within a further 60 minutes, surgical and ICU referrals had been made whilst Mr Stobie was en-route to CT.

- A definitive diagnosis was made within two hours of the first abnormal observations, with appropriate measures put in place in the interim.

- A consultant intensivist and a consultant surgeon attended Mr Stobie late in the evening. An active decision was made for palliation.

- Mr Stobie died 3 days later.

The key questions appear to be (1) whether Mr Stobie's symptoms of some pain and vomiting should have been seen as potential signs of significant internal bleeding before his physiological observations began to deteriorate and, if so, (2) whether they should have prompted earlier imaging and, in turn, (3) whether this might have led to alternative action (i.e., a surgical approach to address the haemorrhage).

On review of the inquest statements and medical records:

- *Mr Stobie was well with normal vitals and was comfortable when he left the endoscopy room* ([redacted]).

- *Mr Stobie was returned to the ward from PEG at 13:45 hours. He complained of stomach pain and had been vomiting. He was prescribed an antiemetic (anti sickness injection) and had an injection of pain killer… In the course of the afternoon, Mr Stobie remained relatively stable* ([redacted]).

- A nursing entry in the electronic patient notes written during the afternoon but verified at 20:15 (i.e., following the deterioration in observations / escalation) references: *Had episode of vomiting and Ondansetron given as prescribed, vomited (40mls). Paracetamol, and* [subsequently] *morphine, given for pain. PEG site was checked – no oozing. Patient re-positioned and made comfortable* (SN Amoah).

As you note, bleeding is a recognised complication of PEG insertion.

Routine CXR (to assess for pneumoperitoneum) is not undertaken following PEG placement as a degree of pneumoperitoneum is common post-PEG insertion, and retroperitoneal issues could not be adequately assessed. Such X-rays would be challenging to interpret. I raise this point as we initially understood (between the inquest and receipt of your regulation 28 report) that this may have been a specific concern.

A 'discharge protocol following PEG insertion' is sent back to the ward with patients. An alert box within the protocol currently states:

	**If there is pain on feeding, or prolonged or severe pain post-procedure, or fresh bleeding, or external leakage of gastric contents, stop feed/medication delivery immediately. Obtain senior medical advice urgently and consider CT scan, TUBOGRAM or surgical review.**

In Mr Stobie's case, the key issue (in terms of compliance with existing protocol) is whether he experienced 'prolonged or severe pain' post-procedure. Prompted by your regulation 28 report, there have been further discussions with Ward 7 staff who were

caring for Mr Stobie on the day in question. It does not seem that Mr Stobie's pain in the earlier part of that afternoon was so pronounced as to have mandated earlier escalation. He was not exhibiting symptoms consistent with peritonism at that point. It is felt that he had an abrupt deterioration around the time his observations deteriorated. By the same token, clinicians do not consider it likely that an earlier diagnosis would have led to a different outcome (given that fluids and intravenous antibiotics had already been administered prior to the deterioration in observations): general anaesthetic and laparotomy would not have been an attractive prospect in view of co-morbidities. However, I recognise that the post-procedure guidance could be clearer, and the opportunity for subjectivity could be reduced.

I have asked the wider gastroenterology team to review the 'discharge protocol following PEG insertion' with a view to determining whether it would be possible or prudent to render the pain element of these cautions more objective (i.e., to use a pain scale or to reference a failure to respond to specific medicines). This work is progressing well and the team has elected to incorporate use of a pain score and/or a trigger of an AMBER score on the NEWS-2 system in order to prompt earlier escalation and to reduce the threshold for consideration of a CT scan. See the enclosure – appendix 3 to the relevant policy and procedure.

They will also liaise with the relevant specialist society (British Society of Gastroenterology) to see whether they are able to signpost excellent practice in respect of post-procedural protocols and/or whether this is an area they could seek to advance towards a national consensus view.

As part of our discussions in response to this regulation 28 report, we have also identified a potential gap in practice in relation to the post-procedural observation of patients undergoing other endoscopic interventions. In the small number of cases where patients are admitted to hospital following a higher risk endoscopic procedure (non-PEG) for observation, we need to be explicit about the nature and level of observation expected by the lead clinicians. The gastroenterology MDT will review this aspect at a planned meeting in September.

I would of course wish to conclude by recognising the very sad circumstances of Mr Stobie's death and passing my condolences on to his family. His untimely death must be particularly distressing for them given the pretty positive trajectory of his recovery from his major stroke (swallowing aside) after thrombectomy.

I trust that this response is helpful.

Yours sincerely,

[redacted]

Chief Executive

Enclosed

Ward nursing care plan for patients post PEG and PEJ insertion: Day 1 (appendix 3 to policy and procedures for pre and post insertion management)

[Affix patient label]

Appendix 3: Ward Nursing Care Plan for Patients Post PEG or PEG-J Insertion: Day 1

1. The patient must remain **Nil by mouth for 4 hours** post PEG insertion.
2. The patient must remain **Nil by PEG or PEG-J for 4 hours** post PEG insertion.
3. **Observations** including **Respiratory Rate, Temperature, HR, BP, SpO2** and **Pain** must be recorded on eCARE as follows:

- **½ hourly for 2hrs**
- **1 hourly for 2hrs**
- **4 hourly for 24hrs**

4. The PEG/PEG-J site **MUST** be checked on the patient's return from Endoscopy. The gauze dressing covering the site must be carefully lifted to check for fresh bleeding or leakage of fluid. If either are observed a senior medical review **MUST** be urgently requested. Following the initial check, the PEG/PEG-J site **MUST** be observed every **4 hours**. Document the observations in the box below.

Date	Time	PEG/PEG-J site check	Signature

5. **Potential complications** following PEG/PEG-J insertion:

- Peritonitis
- Pain
- Haemorrhage

Whilst it is common to have some pain post PEG insertion, if the patient reports severe pain and/or has a **pain score of 6 or above**, request an urgent senior medical review.
N.B for patients unable to communicate assess for non-verbal signs of acute pain.
In addition to the above if the patient has an AMBER NEWS score (3-5) an urgent senior medical review MUST be requested.
There should be a low threshold for requesting a CT scan.

If there is pain on feeding, or prolonged or severe pain post-procedure, or fresh bleeding, or external leakage of gastric contents, stop feed/medication delivery immediately. Obtain a senior medical review urgently and have a low threshold for a CT scan.

6. If there have been no immediate post PEG insertion complications, water can be given via the PEG/PEG-J **4 hours post insertion as follows:**

- 50ml/hr sterile water via an enteral feeding pump for 6 hours. Total volume 300mls. Monitor closely for signs of **pain/ abdominal distension**. If noted stop the water infusion and request an urgent senior medical review.
- **Aspiration is a known complication following PEG/PEG-J insertion.** The patient must be positioned at **45°** to reduce the risk of pulmonary aspiration and assist gastric emptying whilst the water is infusing.
- If there have been **no** complications with the water infusion, enteral feeding and medication can be given via the PEG/PEG-J the following day from 8am.

7. Ensure that the patient is referred, on eCARE to the Nutrition CNS and the Dietitian.