NHS
Nottingham
University Hospitals
NHS Trust

Please ask for the Medical Director's Personal Assistant

[redacted]

Medical Director's Office
3rd Floor, Trust Headquarters
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

[redacted]
www.nuh.nhs.uk

9 February 2022

STRICTLY CONFIDENTIAL
Miss Laurinda Bower
HM Assistant Coroner for Nottingham City and Nottinghamshire
HM Coroner's Court
The Council House
Market Square
Nottingham NG1 2DT

Dear Miss Bower

Inquest: ERCP and Prevention of Future Death Notification

Please find attached a commentary that I have prepared in response to the Preventing Future Deaths Report issued to Nottingham University Hospitals NHS Trust following the inquest into four patients who died following endoscopic retrograde cholangio-pancreatography related complications, within a 6-month period at the Trust.

I was not present at the inquest but note that there are four broad matters of concern identified in the PFD notification.

My response to each of the concerns identified in the PFD have been informed following work undertaken by colleagues involved in the Gastroenterology Service, the Surgical and Medical Divisions and other teams and individuals in the organisation, including the Deputy Medical Director who is also the Chair of the Trust's Consent Committee.

The actions either taken or planned in response to the learning from the inquest are summarised below. The oversight of the delivery of these actions will be through the Surgical Division's Governance Committee. The Quality and Safety Oversight Group will be receiving reports on progress and the Quality Assurance Committee, a sub-committee of the Trust Board will be updated.

I hope that this commentary provides assurance that we are committed to learning from this, and other incidents to significantly enhance the care of patients undergoing ERCP at Nottingham University Hospitals NHS Trust.

Yours sincerely

[redacted]

Dr [redacted]
Medical Director
[redacted]

cc: [redacted], Inspections Manager, CQC ([redacted])

Response to concerns identified through the PFD

1. A lack of robust patient pathway to ensure that all patient factors relevant to the clinical indication for, and safety of, ERCP are identified in advance of the procedure and discussed with the patient.

The following actions have been taken to address this concern:

- The referral pathway has been completely re-designed and will move away from the old 'NOTis' based information system to Medway orders (the current information system in use in the Trust) from 14 February 2022. The Medway order will incorporate: information on the indication, latest blood tests, date and findings of relevant imaging, capacity for consent, awareness of LPA, highlighting potential factors for "higher risk" procedures, and seek history or symptoms of dysphagia for any procedure with side-viewing endoscopes (ie EUS and ERCP).
- The Medway referrals will be vetted daily by consultants who undertake ERCPs in dedicated job planned time.
- Outcomes of vetting will be recorded as Medway notes (including referrals not accepted) and if accepted will be listed for procedures (either sedation or general anaesthetic) by the NUH endoscopy administration teams.
- The new fields on the NUH internal Medway orders will be replicated on the specific "NUH tertiary endoscopy referrals" form that are completed for referrals from outside NUH (eg from surrounding networking trusts) and will also be reviewed in the vetting clinics described above.
- Two new 2-hour clinics have been set up, that will run 52 weeks a year, staffed by consultants who undertake ERCPs. These sessions have already commenced and permanent funding is currently being agreed. This clinic time will be used to meet, either virtually or in person, with all out-patients referred for ERCP to discuss the indications, risks and alternatives.
- We have already formally extended our post-ERCP recovery time to a minimum of 2 hours, with clinical review and if any significant changes to baseline observations or ongoing symptoms this period of observation is extended, or results in hospital admission for observation, investigations or treatment.

2. A lack of robust system for the recording of vetting of the procedure, capturing what information has been considered as part of this process.

- As above this will now be recorded through a clinical note on the Medway information system. This will be visible to all clinicians caring for the patient.

3. Consent is not personalised, contrary to recommendations made by the ESGE in December 2019.

It is not currently possible for individual personalised risk to be calculated precisely although there are aspirations for this at some point in the future. It is possible to provide estimates of the relative risk to an individual patient in relation to the wider population risks and to ensure that this is documented in the patient record. A number of actions to support this have already commenced:

- Endoscopy outreach nurses will supply patient information booklets to ward in-patients but consent will be conducted by the ERCP endoscopist on in-patient ward reviews before attending the endoscopy unit.
- Where patients give their agreement, family members will be actively sought to contribute to the consent process.
- NUH has been accepted as part of the EIDO pilot study of home consent. This will include developing a video explainer similar to one already developed at NUH relating to colonoscopy: https://www.youtube.com/watch?v=D42s37HXIoQ

- Patient information and consent forms will be amended to include a statement that “I understand that you cannot give me a guarantee that particular person will perform the procedure. The person performing the procedure will have appropriate experience or expert supervision”.
- Consent forms will be amended to include the opportunity for clinicians to document enhanced risk where it is appropriate.
- Audit of the NUH ERCP practice over the last 3 years shows that pre-procedure administration of rectal NSAIDs (eg diclofenac 100mg; which reduces the risk of post-ERCP pancreatitis) is consistently above 95%, in line with ESGE 2019 guidelines.
- A cross-departmental (HPB endoscopy, HPB surgery and interventional radiology) meeting with key stakeholders has been convened to design pathways for the best approach for complex HPB cases (eg endoscopic versus percutaneous approaches to treating complex strictures or difficult bile ducts stones; combined laparoscopic cholecystectomy and laparoscopic bile duct exploration versus pre-operative ERCP then laparoscopic cholecystectomy) on 9 March 2022.

4. A Lack of accountability between professionals for ensuring robust vetting and consent.

- It is expected that the vetting and consent arrangements described above will resolve this issue.

  In addition to the above, we have developed our specialist HPB endoscopy team so that 5 out of 6 (previously 3 out of 6) endoscopists can perform lower-risk diagnostic EUS and only proceed if appropriate to ERCP (eg if any residual uncertainty regarding presence of bile duct stones) rather than having to delay treatment for repeat imaging or cancel procedures “on the day”. No other UK HPB endoscopy unit has this level of combined EUS/ERCP service provision.

Summary

The actions set out above are intended to address the matters of concern identified in the Preventing Future Deaths report in relation to:

1. A lack of robust patient pathway to ensure that all patient factors relevant to the clinical indication for, and safety of, ERCP are identified in advance of the procedure and discussed with the patient.
2. A lack of robust system for the recording of vetting of the procedure, capturing what information has been considered as part of this process.
3. Consent is not personalised, contrary to recommendations made by the ESGE in December 2019.
4. A Lack of accountability between professionals for ensuring robust vetting and consent.

Some of these have already been implemented and dates have been provided for completion of the remainder. As Medical Director, I will, via the Quality and Safety Oversight Group, ensure that these actions are monitored to completion.