Board of Directors (Public)

The Rotherham NHS Foundation Trust

Schedule	Friday 6 June 2025, 9:00 AM — 10:00 AM BST
Venue	Boardroom, Level D
Organiser	Alan Wolfe

Agenda

9:00 AM	PROCEDURAL ITEMS	
	P84/25.	Chairman's welcome and apologies for absence For Information - Presented by Kamran Malik
	P85/25.	Quoracy Check For Assurance - Presented by Kamran Malik
	P86/25.	Declaration of interest For Assurance - Presented by Kamran Malik
	P87/25.	Minutes of the previous meeting held on 02 March 2025 - to be taken at 4th July Board For Approval - Presented by Kamran Malik
	P88/25.	Matters arising from the previous minutes (not covered elsewhere in the agenda) For Assurance - Presented by Kamran Malik
	P89/25.	Action Log - to be taken at the 4th July Board For Decision - Presented by Kamran Malik
	OVERVIEW AND CONTEXT	

9:10 AM	P90/25.	Endoscopic Retrograde Cholangio Pancreatography Update Presented by Jo Beahan
	P91/25.	Any Other Business For Discussion - Presented by Kamran Malik
	P92/25.	Questions from Members of the Public on the Business of the Meeting For Discussion - Presented by Kamran Malik
	P93/25.	Date of next meeting - Friday 04 July 2025 Presented by Kamran Malik
		CLOSE OF MEETING Presented by Kamran Malik

Board of Directors' Meeting
June 2025

The Rotherham NHS Foundation Trust

Agenda item	P/90/25
Report	**Concerns regarding the Endoscopic Retrograde Cholangio-Pancreatography (ERCP) Service at The Rotherham NHS FT: Briefing paper and external reports**
Executive Lead	Dr Jo Beahan, Medical Director
Link with the BAF	P1: We will not embed quality care within the five year plan U4: We do not develop and maintain a positive culture
How does this paper support Trust Values	**Ambitious:** Demonstrates that the Trust strives to deliver the highest standards and quality of care possible. **Caring:** Demonstrates that the Trust strives to give outstanding, compassionate care. **Together:** Demonstrates that the Trust strives to ensure that quality improvement and the learning from incidents is achieved through a multidisciplinary approach.
Purpose	**For decision** ☐ **For assurance** ☐ **For information** ☒
Executive Summary (including reason for the report, background, key issues and risks)	This paper updates Board about substandard care provided to a group of patients who underwent a specialised endoscopy procedure, called Endoscopic Retrograde Cholangio-Pancreatography (ERCP) between 2016-2021 at The Rotherham NHS FT. ERCPs make up less than 5% of endoscopies performed in the UK and carry well-recognised risks. ERCPs are undertaken to diagnose and treat problems in the liver, gallbladder, bile ducts, and pancreas. The procedure combines X-ray and endoscopy to look at the bile duct and the pancreatic duct and can also be used to remove gallstones or take tissue samples for analysis. Patients requiring an ERCP often have complex health conditions which can be considered life limiting such as frailty or an underlying malignant disease. The reported mortality rates after ERCP in the UK average 4.2% and the Trust's mortality rate is below this. From 2016, the Trust's ERCP service was delivered by a single operator but following a cluster of adverse incidents and complications, the service was suspended in July 2021. Since then patients from Rotherham needing an ERCP have had this nearby with the support of our partners Sheffield Teaching Hospitals NHS FT. The Trust commissioned the Royal College of Physicians (RCP) to undertake an external review which reported in January 2023. The RCP report found a range of failures of care including inadequate recording of informed consent, deficiencies in the ERCP report, poor radiological documentation, no documentation regarding prophylaxis to reduce risk of pancreatitis, concerns regarding stent choice, concerns regarding sedation, discharge processes and lack of responsiveness to

	deteriorating patients, lack of appropriate Multi-Disciplinary Team discussion and decision making, and deficiencies in case records. A number of recommendations were made which were accepted and have been implemented. We identified 959 ERCP procedures undertaken from 2016 to 2021 and, as recommended by the RCP, the care of 68 patients who had died or suffered a complication within 30 days of the procedure were externally reviewed by independent experts. A similar pattern of care failures was identified. Overall the care of 58 patients was found to have had failures with 25 having suffered some degree of harm. It is important to note that ERCP has an inherent risk of harm and it isn't necessarily the case that a deficiency in care was the cause of harm. The Trust is contacting all 68 patients or their families on 4th and 5th June to apologise, to explain what has happened and to outline what the external review has said about their individual care. This initial contact will be followed up on an individual basis. The external reports will be published through our Public Board papers on the Trust website on 6th June and discussed in Trust Board that day. Support will be put in place to respond to any queries from people who have concerns about their care. We have implemented the recommendations from the RCP report. In the last few years, the Trust has successfully appointed a number of medical Consultant Gastroenterologists, either directly or through partnership with Barnsley Hospital NHS FT, and in due course will re-establish a high quality local ERCP service in Rotherham. An external review of the circumstances around the establishment of the service and its oversight between 2016 and 2021 is underway and will be reported through the Public Trust Board in due course. The report may be the focus of forthcoming media attention.
Due Diligence (include the process the paper has gone through prior to presentation at Board of Directors' meeting)	Update report submitted to Confidential Board at various stages with the last update provided in April 2025.
Board powers to make this decision	No decisions are required.
Who, What and When (what action is required, who is the lead and when should it be completed?)	The Medical Director will continue to keep the Board appraised of the position.
Recommendations	It is recommended that the Board note the report and the next steps.
Appendices	1. Royal College of Physicians Invited Service Review (RCP ISR) 2. Case review of deaths following ERCP in Rotherham Hospital – Dr Painter

	3. Independent Review of ERCP Practice at The Rotherham NHS Foundation Trust – Dr Woodward 4. Actions taken following RCP ISR

Overview

This paper reports on deficiencies in the Endoscopic Retrograde Cholangio-Pancreatography (ERCP) service at The Rotherham NHS Foundation Trust between 2016 and 2021. The paper describes the background to the service and the key findings from external reviews that were commissioned. The Trust accepts the findings of the reports and has implemented the recommendations. The Trust strives to provide high standards of care to all patients and to consistently improve. As part of this, we welcome reviews into any aspect of care at the point concerns are raised and will act in full accordance with findings.

We apologise unreservedly to patients and their families affected by the failures identified in the ERCP service review. The care provided to some of the patients who underwent the procedure was unacceptable. A process of contacting affected patients or their families has been undertaken and is described.

1. Introduction

1.1 ERCP is a type of endoscopy procedure used to investigate or treat diseases of the biliary system or pancreas. The procedure involves passing a thin, flexible tube through the mouth, the gullet/oesophagus and the stomach and into the duodenum which is the first part of the small bowel. A special type of endoscope is used that allows the operator to visualise the orifice in the duodenum which connects to the biliary system and the pancreas. The operator may inject a dye that allows the structure of the biliary and pancreatic ducts to be visualised using x-rays. The procedure can also remove gallstones or use stents (a thin tube that can be inserted to bypass a blockage) to keep the ducts open. A biopsy (sample of cells) may be taken to diagnose conditions such as cancer.

1.2 ERCP is used for the following indications; removal of gallstones, treatment of acute pancreatitis, diagnosis of pancreatic or biliary malignancy and palliative therapy for inoperable malignancies. ERCP can be used to remove stones without open surgery for patients who are unfit for an operation. As a result of the underlying condition requiring ERCP, many patients having the procedure are frail. The underlying condition may already have caused sepsis or jaundice which means patients are high risk and extremely unwell prior to the procedure and at risk of death due to overwhelming infection and bleeding. Sometimes the procedure is done in patients who have an underlying inoperable cancer to provide relief from blockages.

1.3 ERCP is recognised as a high risk procedure with risks of complications between 10-14% and risk of 30 day mortality an average of 4.2% in recent data, with a reported mortality rate of up to 8.5%.

1.4 Complications are relatively common and include:

- Pancreatitis – inflammation of the pancreas which is potentially fatal. Risk 5-10% (up to 30% in high risk patients). This risk can be reduced by 50% with prophylaxis.
- Bleeding – 1-2% risk. This risk increases with a sphincterotomy (a small incision that is sometimes necessary to help remove a gallstone). Should a bleed occur, the mortality is high at around 40%.
- Perforation (a hole in the digestive tract) – 2% risk. Mortality 16-18%.
- Cholangitis (inflammation or infection of the bile ducts) 1% risk.
- Risks from sedation.
- Complication rates are significantly higher than many surgical procedures such as cholecystectomy (removal of the gall bladder).

1.5 Careful holistic consideration is required to determine whether proceeding with ERCP is in a patient's best interests and requires clinical consideration and clear communication with patients, and with their next of kin if the patient lacks the capacity to consent.

1.6 Clinical decision making regarding the indication and appropriateness of ERCP can be complex and requires detailed knowledge of hepatobiliary (liver, biliary or pancreatic) cancer pathways and detailed knowledge of surgical alternatives for benign biliary disease, especially for common bile duct (CBD) stones.

2. Concerns identified and outline of investigation

2.1 From 2016 to 2021 ERCP was almost exclusively carried out by a Consultant Nurse as a single operator in Rotherham; a small number of cases were done by temporary medical staff. During this time there were no other substantive staff who had been trained to undertake ERCP. This situation had developed following the departure of all previously employed substantive consultant medical gastroenterologists and the Trust had not been able to recruit ERCP-trained medical consultant gastroenterologists. Medical practitioners from another provider provided cover when this member of staff was not available, for example on leave.

2.2 In 2020 an audit of 147 ERCP procedures had a mortality rate of 2.0%. In 2021 (January – July) an audit of 83 ERCP procedures had a mortality rate of 3.4%. Both these results were within the reported national rate for mortality.

2.3 The Trust suspended the ERCP service in July 2021 due to concerns around a cluster of 6 adverse incidents/complications. Incidents had been investigated as serious incidents or red incidents and there had been two coronial inquests.

2.4 Concerns were also raised through the Joint Advisory Group on Gastrointestinal (GI) endoscopy (JAG) accreditation process who noted 5 deaths within 30 days of ERCP and 4 re-admissions out of 147 cases. JAG is a national body run by The Royal College of Physicians and oversees endoscopist training and accreditation in the UK.

2.5 In February 2022, the Trust commissioned the Royal College of Physicians (RCP) to undertake an Invited Service Review of the Trust's ERCP service. The purpose of the review was to gain an independent and objective understanding of the pathways and protocols in action. This also included considering whether the care provided was in line with national good practice and guidelines.

2.6 The on-site component of the review, which took place in June and July 2022, was subsequently followed up with a formal letter on 21st July 2022 and a final report on 25th January 2023. In light of the verbal feedback received on 8th July 2022, the Trust established an ERCP Control Group.

2.7 To maintain patient safety, the service was suspended when the concerns arose; this involved support from a neighbouring NHS Trust who have undertaken any required ERCPs since then. The processes required to commission an external invited service review were undertaken. An invited review is a complex process requiring coordination of a team of experts such that it often takes some time to establish appropriate terms of reference and assemble the team needed to complete a review.

2.8 A number of staff were interviewed as part of the RCP review in addition to the review of case notes. This allowed the reviewing team to comprehensively assess the service and provide a fair report.

2.9 In response to the findings of the RCP Invited Service Review, the Trust established an ERCP Control Group. Membership of the Group includes the Managing Director, Medical Director, Chief Nurse, Director of Corporate Affairs, Director of People, Director of Communications and other colleagues as required. The group has continued to address the recommendations of the RCP.

2.10 Regional meetings have kept NHS England (NHSE) and the South Yorkshire Integrated Care Board (ICB) updated and have included the Care Quality Commission (CQC).

2.11 The ERCP Control Group and the NHSE control group have addressed the comprehensive recommendations of the RCP report. The recommendations and required actions were extremely detailed and are attached as Appendix 4.

3. The Royal College of Physicians Invited Service Review

3.1 The RCP reviewed 25 case records of patients who had an ERCP between July 2019 and July 2021. The review also looked at the staffing, governance, quality, safety and oversight of the ERCP service. 13 cases reviewed were 'index' patients who had died or had significant complications and 12 cases were selected at random.

3.2 The overriding conclusion of the review team was that the isolated practice by a Consultant Nurse had not provided high standards of performance and safety and resulted in a higher than expected complication rate for ERCP.

3.3 Key Findings

The review team identified a range of issues along the ERCP pathway.

Themes of concerns from the review included:

- Inadequate recording of informed consent.
- Deficiencies in the ERCP report, poor radiological documentation, no documentation regarding prophylaxis to reduce risk of pancreatitis, concerns regarding stent choice.
- Concerns regarding sedation including pre-assessment and levels of sedation with patterns of excessive sedation.
- Discharge processes and lack of responsiveness to deteriorating patients.
- Lack of appropriate Multi-Disciplinary Team discussion and decision making.
- Deficiencies in case records.

3.2 Recommendations

A number of recommendations were made including:

- Review all ERCP cases performed by the Consultant Nurse between 2016 and suspension of the service (excluding the cases already reviewed) where the patient suffered a potential complication as well as all deaths within 30 days of ERCP.

- Recommendations related to:
  - Staffing of the service
  - Service Design
  - Audit and governance
  - Sharing the report

The Trust has completed the recommendations of the report as detailed in Appendix 4.

4. Review of all ERCP Cases

4.1 In line with RCP recommendations, the Trust identified all ERCP procedures undertaken between 2016 and 2021. There were 959 ERCP procedures involving 790 patients as some patients had more than one procedure. All records were reviewed unless they had already been reviewed by the RCP.

4.2 Three categories of patients were identified:

Category 1 - 17 patients who died within 30 days of the procedure (1.7% of the total).

Category 2 - 172 patients who had a re-admission or complication within 30 days of the procedure. These were reviewed by a Doctor and a nurse and 27 of these patients were identified as requiring an expert review. Patients who had been admitted for unrelated reasons were not included.

Category 3 - All remaining patients had an uneventful ERCP or other practitioner performing the procedure.

4.3 The Trust then commissioned additional reviews from independent medical consultants with expertise in ERCP – these are detailed below and provided in the Appendices.

5. Dr Painter Review of patients who died following ERCP

5.1 Dr Painter is an independent Consultant Gastroenterologist, a Clinical Director and performs ERCPs in his own clinical practice. Dr Painter reviewed the case notes of patients who died following ERCP.

5.2 Dr Painter concluded that the reviews highlighted significant concerns regarding the delivery of the ERCP service including consent process, case selection, consideration of alternative approaches and senior decision making. These findings are consistent with the RCP report.

5.3 Dr Painter stated ‘The case reviews showed no prolific questionable practice, most practice was within expected clinical variation.’ Three deaths directly related to ERCP were all recognised complications and individually did not raise significant concerns.

6. Dr Woodward Review of patients with complications following ERCP

6.1 Dr Woodward is a Consultant Gastroenterologist in a tertiary regional centre, has been a clinical lead and provides a regional ERCP service. Dr Woodward reviewed 27 cases where complications may have arisen as a result of ERCP.

6.2 Dr Woodward identified examples of unsafe practice and concerns about consent, selection of patients, sedation, use of stents and their follow up, consideration of prophylaxis, documentation of the procedure and technical performance.

6.3 Dr Woodward identified seven individuals who experienced complications directly arising from the ERCP.

6.4 Dr Woodward raised concerns about the follow up of patients with long term stents and recommended a review of patients with stents.

7. Review of patients with stents

7.1 As recommended by Dr Woodward, 44 patients' notes have been reviewed to ascertain if a stent is in place and requires follow up. A Consultant Gastroenterologist has reviewed the notes of patients who may need a clinical review and individual plans have been put in place. The Trust is not aware of any harm arising in these patients.

8. Coronial Cases

8.1 Four of the cases reviewed by the RCP ISR have had coronial inquests. Two of these were prior to the receipt of the RCP report. For one patient, as part of the coronial investigation, the conclusion was reached that the ERCP procedure had not caused or contributed to the death. In another patient a Serious Incident investigation report had been completed prior to the inquest. The Coroner concluded that there had been a missed opportunity for specialist input and management but this had not changed the outcome. The RCP review identified findings in line with the Coroner's conclusions.

8.2 Two patients underwent Coronial investigations after the RCP report was complete. The summary of the findings related to each patient were presented at inquest. In both of these cases a narrative conclusion was given. Both families have initiated litigation processes.

9. Patient Harm / Duty of Candour Process

9.1 When there are incidents of harm in the NHS, a classification is made of the severity of that harm. The NHS categorises harm as follows:

Harm Level	Description
No Harm	No injury or harm occurred to the patient.
Low Harm	Patient required extra observation or minor treatment.
Moderate Harm	Patient required further treatment or experienced an extended hospital stay, but did not suffer permanent harm.
Severe Harm	Patient experienced permanent or long-term harm.
Death	Death not relating to natural progression of an illness or progression

9.2 The NHS has a formal Duty of Candour to patients who have suffered Moderate or higher degrees of harm. This requires NHS Trusts to be open and transparent with patients and their families when something goes wrong. They must be informed about what has happened, provided with an apology and given the support they need. In the case of the ERCP service described in this paper, the Trust has gone beyond the required Duty of Candour process and has committed to inform all 68 patients, who have been the subject of an external review, of the findings in relation to their care, regardless of the degree of harm.

9.3 For each patient whose care has been reviewed, two assessments have been made – the degree of harm and whether or not there were deficiencies identified in their care. One of the challenges in understanding such a complex procedure in patients who often had serious underlying conditions is in determining whether or not a deficiency in care caused the harm or not. As described earlier in this report, ERCP carries with it significant risks and adverse outcomes and complications can occur even when there have been no deficiencies in care

9.4 The following categories were identified:

Deficiencies in care?	Degree of Harm	Number of patients
No	No harm	10
Yes	No harm	33
Yes	Low harm	1
Yes	Moderate harm	17
Yes	Patient died	7

9.5 In total, 58 patients were found to have deficiencies in their care. 25 of these patients are believed to have experienced harm as a result of these procedures and of these patients, there were 7 deaths. It is difficult to be certain that the deficiencies in care were always the cause of the harm given that the harm was often an expected complication of the procedure but it is likely that the risk of an adverse outcome was increased overall by deficiencies in care. Similarly, it is difficult to definitely say in many cases how significantly a deficiency of care contributed to the level of harm. It is worth noting that the overall mortality rate for the service was within the range reported in the UK.

9.6 <u>Duty of candour process</u>

9.7 The care provided to some of the patients who underwent the procedure was unacceptable and the Trust is committed to apologising to the patients and, where appropriate, to their families.

9.8 The care of 2 patients has already been examined in a Coroner's inquest at which those families are aware of the RCP investigation. In addition, patients whose care has already been subject to investigation through the Serious or Red Incident process have already had a Duty of Candour process.

9.9 In advance of this paper and the investigation reports being put into the public domain, the Trust has taken action to inform all affected patients or their relatives including those who have had already had contact in relation to an incident investigation or inquest.

9.10 The process undertaken was as follows:

- Duty of Candour phone calls will be undertaken by nursing and medical staff over a 2 day period on the 4th and 5th June 2025.
- All patients will receive a Duty of Candour letter following the telephone call.
- If it isn't possible to make contact by telephone, a letter will be sent by post on 5th June.
- During this process an apology will be made to patients or their relatives and they will be provided with an opportunity to understand what the report has said about their care.

- Contact details for one of the Trust senior nurses will be provided to support ongoing communication.
- All patients or families will be offered the opportunity of a face-to-face meeting or telephone call as a follow up with a senior trust clinician.

The board will be provided with a further update on the duty of candour process.

10. External Governance Review

10.1 The RCP review understandably raised concerns about how the ERCP service came to be set up as it was and also about the management of the service between 2016 and 2021. In order to understand these issues, not least in relation to changes in senior management of the Trust since that time, an independent review of the governance of these processes has been commissioned. This review has been examining the documentary evidence in relation to these matters and interviewing relevant current and past members of staff. This has been a complex process and it is anticipated that the Trust will receive this further report over the coming months. It is the Trust's intention for the Board to receive and publish the report along with an appropriate action plan.

11. Human Resources

11.1 Concerns around the practice of an employee were reported to the Nursing and Midwifery Council as per the recommendations of the RCP review. The employee has subsequently been dismissed by the Trust.

12. NHSE Regional Coordination Group

12.1 The Trust has met with the NHSE Regional Coordination Group at regular intervals since 2022. Actions taken by this group have included facilitation of a review of the clinical practice of the Consultant Nurse at other Trusts that he practiced in as per the recommendations of the ISR. No concerns were identified in other organisations.

12.2 The control group have retained oversight and provided advice to the Trust. The group is chaired by the regional Medical Director with representation from Director of Nursing and other colleagues. The group has linked with the Care Quality Commission and other relevant bodies. ICB and place colleagues have also been kept informed of progress.

13. ERCP service: current status

13.1 The ERCP service is currently provided by Sheffield Teaching Hospitals NHS Foundation Trust (STH). There were a number of recommendations made by the ISR that will need to be met prior to the resumption of the ERCP service at the Trust; there are no imminent plans to resume the ERCP service in Rotherham.

13.2 The endoscopy unit is now in Care Group 1, which is responsible for medical services. A Consultant Gastroenterologist who is a JAG accredited assessor has recently been employed at the Trust and has taken the role of Clinical Lead for Endoscopy. Other Consultant Gastroenterologists now work in the Trust, directly employed or through partnership with Barnsley Hospital NHS FT. A new endoscopy reporting system that is compliant with the National Endoscopy Database and enables audit of JAG Key Performance Indicators is now in place and well established.

13.3 There were a number of recommendations made by the ISR that will need to be met prior to the resumption of the ERCP service at the Trust. The service would be provided by trained Consultant Gastroenterologists with appropriate MDT decision making and consent processes. A Consultant Gastroenterologist is being supported by STH and Barnsley Hospital NHS FT to complete her training and maintain competencies. A Standard Operating Procedure has been developed with the support of colleagues at Barnsley Hospital NHS FT.

13.4 The service would be regularly audited to ensure appropriate numbers per practitioner to maintain skills and competency and ensure minimum standards of the key performance indicators are met as per the invited service review recommendations and the way ahead document from the British Society of Gastroenterology. The service will not resume until there is assurance that a safe, well governed and high quality service can be maintained.

14. Communication for patients

14.1 The Trust is committed to contacting all affected patients and are aware that publication may cause concern for other patients who have been treated at the Trust.

14.2 There will be a telephone number and email address available to patients or relatives of affected patients who would like to speak to someone about any aspect of their care or for concerned members of the public. This will be provided in the duty of candour letter.

14.3 Concerned members of the public will be directed to contact the patient experience team through the usual Trust process.

15. Communication for staff

15.1 Staff at the Trust who have been affected by this report will be offered support. This will be tailored to individuals and the departments which have been impacted. TRFT operates and promotes a comprehensive Freedom to Speak Up policy for all colleagues across all areas of the organisation and actively encourages everyone to share any concerns about any area at any time.

15.2 The Board are aware of developments in the Freedom to Speak Up process, Learning from Deaths process, Patient Safety Systems and the introduction of Martha's law which all contribute to improved quality of care and earlier recognition of concerns about clinical practice.

16. Next Steps

16.1 The 6th June board meeting will include a verbal update on progress of the Duty of Candour process taking place week commencing 2nd June.

16.2 The three external reports and action plan will be published in the Trust Board papers and shared as the recommendations in the ISR. The reports have been redacted where appropriate to do so.

16.3 Following receipt of the External Governance Review in the coming weeks, an action plan will be developed. The review, action plan and progress on delivering the actions will be presented to the board on the 5th September.

16.4 Internal ERCP control group meetings and the external NHSE control group meetings will continue for the foreseeable future.

16.5 The Trust will continue to support the affected patients and families involved in these reports. We appreciate this will be a difficult time for them and the Trust apologises unreservedly and will ensure they have the opportunity to understand the care they or their relative received.

Dr Joanne Beahan
Medical Director

Royal College of Physicians

Setting higher standards

Invited Reviews

Report of the invited service review to

The Rotherham NHS Foundation Trust on 13, 15 June and 7, 8 July 2022

Contents

1 Executive summary

This invited review was commissioned following an assessment of the Trust's endoscopy service in July 2021 by the Royal College of Physicians (RCP) Joint Advisory Group on GI Endoscopy (JAG). The assessment report concluded that the service had not met accreditation standards and that an external review was required of the ERCP service *'to establish its safety and identify a long-term sustainable delivery plan'*.

1.1.1 ERCP

ERCP stands for endoscopic retrograde cholangio-pancreatography. ERCP is a procedure that combines upper gastrointestinal (GI) endoscopy and x-rays to treat problems of the bile and pancreatic ducts, such as removing gallstones from the common bile ducts (CBD), acute and chronic pancreatitis, cancers of the bile ducts and pancreas, trauma or surgical complications in the bile or pancreatic ducts.[1] In addition to treating problems of the bile and pancreatic ducts, ERCP can be used to diagnose problems of the bile and pancreatic ducts alongside MRCP[i] and EUS[ii], whilst treatment is taking place.

During ERCP an endoscope (a long, thin flexible tube with a camera at the end) is passed through the mouth down to where the bile duct opens into the duodenum, part of the small intestine. The opening of the bile duct can be widened with a small cut or an electrically heated wire (sphincterotomy). Sometimes a stent (a small tube) is placed in the bile duct. This facilitates stone removal, bile drainage or other therapies. ERCP is carried out under sedation or general anaesthesia.[2]

ERCP is generally a safe procedure with well recognised risks of morbidity and mortality. The potentially serious and life-threatening risks associated with an ERCP make the risk-benefit ratio an important consideration for patients undergoing this procedure. The most common serious complication is post-ERCP pancreatitis[iii] (PEP)[3], which in severe cases can result in death. Other complications include infection; bleeding (which in severe cases can be fatal); allergic reaction to the sedation or dye; and perforation in the small bowel.[4] The consideration of the risks of the procedure and sharing the decision making with the patient is a crucial part of any ERCP service.

An American source[5] has suggested that ERCP is associated with a 5%-10% risk of pancreatitis. The risk is increased in those cases where cannulation of the ducts is difficult, the pancreas is normal, or when a sphincterotomy[iv] is performed in the setting of sphincter of Oddi dysfunction. A prior history of ERCP-related pancreatitis is also a risk factor. Other risk factors for PEP include being female; first endoscopic biliary drainage procedure without endoscopic sphincterotomy; and performing additional diagnostic procedures on the pancreatobiliary duct.[6] Steps to prevent PEP (i.e., prophylaxis) are strongly recommended to reduce the incidence and severity of pancreatitis. Use of rectal NSAID[v] (such as diclofenac[vi]) has been the standard prophylaxis for many years and its use was confirmed by the European Society of Gastrointestinal Endoscopy (ESGE) in 2019. The first recommendation within ESGE guideline 'ERCP-related adverse events'[7] was for *'routine rectal administration of 100mg of diclofenac or indomethacin immediately before endoscopic retrograde cholangiopancreatography (ERCP) in all patients*

[i] Magnetic resonance cholangiopancreatography (MRCP) is a type of magnetic resonance imaging (MRI) exam that produces detailed images of the hepatobiliary and pancreatic systems
[ii] Endoscopic ultrasound (EUS) combines endoscopy and ultrasound to diagnose and treat a range of gastrointestinal problems
[iii] Pancreatitis is inflammation of the pancreas
[iv] Sphincterotomy involves cutting the muscle that surrounds the opening of the ducts, or the papilla, using a small wire on a specialised catheter with electric current to cut the tissue.
[v] Non-steroidal anti-inflammatory drugs
[vi] Diclofenac is a non-steroidal anti-inflammatory medication

without contraindications to nonsteroidal anti-inflammatory drug administration'. This was described as a strong recommendation, supported by moderate quality evidence.

Aside from the arrangements at Rotherham, there are no known examples in the UK of a nurse/clinical endoscopist delivering ERCP, within a team or as sole operator.

1.1.2 The ERCP service at Rotherham

Between 2016 and the summer of 2021 (with a year gap between 2017 and 2018), ERCP was carried out by a single operator at the Trust, a nurse consultant[vii]. No other staff at the Trust during this timeframe had been trained to undertake ERCP, which thwarted the ability of staff to undertake internal assessment of the ERCP service and associated complication rates. The factors that led to the arrangement whereby a single-handed clinical endoscopist undertook ERCP are set out at 6.2.1.

A cluster of serious incidents following ERCP procedures, including patient deaths, led to the decision by the Trust to suspend the ERCP service in July 2021. The clinical endoscopist was also suspended from the Trust in July 2021. A referral had been made to the Nursing and Midwifery Council (NMC), which was said to relate to non-clinical issues and the NMC had imposed an interim suspension order, which meant that the clinical endoscopist could not practice at the Trust, or elsewhere, until the matter was resolved by the regulator.

Since July 2021, patients requiring ERCP have been transferred to Sheffield Teaching Hospitals NHS Foundation Trust. See 6.2.2 for further details. The Trust's objective was to reintroduce the provision of ERCPs, as part of partnership working with Barnsley Hospital NHS Foundation Trust, and with the continued support of Sheffield Teaching Hospital, as the tertiary centre.

1.1.3 RCP invited review

This review was undertaken by three specialist reviewers, in addition to a lay reviewer and the medical director for invited reviews. Two of the specialist reviewers (a consultant gastroenterologist and a consultant pancreaticobiliary physician) had expertise in ERCP. The third reviewer was an experienced nurse consultant endoscopist in gastroenterology (although not an ERCP provider), who was able to contribute a senior nursing perspective of endoscopy services.

The review comprised two key elements:

- Structured judgement review of 26 clinical case records – for details, see section 4.3
- Interviews with Trust staff, including the clinical endoscopist who undertook ERCP – for details, see section 4.2

The findings from the structured judgement review and the interviews can be found at section 6. The conclusions of the review team specific to each of the terms of reference can be found at section 2.

The overriding conclusion of the review team was that the isolated practice by a clinical nurse endoscopist has not provided for high standards of performance and safety and has instead resulted in a higher-than-expected complication rate for ERCP. The review team identified a range of issues along the ERCP pathway including the performance and conduct of the ERCP clinical endoscopist, inadequate oversight of their practice, lack of understanding of ERCP, and weak mechanisms for clinical governance of the service.

The review team has recommended that there should be a complete redesign of the ERCP service, with a move to a medically qualified, consultant-led service (such as by suitably trained gastroenterologists, upper

[vii] Nurse consultant

GI or Hepato-Pancreato-Biliary (HPB) surgeons) and one that places emphasis on teamworking and peer review. The new ERCP service should strictly follow the British Society of Gastroenterology (BSG) standards framework *The Way Forward* (2014[8]), which puts quality and patient safety at the heart of the service.

The full recommendations arising from this review are found at section 3.

2 Overall conclusions

2.1.1 To undertake a clinical review of 26 case records of patients[viii] who received ERCP between July 2019 to July 2021, to gain an understanding of the pathways and protocols in action.

Overall, 11 of the 12 index cases reviewed were found to be unsatisfactory. These 12 index cases comprised patients who had died following an ERCP or who had suffered significant complications. The unsatisfactory grading reflected that several aspects of clinical care were well below what the review team would expect. Only one of the index cases received a different grading, which was room for improvement for clinical reasons.

Seven of the 13 cases selected randomly were found to be unsatisfactory. The remaining six were graded room for improvement for clinical reasons. It is notable that none of the cases selected randomly were found to constitute good practice. No organisational issues were identified from review of the clinical records.

Several themes emerged from the case record review. The process of recording informed consent was consistently inadequate. The review team frequently identified a lack of documented meaningful discussion by the clinical endoscopist performing the procedure, with the patient, regarding the risks of the ERCP specific to the individual patient, as detailed in the GMC's guidance on consent[ix]. The clinical endoscopist's handwriting was often difficult to decipher, making it hard for the review team to establish the exact risks highlighted. A recurring theme related to the patient's capacity to provide informed consent, in the absence of evidence of a capacity assessment. Consent was often taken in the endoscopy suite, immediately prior to the ERCP and the review team was concerned this could create pressure on the patient to consent to the procedure without having time to properly consider the risks. In interview, it was evident that the clinical endoscopist had no understanding of the implications for the consent process of the Montgomery judgment.[9] (see section 6.1.3)

The review team observed several deficiencies in the ERCP reports completed by the clinical endoscopist, including insufficient detail to explain the approach taken, which was important to understanding the risk of post-procedural complications. The procedural approach was often badly described, making it difficult for the review team to understand the exact nature of the procedure. Some ERCP reports failed to reference that a previous ERCP had taken place or make clear how the subsequent ERCP sought to build on previous therapeutic approaches. Radiological documentation of the procedure was often of a poor standard. There was no documentation across the cases to indicate that prophylactic approaches were used to reduce the risk of pancreatitis. In several cases, the review team expressed concern regarding stent choice. The lack of detail contained in some ERCP reports surrounding procedural complications indicated a concerning lack of transparency. (see section 6.1.4)

Sedation is a very important aspect of delivering ERCP care. An ERCP often requires more sedation than for other endoscopic procedures. Many ERCP departments will have a relationship with the anaesthetic

[viii] 13 index cases and 13 cases selected randomly

[ix] GMC guidance is relevant as ERCP would usually be undertaken by someone medically qualified

department as part of assessing the suitability of cases and the approach taken to sedation (for example, in some units most ERCPs are conducted under general anaesthesia). The review team did not identify any evidence that ERCP by the clinical endoscopist was undertaken with any anaesthetic support or input. Moreover, the review team concluded that insufficient care and attention was paid to sedation, including inadequate consideration of risks in the pre-assessment of some patients (see section 6.1.2); and discordance between some nursing records and the ERCP report regarding the levels of sedation used (see section 6.1.9).

Occasionally, high doses of sedation are required to allow procedures to be performed but the review team found a consistent pattern of excessive sedation administered by the clinical endoscopist. (see heading 6.1.4). The levels of sedation used for some patients indicated that additional sedation was administered once, twice, or more after the initial dose; it was not evident that before administering more sedation, the clinical endoscopist had paused to consider whether this was in the patient's best interests. Patients can disinhibit as they go deeper into sedation and their ability to co-operate and remain still can be lost as they fall into lower levels of consciousness. The table below, taken from the JAG guidance, shows suggested doses for these drugs. Examples of excessive sedation included the following: administering 8.5mg of midazolam and 150mcg of fentanyl to a female patient in her forties; administering 9mg of midazolam and 175mcg fentanyl to a female patient in her twenties; and 8mg of midazolam and 75mcg of fentanyl to a female patient in her thirties. The review team considered these levels almost amounted to deep sedation (ERCP should be a conscious sedation procedure and not a deep sedation procedure (in the absence of formal anaesthetist involvement)) and questioned whether staff present had the capabilities to monitor patients in deep sedation. Some older patients also received excessive levels of sedation, including an elderly and frail patient who was documented as being confused and was given 6.5mg midazolam and 100mcg fentanyl.

JAG guidance on sedation, as reflected in *The Way Forward*, is shown below:

Median dose (Age <70) Midazolam*	≤5mg	
Median dose (Age <70) Pethidine	≤50mg	
Median dose (Age <70) Fentanyl	≤100mcg	
Median dose (Age >70) Midazolam	≤2mg	
Median dose (Age >70) Pethidine	≤25mg	
Median dose (Age >70) Fentanyl	≤50mcg	

*The sedation dosages are extrapolated from the colonoscopy and OGD guidance. JAG acknowledges that there is not currently a standard for ERCP but follows this guidance until this is determined particularly as patients may be septic, frail and comorbid.

The review team raised concern that many patients in the cohort reviewed were discharged too quickly after the ERCP. This was compounded in some instances by a lack of responsiveness from the clinical endoscopist to nursing concerns regarding patients post ERCP with deteriorating observations. (see section 6.1.5)

There was limited evidence across the 25 cases of any meaningful multidisciplinary discussion. There was a lack of documented communication between the clinical endoscopist and colleagues, including, for example, regarding whether surgical options should be considered. A lack of documented communication was also thought to undermine management of complications. (see section 6.1.7)

The review team observed good interactions across several cases between ward staff and patients and family members. The same applied to interactions with intensive care staff. Good practice along these lines was not identified from the records with respect to the ERCP procedure and there was a lack of evidence of

interactions by the clinical endoscopist with patients. In several cases, there was no documented communication by the clinical endoscopist when the patient deteriorated, and complications occurred. Moreover, the review team observed an apparent lack of transparency regarding complications. Several cases gave rise to concern that the clinical endoscopist had not provided a clear explanation to the patient or family members about complications and in some instances the review team questioned whether the lack of transparency might indicate probity issues. (see section 6.1.8)

The review team identified a range of deficiencies in the case records, including: the absence of documentation articulating clinical decision making (or who the key decision maker was) regarding plans for the patient; inconsistencies between the ERCP report and other entries in the patient record, including over the levels of sedation used and whether a sphincterotomy had taken place; a lack of transparency regarding the completeness of the procedure or failure to reflect the actuality of the procedure; omissions in the ERCP report or reference to previous ERCPs, or the absence of any documented entry by the clinical endoscopist relating to complications associated with the ERCP; imaging documentation of procedures was often of a poor standard. (See section 6.1.9)

2.1.2 To review the current ERCP service design for the delivery of care, including protocols and pathways, facilities, links with other centres, capacity, activity and workload.

A previously mature ERCP service was withdrawn due to a lack of consultant gastroenterology staff. The solution to restore the service was to recruit a clinical (nurse) endoscopist into a unique and unprecedented role, by providing the ERCP service single-handedly, without a medical qualification. The appointment was contrary to existing BSG guidance on non-medical endoscopists (2005[10]). The supervision for this novel arrangement was provided by two surgical consultants, neither of whom were trained in ERCP, with line management via [*a senior member of the nursing hierarchy*]. (See section 6.2.1-6.2.6)

Pressure to continue to provide an ERCP service at Rotherham allowed the situation to continue despite a lack of clear leadership or robust clinical governance processes. There appeared to have been an overemphasis on the continuation of the service over patient safety. Closer attention should have been paid to the problems that arose between the clinical endoscopist and the radiology department soon after the endoscopist's appointment. These issues were discussed with the clinical endoscopist at an appraisal meeting in 2018 but were thought to be *'no longer an issue'* at the next appraisal discussion in 2020. These issues should have been explored in further detail as they were a precursor to some of the issues that followed, and they led to the unusual arrangement between the clinical endoscopist and The Christie NHS Foundation Trust (see 6.2.1).

A new management team at divisional level brought a fresh perspective to the service, questioned accepted arrangements, and took action when, sadly, a cluster of patient deaths occurred. The review team was entirely supportive of the decision taken to suspend the service and concluded that there should be a complete redesign of the ERCP service moving forward. The draft standard operating procedure (SOP) for ERCP at the Trust (May 22), stated that future ERCPs would be undertaken by a mix of consultants from Sheffield Teaching Hospital or Barnsley Hospital, and consultants or non-medical endoscopists from the Rotherham Trust. This SOP, which had not yet been ratified, did not align with the BSG guidance on non-medical endoscopists performing ERCP. The Trust will continue to find itself in a uniquely vulnerable position if it allows non-medical endoscopists to perform ERCP. Interviews with senior leaders at the Trust suggested an understanding of this and efforts have focused on having 2.5 whole time equivalent (WTE) gastroenterologists and an upper GI surgeon undertaking ERCP in future, as part of an upper GI unit developed in partnership with Barnsley Hospital NHS Foundation Trust. The Trust's strategic focus on partnership working with Barnsley is supported by having a shared Interim Chief Executive working across both Trusts.

Linking with Barnsley should secure sufficient activity for practitioners to maintain expertise in ERCP and meet the standards set out in *The Way Forward* (detailed in the recommendations, section 3. It should also free up Sheffield to focus on tertiary referrals, in addition to its own patient population. This hub and spoke model will put the ERCP service on a stronger, more sustainable footing, supported by peer review across the hub and spokes. It will further strengthen hepatobiliary networks across the South Yorkshire Integrated Care Board (ICB) and within the larger Northeast and Yorkshire NHS region.

The draft SOP document sets out the ERCP pathway and addresses aspects that had appeared from the clinical record review to have been previously ill-defined. In terms of pre-procedure, these include ensuring that any abnormalities arising from pre-assessment are drawn to the attention of the responsible upper GI consultant, and sending patients an information leaflet. This SOP should establish the ERCP on a surer footing, however the Trust will first need to ensure that it aligns with the framework set out in *The Way Forward* – incorporated into the recommendations at section 3. The Trust should also consider the SOP used by Barnsley to ensure a unified approach across the two Trusts.

The review team concluded that compliance with pathway documentation had been an issue under the clinical endoscopist. The review team concluded that there was frequent discrepancy between the expectations laid out in the Endoscopy Policy (issued in 2009 and most recently reviewed in July 2019), and what happened in practice. For example, the policy addressed issues of consent, including assessment of capacity and the timing of consent. However, in practice, the clinical records did not demonstrate that this policy was being followed. The policy detailed the complications associated with ERCP, including the likelihood of these occurring, and suggested strategies for their avoidance. In the case of post ERCP bleeding, this included for all patients undergoing any form of ERCP to have a platelet count and INR measured prior to the procedure, preferably within the preceding 24 hours. This did not align with observations the review team made on some of the clinical records. Another example was the guidance on sedation, which stated that *'most endoscopic practices recommend that 5mg of Midazolam should usually be the maximum dose given'*, with small initial doses for elderly patients. This statement did not align with the approach to sedation observed in several of the clinical records, which the review team described as a significant departure from normal practice.

2.1.3 To review the quality of staffing and team working within the department and to give a view on whether this supports the delivery of high quality and safe care.

The issues highlighted in the section above regarding compliance by the clinical endoscopist with the endoscopy policy, demonstrate the centrality of the performance and conduct of the single clinical endoscopist to the safety and performance of the ERCP service.

The review team received positive comments regarding the clinical endoscopist's skill, work ethic and productivity. Set against these comments was criticism of the clinical endoscopist's failure to follow direction, a tendency to circumvent established pathways, concern over professional behaviours, and conduct issues. Details of the findings relevant to this summary can be found at section 6.3.1. Examples included the clinical endoscopist allegedly misrepresenting their position as a nurse consultant, causing patients and colleagues to be misled; undermining a visiting gastroenterologist by telling a patient that they would undertake a procedure contrary to plans made by the gastroenterologist; and a lack of responsiveness to complications or concerns from nursing colleagues. Many of the significant concerns expressed about the clinical endoscopist were felt to have had a highly negative impact both on individual staff and clinical teams, as well as on patient safety and the quality of care.

The review team considered these issues in the context of concerns identified from the clinical record review with respect to an apparent lack of transparency by the clinical endoscopist over the approach taken during the ERCP – see section 6.1.4 – as well as afterwards, when complications arose (see section 6.1.8. In some instances, the review team questioned whether a lack of transparency around complications might indicate potential probity issues.

The review team found some of the descriptors used by the clinical endoscopist to be misleading. These included that they were a national accreditor and trainer; the review team was unaware of the existence of any national trainer title and observed that training has been devolved to local teams with capacity to run JAG courses. Another example was the clinical endoscopist's description of themself as a *'level 4 operator'*. The levels relate to case complexity, not the skills of the ERCP practitioner; many level 3 cases and all level 4 cases would usually be referred to a tertiary centre. Most of the cases seen by the review team were level 2, with the occasional level 3 case. There is no national list of operators recognised as *'advanced'* ERCP endoscopists.

Oversight arrangements for the clinical endoscopist as an ERCP operator were concluded to be inadequate. The clinical endoscopist was line managed by [*a senior member of the nursing hierarchy*], with clinical accountability to two general surgeons (neither of whom was trained in ERCP). There was an overreliance by nursing managers on the two general surgeons, who were said repeatedly to have given assurances that there were no problems, despite being ill-equipped to provide such assurance. Fundamentally, there was no-one at the Trust able to provide scrutiny of the clinical endoscopist's performance of ERCP and it was not apparent that any attempt was made to seek the input of a practitioner trained in ERCP to assist with assessing their performance in this procedure. The review team did not receive evidence of any appraisal documentation and the notes provided of two appraisal meetings suggest discussion was only superficial and did not meet current expectations regarding appraisal. It was not evident that there was any oversight or governance of the clinical endoscopist's activities outside of their employing Trust.

The clinical endoscopist was regarded as aligned with, and heavily supported by, the general surgery team, and the extent to which surgical colleagues supported the clinical endoscopist proved a significant challenge for senior management. Interviewees described a very defensive response from the surgeons, which posed a significant barrier to addressing the concerns about the clinical endoscopist's practice.

2.1.4 To review the quality of clinical governance arrangements currently in place to support and maintain oversight of the service.

The review team concluded that there have not been robust governance arrangements to support and maintain oversight of the ERCP service. The minutes of three separate general surgery governance meetings held in 2019 demonstrated discussion of three patient deaths following ERCP. However, the clinical endoscopist was not an attendee at these meetings, making it difficult to understand how learning was derived. (See section 6.4.1-6.4.5)

There was evidence that an endoscopy governance meeting held in October 2020 discussed the outcome of an inquest into the death of a patient the year before following ERCP. However, there was no evidence of a systematic approach to reviewing morbidity and mortality related to ERCPs, or of identifying learning in a structured and meaningful way. For example, regarding the inquest, the patient developed pancreatitis post ERCP, which the minutes stated was *'not in itself significant as the rate of developing this post procedure at TRFT [The Rotherham Foundation Trust] is lower than average'*. Attendees at the meeting should have requested robust evidence to demonstrate the veracity of this comment, which the review team considered to have been complacent.

The post-pancreatitis audit conducted internally showed that the ERCP service was an outlier. Whilst 30-day mortality appeared similar to other units, the procedure-related mortality rate was significantly higher than other units used for comparison. This indicated that those reviewing the audit data did not recognise that the complication was therefore related to the ERCP rather than the underlying disease.

The Trust's failure to adhere both to local and national guidelines in relation to the management of a patient with a common bile duct stricture was one of the points of learning from this inquest case, reflecting that the patient was discussed with the clinical endoscopist but not discussed at Sheffield's MDT meeting and the consultant responsible, as it should have been. Such learning should have been triangulated with other accounts, of which the review team received many, that the clinical endoscopist frequently failed to adhere to agreed pathways. These issues should have been pursued with the clinical endoscopist in appraisals, with actions identified to improve performance and safeguard patient care. In short, it appeared there was no effective mechanism to close the loop and bring about quality improvement.

The situation was compounded by a reported reluctance within the division of surgery for staff to raise concerns. When concerns were raised, via Datix reports, it was not clear that these had been acted upon. For example, the review team heard that several Datix reports had raised concerns regarding the levels of sedation used for ERCP, however it was not evident that any action had been taken to examine this issue further despite the obvious patient safety implications.

Audits undertaken by the Trust specific to ERCP should have received the input of clinicians with expertise in ERCP (such as from the tertiary centre). Some of the comments made in interview highlighted misunderstandings about the nature of ERCP complications – for example, disregarding pancreatitis as a complication of ERCP – and suggested that colleagues were too eager to accept the clinical endoscopist's account that cases were of higher complexity than elsewhere. Some audits were let down by a failure to compare *'like with like'*. The post-ERCP pancreatitis audit, for example, compared ERCP cases at the Trust during 2020 with figures for other centres in 2006 and 2007.

A new senior leadership team has increased attention on governance and quality improvement. This new team appeared to have a good grasp of the issues requiring attention.

2.1.5 To highlight any new area of concern that arises during the ISR.

The issues raised under the terms of reference above highlighted inadequacies in the governance and oversight provided by the general surgical team, and raised wider issues regarding the governance of the general surgery service and the reporting of incidents. The review team supported the plans articulated by Trust leaders to undertake work within the division of surgery, which should help to re-focus the division more firmly on patient safety.

Finally, the review team observed that the clinical lead for the endoscopy service was an upper GI surgeon who had been acting up as a consultant general surgeon for [*xx*] years, first from the role of associate specialist surgeon and, since [*yyyy*], as a locum. Guidance on SAS (specialty and specialist grade) doctors acting up states that doctors asked to act up for more than six months continually should explore the possibility of being appointed as a locum for a year or having the role advertised as a substantive position.[11] This surgeon has clearly acted up beyond these timeframes.

3 Recommendations

Key for timelines for implementing recommendations:

> **Immediate (0-3 months)** – action should be completed within 3 months of receipt of the initial invited review feedback letter.

> **Short term (0-6 months)** - action should be completed within 6 months of receipt of the invited review report.

> **Medium term (6-12 months)** – action should be completed within 12 months of receipt of the invited review report. Planning for actions resulting from these recommendations should start as soon as possible.

> **Long term (12-24 months)** - action should be completed within 24 months receipt of the invited review report. Planning for actions resulting from these recommendations should start as soon as possible.

Staffing the ERCP service

Recommendation	Timelines
a. In line with BSG guidance, the clinical endoscopist should not undertake ERCP in any healthcare institution that provides an ERCP service.	**Immediate (0-3 months)**
b. The unusual circumstances of a nurse providing interventionist procedures raises the question over whether contact should be made with the Trust's GMC Employer Liaison Advisor, in the absence of equivalent mechanisms for nurse consultants providing therapeutic interventions.	**Immediate (0-3 months)**
c. There is sufficient concern within the clinical case review to advise the Trust to re-refer the clinical endoscopist to the NMC for their clinical decision making, conduct and competence.	**Immediate (0-3 months)**
d. The Trust should inform relevant units, both in the public and private sector, where the clinical endoscopist has provided services (ERCP and other interventional procedures) of the concerns raised by this review, to enable them to consider the relevance of the findings to the clinical endoscopist's wider practice.	**Immediate (0-3 months)**
e. The Trust should undertake internal review of its processes for employing clinicians to ensure that the concerns raised by this review are not duplicated for other staff. This may include ensuring that there are robust arrangements for clinical and managerial oversight of any new appointee, and that there is a clear process for considering any activity undertaken at other healthcare organisations (including governance and financial implications).	**Immediate (0-3 months)**
f. The ERCP service should move to a medically qualified, consultant-led service (such as by suitably trained gastroenterologists, upper GI or Hepato-Pancreato-Biliary (HPB) surgeons).	**Short term (0-6 months)**
g. ERCP endoscopists should demonstrate that they undertake a minimum of 75 cases per annum, with the aim for a minimum of 100 cases, as per *The Way Forward* 2014.	**Medium term (6-12 months)**

h. Minimum standards for independent practitioners should be based on intention to treat and include a >=85% cannulation rate of virgin papillae, CBD stone clearance for >=75% of those undergoing 1st ever ERCP, and for patients with an extra-hepatic stricture, successful stenting with cytology or histology where appropriate at 1st ERCP in >=80%, as per *The Way Forward* 2014.	**Medium term (6-12 months)**
i. Performance criteria should be monitored by a detailed audit and feedback process and incorporated into consultant appraisal, as per *The Way Forward* 2014.	**Long term (12-24 months)**
j. The organisation and standards for training for ERCP should follow from the performance criteria detailed under (h), as per *The Way Forward* 2014.	**Long term (12-24 months)**
k. Newly appointed consultants should be mentored to ensure a safe and effective transition from trainee to independent practitioner, as per *The Way Forward* 2014.	**Short term (0-6 months)**

Service design

Recommendation	Timelines
l. The new ERCP service should strictly follow the British Society of Gastroenterology (BSG) standards framework *The Way Forward* (2014[12]). This requires the Trust to ensure that, amongst other things, key performance indicators (found in *The Way Forward* and in JAG Accreditation Programme guidance[13]) are measured and delivered against, and there should be 150 cases minimum per facility per year, with the aim of 200 cases.	**Medium term (6-12 months)**
m. The new ERCP service should work collaboratively in a regional hub-and-spoke model, with simple and rapid referral pathways established. Facilities for urgent or emergency ERCP should be available, as per *The Way Forward* 2014.	**Medium term (6-12 months)**
n. In formalising a SOP for the ERCP service the Trust should refer to the SOP used by Barnsley to ensure a unified approach across the two organisations.	**Medium term (6-12 months)**

Audit and governance

Recommendation	Timelines
o. The behaviour and performance of the clinical endoscopist suggests that their wider endoscopic practice should be considered further by the Trust. This should include: a. Review of all ERCP cases performed by the clinical endoscopist between 2017 and suspension of the service (excluding the cases already reviewed), where the patient suffered a potential complication (including post-ERCP pancreatitis (PEP), infection, bleeding, allergic reaction to the sedation or dye, and perforation in the small bowel), as well as all deaths within 30 days of ERCP, to	**Immediate (0-3 months)**

determine whether the ERCP procedure was in line with good practice, and whether the complication was avoidable. The RCP/BSG may be able to assist with this review, if required. b. Audit of non-ERCP therapeutic interventions undertaken by the clinical endoscopist (for example, ureteric stenting) and all relevant hospitals where these interventions took place. These other interventions should be evaluated against appropriate benchmarks.	
p. The governance arrangements for a single-handed clinical endoscopist providing ERCP were deeply unsatisfactory. As part of their discussions with the GMC employment liaison officer, the Trust should consider whether the two surgeons responsible for overseeing these arrangements fulfilled their duty of care as detailed in GMC good medical practice, Leadership and Management for all doctors.	**Short term (0-6 months)**
q. The Trust should review the endoscopic reporting software and its ability to both upload to the National Endoscopy Database (NED), which requires the software to be NED compliant[x], and to automate audit of all JAG mandated key performance indicators (KPIs), especially those relating to sedation across all modalities and ERCP. There should be at least annual audit of ERCP numbers and outcomes, as per KPIs set out in *The Way Forward*. Endoscopy reporting software should be NED compliant.	**Medium term (6-12 months)**
r. The Trust should consider how, once its new ERCP service is established, it can support high quality ERCP research, as per *The Way Forward* 2014.	**Long term (12-24 months)**

Sharing the report

Recommendation	Timelines
s. The Trust should share this report with the following regulator(s): Care Quality Commission; Nursing and Midwifery Council.	**Short term (0-6 months)**
t. The Trust should share this report with service commissioners and the Integrated Care Board.	**Short term (0-6 months)**
u. The Trust should share this report with JAG on GI Endoscopy; the NHSE/I[xi] endoscopy transformation team; and the BSG president and endoscopy committee chair.	**Short term (0-6 months)**

[x] https://ned.thejag.org.uk/Default.aspx?ContentId=Suppliers

[xi] NHS England and Improvement (NHSE/I)

4 Introduction

Dr Callum Gardner, medical director of The Rotherham NHS Foundation Trust contacted the Royal College of Physicians (RCP) regarding the ERCP service on 19 January 2022. Dr Gardner discussed the review with [*Name redacted*], medical director for invited reviews at the RCP. It was agreed that an invited review of the ERCP service at The Rotherham NHS Foundation Trust would be undertaken on 13 and 15 June, and 7 and 8 July 2022.

4.1 Terms of reference for this invited review

To undertake an invited service review (ISR) at the Rotherham NHS Foundation Trust and the medical specialty is gastroenterology.

The review will take place using remote media or teleconferencing facilities, and the findings will be based on interviews with key individuals, review of patient medical records and background documentation.

1. **To undertake a clinical review of 26 case records of patients who received ERCP between July 2019 to July 2021**, to include:

• 13 index cases (to include patients who died and any others with significant complications)
• 13 random cases (every 5th case from the time period chosen).

The purpose of this would be to gain a greater understanding of the pathways and protocols in action. This will include taking into account whether the care is in line with national good practice and guidelines, and/or what would be considered by the view of a body of clinical professionals in a similar situation.

2. **To review the current ERCP service design for the delivery of care**. Consideration will be given to protocols and pathways, facilities, links with other centres, capacity, activity and workload. This will take account of performance against national audit data and outcomes.

3. **To review the quality of staffing and team working within the department and to give a view on whether this supports the delivery of high quality and safe care**. Consideration will be given to ways of working, clinical leadership, interactions with members of the wider medical team, to include nursing, and job planning.

4. **To review the quality of clinical governance arrangements currently in place to support and maintain oversight of the service**. Consideration will be given to raising and responding to concerns, audits, clinical incident reporting, and reviews of mortality.

5. **Highlight any new area of concern** that arises during the ISR.

4.2 Approach to this review

The RCP consulted with the British Society for Gastroenterology (BSG), which nominated specialist reviewers. The RCP convened a review team, as set out in Section 4.4.

In advance of the review, the specialist review team received 26 clinical records to review (methodology described in Section 4.3) and documentation provided by the healthcare organisation was examined for the

insights it offered in respect of the terms of reference. The review team held face to face interviews with staff using videoconferencing facilities on 7 and 8 July 2022. Details of these interviews have been included in appendix 2.

The findings contained in this report are outlined in Section 6 and represent a summary of the information gathered by the review team during both the interviews and from the documentation submitted. The findings are organised under the headings of the agreed terms of reference. The information presented sometimes reflects the viewpoints of those individuals being interviewed and where this is the case it will be made clear; it will not necessarily reflect the views of the healthcare organisation, the RCP or its reviewers. The views of the review team are provided in the conclusions, with recommendations made in light of these conclusions.

4.3 Clinical record review methodology

The RCP was provided with clinical records for 26 patients, as detailed in the terms of reference (Section 4.1). Each of the 26 cases were considered independently by two specialist clinical reviewers – see Section 4.4 for details of the review team. Each reviewer used a structured form adapted from the RCP National Mortality Case Record Review (NMCRR) programme[14] to independently examine phases of care that the patient received. These were graded by the reviewers as **1 = very poor care; 2 = poor care; 3 = adequate care; 4 = good care, or 5 = excellent care**. The review team also utilised a grading system[15] developed by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)[16] to give an overall perspective on the quality of care provided. This considers both clinical and organisational care. The overall gradings were as follows: **good practice, room for improvement – clinical, room for improvement – organisational, room for improvement – clinical and organisational, unsatisfactory, insufficient information**.

Having independently reviewed the cases, the review team presented them at two meetings, held using videoconferencing facilities, on 13 and 15 June 2022. The meeting was chaired by the medical director for IRs and supported by an RCP review manager. Each case was considered in turn, the specialist reviewers presented their views, followed by a 'confirm and challenge' discussion to agree the grading of phases of care and the overall care. In making judgements about the overall care provided to the patient, the review team considered national good practice and guidelines.

4.4 Invited review team

Name	Role
[*Name redacted*]	Medical director and chair of invited reviews
[*Name redacted*]	Consultant gastroenterologist, Airedale NHS Foundation Trust
[*Name redacted*]	Consultant pancreaticobiliary physician, The Newcastle upon Tyne Hospitals NHS Foundation Trust
[*Name redacted*]	Nurse consultant in gastroenterology, London Northwest Healthcare NHS Trust
[*Name redacted*]	Lay reviewer and occupational psychologist (interviews only)
[*Name redacted*]	Review manager

5 Description of the service

The RCP Joint Advisory Group on GI Endoscopy (JAG) report of an assessment of the Trust's endoscopy service conducted on 16 July 2021, detailed that the service had not met the accreditation standards and the award of accreditation was deferred for up to six months. This report described the service as follows:

> *'The Rotherham Endoscopy Department is purpose built and operates from 8am to 6pm Monday-Friday and Sunday. The service routinely sees 10,000 patients per year. The main unit offers five treatment rooms and provides a diagnostic, screening and therapeutic service for patients, additionally, they also host other diagnostic services for non-GI patients. This is an exceptionally busy service that is constrained by multiple aspects of the infrastructure. The unit design and decoration is in need of urgent updates to support an improved experience for patients. There are a number of aspects of clinical practice that need to improve which are detailed in this report. The ERCP service is most at risk, and we have asked for an external review. We have also proposed some external support to ensure that endoscopist upskilling is commissioned. We commend the work of the team to improve waits for patients and this demonstrates an incredible effort from all involved. We will continue to work closely with the team to support them during the deferral period and will arrange a call at 3 months to review progress against the service action plan.'*

The JAG report stated:

> *'The ERCP and stent service remains an area of clinical concern due to the service being delivered by a single-handed operator. It has been noted that there have been 5 deaths within 30 days of ERCP and 4 cases of readmissions out of a total of 147 cases during the last audit period. Currently, the service is suspended due to ongoing investigations of clinical incidents. There must be an invited external review of the ERCP service to establish its safety and identify a long-term sustainable delivery plan. Evidence of external review and recommendations to Clinical Lead Assessor.'*

This invited review arose from the JAG assessment.

6 Findings

6.1 Terms of reference 1 – Clinical record review

To undertake a clinical review of 26 case records of patients who received ERCP between July 2019 to July 2021, to include:

- 13 index cases (to include patients who died and any others with significant complications)
- 13 random cases (every 5th case from the time period chosen)

6.1.1 Overall rating for quality of care

Whilst case RCP21 (an index case) had been coded as having an ERCP, the procedure had not gone ahead. This case was therefore excluded from the clinical case record review.

The review team's overall ratings for the quality of care provided in the remaining 25 cases were as follows (a full breakdown of gradings by phase of care and overall can be found in Appendix 3):

> 7 were graded "room for improvement" for clinical reasons
> 18 were graded "unsatisfactory"
> 0 were graded "good practice", "room for improvement" for organisational reasons, or "room for improvement" for both clinical and organisational reasons

11 of the 12 index cases reviewed were found to be unsatisfactory. These index cases included patients who had died following an ERCP and another patient who suffered significant complications. The unsatisfactory grading reflected that several aspects of clinical care were well below what the review team would expect. Only one of the index cases (RCP24) received a different grading, which was room for improvement for clinical reasons.

Seven of the 13 cases selected randomly were found to be unsatisfactory. The remaining six were graded room for improvement for clinical reasons. It is notable that none of the cases selected randomly were found to constitute good practice – a standard that the review team would accept from themselves, their trainees, and their institution. No organisational issues were identified from review of the clinical records.

Themes arising from cases graded room for improvement

Cases graded room for improvement for clinical reasons included concerns regarding consent and sharing information with patients about the quantified risks associated with ERCP, including the risk of death, or the timing of consent (RCP1, RCP2, RCP5, RCP7, RCP10, RCP13). This grading sometimes reflected the opinion of the review team that the incorrect stent had been used for the ERCP procedure (RCP1, RCP10), that the levels of sedation had been high (RCP13, RCP24), and that the ERCP had been incomplete and there was no evidence that this was discussed with the patient or clinical colleagues or followed up in clinic (RCP5). A lack of transparency in explaining the outcome of the ERCP was a recurring theme across many of the cases. For some cases graded room for improvement for clinical reasons, the review team emphasised that care provided on the surgical ward prior to the ERCP, or after the procedure, was of a high standard and that concerns focused upon the ERCP (RCP2). These issues are explored in further detail in sections 6.1.2 to 6.1.9.

Themes arising from cases graded unsatisfactory

Cases were graded unsatisfactory for several reasons. This included where the clinical indication for ERCP was not evident to the review team (RCP3) or where ERCP was performed on patients whose ability to provide informed consent was in question (RCP16, RCP23). This grading often reflected serious complications following ERCP procedures and the response to these, or lack thereof, by the clinical

endoscopist who performed the ERCP. These complications included perforation (RCP8, RCP25, RCP26), bleeding (RCP20, RCP22) and pancreatitis (RCP11), which in some cases led to death of the patient (RCP14, RCP19). One patient was in severe pain after their procedure, and it was not evident from the records that the clinical endoscopist was responsive to the patient's condition or communicated with colleagues regarding a potential complication (RCP9).

For several cases, the review team identified concerns that important aspects of the patient's medical history, such as having a permanent pacemaker, abnormal clotting or deranged (abnormal) blood results, were not actively managed before or during the ERCP procedure, therefore increasing the risk of complications for these patients (RCP17, RCP18, RCP19, RCP20, RCP23). For example, case RCP23 concerned a patient who was coagulopathic (i.e., the patient's ability to coagulate (form clots) was impaired). The procedure involved sphincterotomy, which carries a risk of bleeding after the procedure. This patient died following ERCP, although the cause did not appear directly related to the ERCP. The review team considered this to have been a near miss incident (an event not causing harm, but with the potential to cause injury or ill health), given the high risk of bleeding. Case RCP19 concerned a patient with an increased risk of pancreatitis and the review team was unable to identify documentation to show that this risk was managed by using recommended prophylaxis; this patient died from PEP (COVID-19 was a secondary cause of death).

A recurring theme was that the clinical endoscopist used levels of sedation for ERCP procedures that the review team considered to have been excessive (RCP3, RCP6, RCP9, RCP15). This was particularly concerning given that many patients in the cohort were elderly and frail.

These themes are explored further in the sections that follow.

6.1.2 Assessment of the patient and decision to arrange ERCP

The review team was asked to consider evidence relating to the assessment of the patient and the decision to arrange ERCP. The ratings were as follows:

- 1 case was rated excellent care
- 5 cases were rated good care
- 9 cases were rated adequate
- 7 cases were rated poor care
- 3 cases were rated very poor care

Across the cases, the clinical endoscopist who undertook the ERCP in these cases did not appear to have any involvement in assessment of the patient's suitability for the procedure. As such, the gradings given in this section often apply to assessment of the patient on the wards by other clinicians. However, the review team articulated an expectation that the clinical endoscopist undertaking the ERCP would additionally consider the patient's suitability for the procedure on the day.

Good or adequate patient assessment

One case, RCP2, was graded excellent care under this heading, reflecting that the patient was assessed as having obstructive jaundice, with a possible mass, which provided adequate clinical indication for the ERCP procedure. Discussions on the ward involving surgeons and a clinical nurse specialist were well documented. Cases graded good care under this heading similarly reflected that the assessment was

appropriate, and the review team could comprehend the clinical justification for ERCP, with appropriate use of investigative tests, such as ultrasound, CT[xii] and MRCP[xiii] (RCP9, RCP10, RCP19, RCP22, RCP26).

Where cases were graded adequate for this phase of care, the review team believed that the decision to proceed with ERCP was reasonable, however the decision-making was not always well documented and sometimes additional investigatory tests would have been helpful (RCP1, RCP5, RCP6, RCP8, RCP11, RCP15).

Lack of documented discussion

Gradings of poor care for assessment tended to reflect the absence of sufficient documented discussion of the need for ERCP. For example, one patient (RCP14), who developed pancreatitis the day after having an ERCP and died shortly afterwards, was admitted with suspected obstructive jaundice, however the review team believed that the patient was only mildly jaundiced and that other treatment options (such as surgical resection) could have been explored as a first treatment. A Datix was completed by intensive care staff that the patient was not thought to have needed an ERCP as an emergency.

Case RCP16 concerned a patient with a diagnosis of pancreatic cancer, who had multiple comorbidities and was admitted with confusion, agitation, and jaundice. There was evidence of some multidisciplinary discussion of the patient, involving a palliative care doctor and a surgeon on the ward, and it was felt that a palliative stent would be beneficial. However, the patient was noted to have confusion and the patient's wife was concerned regarding the risks of the procedure. It was not evident whether the clinical endoscopist played any role in discussing the patient's suitability for ERCP. The review team concluded that the assessment of this patient and the decision to arrange ERCP was poor care.

Case RCP18 concerned a patient admitted with jaundice and abdominal pain. There was multidisciplinary team (MDT) discussion of this patient, and the plan was for a biliary stent. However, the patient was taking warfarin[xiv] and the clinical endoscopist was noted as having been made aware of this and was content to proceed with the ERCP without undertaking an INR[xv]. The review team considered this to have been poor care as the patient could have been at risk of bleeding issues during the ERCP and should have been optimised before the procedure. Further, it was unclear whether the patient had ongoing symptoms, and the review team considered that the MDT should have recommended a biliary stent only if the patient's symptoms required this.

Insufficient clinical indications for ERCP

For case RCP24, ERCP was recommended based solely on ultrasounds; the review team could not identify evidence that an MRCP or other radiological investigation was undertaken to confirm that an ERCP was indicated. For RCP25, the ERCP report completed by the clinical endoscopist indicated that 'abnormal enzymes' had been the indication for ERCP, when the proper indication was stones in the bile duct (reflecting the nature of the ERCP procedure that was undertaken).

Case RCP3 concerned a patient identified as having a stone in the gallbladder (not in the bile duct as detailed in the clinical record), which had remained unchanged over two years. The patient's liver function

[xii] Computerised tomography scan https://www.nhs.uk/conditions/ct-scan/

[xiii] Magnetic resonance cholangiopancreatography (MRCP) is a type of magnetic resonance imaging used to diagnose problems of the bile and pancreatic ducts.

[xiv] Warfarin is an anticoagulant used to prevent blood clots. The most common side effect of warfarin is bleeding more easily than normal, and patients require a blood test every 12 weeks to check that they are taking the correct dose of warfarin (the blood test is called the internal normalised ration (INR)).

[xv] INR is a blood test to measure how long it takes the blood to clot.

tests were normal, and the review team could not identify the clinical indications for ERCP in this patient and believed the procedure was therefore inappropriate.

In case RCP12, the decision to undertake an ERCP in [*mm yyyy*] was appropriate, however the patient was scheduled for stent removal four to six months' later and the work-up for this second ERCP ([*mm yyyy*]) was poor. The second ERCP took place, only to find that the previous metal stent had migrated and therefore removal was not needed. The review team observed that the requirement for a second ERCP could have been established by checking whether the stent was still in place. The endoscopist could have requested an x-ray or ultrasound or checked on the stent using fluoroscopy imaging. These steps would have avoided needlessly exposing the patient to the risks associated with ERCP.

Insufficient consideration of risks

Case RCP17 was graded very poor care under assessment. This case concerned a patient who had a permanent pacemaker, who was admitted with acute low sodium levels (such that endocrinologists were involved in the patient's care), was taking Apixaban (an anti-coagulation medicine to prevent blood clots), and who had several comorbidities that caused disability (performance status 3[xvi]; ASA IV[xvii]). The review team could not identify any documented discussion by the clinical endoscopist of the patient's low sodium levels, which the review team believed should have prevented the ERCP from proceeding. The records indicated that the nursing team asked the clinical endoscopist whether a pacemaker form should be completed and the endoscopist was said to have responded that this was not necessary. The ERCP involved sphincterotomy. The electric current used in the sphincterotomy may have caused the pacemaker to detect incorrectly that the patient had gone into ventricular fibrillation (VF). The proper protocol would have been to complete the pacemaker form, so that arrangements could be made for the pacemaker to be switched off during the ERCP and turned on again afterwards. This patient arrested a week after the ERCP and died soon afterwards.

Case RCP23 was graded very poor care as the patient was not optimised before an ERCP was undertaken. There seemed to be a hurry to undertake ERCP in this elderly patient, who had an extensive cardiac history and multiple comorbidities. The clinical endoscopist proceeded with ERCP whilst the patient was coagulopathic, and the review team believed the patient's abnormal clotting should have been addressed before the decision was made to proceed with ERCP. The procedure would have been reasonable to undertake if the patient had been optimised first.

Case RCP20 was an example of a frail elderly patient, who had a high risk of bleeding and abnormal blood tests. The hospital's haematology team provided good advice regarding management of the patient's medication; however, the review team believed the plan for ERCP involving sphincterotomy was too aggressive in this patient at that time.

6.1.3 Consenting the patient for ERCP and information sharing regarding risks

The review team was asked to consider evidence relating to consenting the patient for ERCP. The ratings were as follows:

- 0 cases were rated excellent care
- 2 cases were rated good care
- 2 cases were rated adequate

[xvi] World Health Organisation performance status 3 = Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours

[xvii] ASA IV = A patient with severe systemic disease that is a constant threat to life https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system

- 16 cases were rated poor care
- 5 cases were rated very poor care

The General Medical Council (GMC) has published ethical guidance specific to decision making and consent, which came into effect in November 2020.[17] The consent forms completed for the patients in this cohort were sometimes completed by consultant surgeons on the ward. However, most often, the consent forms were completed by the clinical endoscopist, a nurse consultant, making *The Code*[xviii], setting out the Nursing and Midwifery Council's professional standards for nurses, midwives and nursing associates, of relevance. *The Code* includes the following statement at paragraph 4.2: *'make sure that you get properly informed consent and document it before carrying out any action'*.[18]

Consent by consultant surgeons was of a higher standard

In the cases rated good or adequate care for consenting the patient for ERCP (RCP9, RCP11, RCP14, RCP24), this grading reflected that consenting was led by a consultant on the surgical ward and covered the risks associated with ERCP, with exception of the risk of death.

Failure to document patient-specific risks

Gradings of poor or very poor care with respect to consent tended to reflect a lack of documented meaningful discussion with the patient regarding the risks of the ERCP procedure specific to the individual patient, as detailed in the GMC's guidance on consent.[xix] [xx] [xxi] The clinical endoscopist's handwriting was often difficult to decipher, making it hard for the review team to establish the exact risks highlighted. The risks commonly detailed were bleeding, perforation, discomfort and pancreatitis. The likelihood of risks occurring, such as bleeding or PEP, was not detailed, either as a percentage standardised to the general population or specific to the patient (RCP1, RCP2, RCP5, RCP6, RCP18, RCP19, RCP22, RCP25, RCP26).

For example, case RCP18 concerned a patient admitted with jaundice and abdominal pain and a question was raised over whether the patient had a mass in the pancreas or pancreatitis. This patient was taking warfarin, as mentioned in section 6.1.2, and the clinical endoscopist was recorded by nursing staff as happy to proceed with the ERCP without checking the INR. The risks specific to this patient, including an increased risk of bleeding, were not documented.

Case RCP6 concerned a patient who underwent three ERCP procedures. Consent for the first ERCP was taken by a junior doctor (SHO) on the ward; the review team considered this to have been inadequate given the risks associated with the procedure. The consent forms for the subsequent ERCPs made no mention of the risk likelihood (e.g., percentage risk) of PEP or patient specific factors.

RCP20 was graded very poor care in terms of consent, as it was not documented whether the risks specific to this patient in terms of bleeding were discussed. This patient had abnormal blood tests and clotting issues, with an INR of 3.8 – a value higher than 1.5 would lead to caution in most ERCP practitioners and prevent the ability to perform a sphincterotomy. The consent form indicated the risk of bleeding, but not the likelihood of this happening and it did not mention the risk of death or what might happen if

[xviii] The Code became effective from March 2015, updated 2018

[xix] The seven principles of decision making and consent identified by the GMC include: *Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient*.

[xx] GMC guidance on consent states: *'You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.'*

[xxi] GMC guidance on consent states that doctors should usually include information on the following: *'The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring.'*

complications arose. This patient died of a post ERCP GI bleed four days after the procedure.

Consent in patients with documented confusion

A common theme arising from cases graded very poor care in terms of consent related to the patient's capacity to provide informed consent. For example, case RCP15 concerned a patient who was documented as being confused and frail. This raised questions over their ability to provide informed consent. An assessment of capacity would have been required and if the patient was judged not to have sufficient capacity, then a consent form 4 should have been completed following a best interests test. It was not evident that these steps were undertaken. The review team could not identify any documented discussion with the patient's family regarding the risks of ERCP.

Similarly, case RCP23 concerned a patient who had a Montreal cognitive assessment score of 13 out of 30 (a score of 26 and above is considered normal), which led the review team to question whether the patient had capacity to give informed consent and whether consent form 4[xxii] should have been used. The consent form did not appear to have been signed by the patient (the space where the signature should be entered was obscured, however there was no date entry).

Consent forms 1[xxiii] and 4 were used in case RCP16, which concerned a patient admitted with confusion, agitation and jaundice. Consent form 4 was completed by the clinical endoscopist but the second signature was left blank. The review team considered it to be good practice for the consultant in charge of the patient's care to have counter-signed the consent form 4. The records indicated that the patient's wife was keen to discuss the risks associated with the procedure. Nursing staff approached the clinical endoscopist, who was scoping at the time, however the endoscopist indicated on consent form 4 that they had discussed the procedure with the patient's wife. The review team would have expected the clinical endoscopist to have written a detailed entry in the clinical records documenting discussion with the patient's wife regarding her husband's clinical situation.

Case RCP17 was graded very poor care, as the patient's acute low sodium levels were likely to have caused confusion in the patient, which would have impacted their normal cognition and their capacity to give informed consent. It was not evident that a capacity assessment was undertaken and consent form 1 was used, when consent form 4 should have been considered. This patient also had a permanent pacemaker and the clinical endoscopist declined a nursing request for a pacemaker form to be completed. It was not evident that the risks associated with the pacemaker during the sphincterotomy were discussed with the patient.

Other consent issues

Consent was often taken in the endoscopy suite, immediately prior to the ERCP (RCP10, RCP13, RCP22), and the review team was concerned this could create pressure on the patient to consent to the procedure. In case RCP7, the clinical endoscopist had been asked to consent the patient for ERCP on 8 July. Three days later, a junior doctor noted that consent had not been taken. The ERCP procedure took place on 12 July. In case RCP12, the clinical endoscopist partially completed a consent form.

Some consent forms were not dated (RCP2, RCP3, RCP4, RCP5, RCP8, RCP19). For example, in case RCP3, the consent form was not dated, some of the handwritten risks were difficult to decipher and abnormal liver function tests were documented as the indication for the ERCP, when these tests were normal.

None of the consent forms detailed what actions may be required if a complication occurred.

[xxii] Consent form 4 is used for adults who lack the capacity to consent to investigation or treatment.
[xxiii] Consent form 1 captures a patient's agreement to investigation or treatment.

6.1.4 Undertaking the ERCP procedure

The review team was asked to consider evidence relating to undertaking the ERCP procedure. The ratings were as follows:

- 0 cases were rated good or excellent care
- 3 cases were rated adequate
- 13 cases were rated poor care
- 9 cases were rated very poor care

'Adequate care' the highest grading

Cases were most likely to be graded poor or very poor care in terms of undertaking the ERCP. Three cases were graded adequate care under this heading, reflecting that the procedure took place without problems, however some issues or omissions were identified.

For case RCP7, the ERCP proceeded uneventfully and the ERCP report contained sufficient detail to understand the approach taken to the procedure. However, the clinical endoscopist did not reference two previous ERCPs this patient had, which was relevant previous history.

For case RCP2, the ERCP report was difficult to follow – the report indicated that the procedure did not enter the common bile duct, when clearly this is what happened. The report also said that pathology samples were not taken and yet the management plan and aftercare records indicated that samples were taken. The review team questioned whether these inconsistencies reflected the ERCP reporting software.

For case RCP13, the ERCP was performed successfully and rapidly (the patient had previously had a failed ERCP at another centre), however the review team raised concern regarding the amount of sedation used – 7mg of midazolam and 100mcg of fentanyl. This led the review team to grade this phase of care as adequate, instead of good care.

Inadequate ERCP reports

The ERCP reports often contained inconsistent information – a recurring finding was for the ERCP report to state that the common bile duct was not cannulated and for information on the following sheet to contradict this (e.g., RCP3, RCP4). The review team was unfamiliar with the software used to generate the ERCP reports and questioned whether this software might have been the cause of these inaccuracies.

Concerns were raised by the review team that the ERCP reports lacked detail explaining the approach taken and the rationale for this. Examples included stating that a lesion was identified and yet not describing this; failing to detail whether it was the first ERCP; or how difficult the cannulation was (RCP1). Such details are important to understanding the risk of post-procedural complications. For example, the risk of PEP is increased where the endoscopist enters the pancreatic duct with the cannula, or where too much contrast is used.

Sometimes the procedural approach was badly described, making it difficult for the review team to understand the nature of the procedure. For example, in case RCP4 the clinical endoscopist described placing a fully covered metal stent via a T-tube (a draining tube placed in the common bile duct after common bile duct (CBD) exploration). The review team suspected that the stent must have been inserted alongside the T-tube and not down it, as recorded.

For cases RCP9, RCP14, RCP22 and RCP23, the ERCP reports by the clinical endoscopist did not detail a sphincterotomy and yet the nursing notes indicated that this was done. This inconsistency had profound implications for the ongoing care in case RCP22 – the patient become unwell after the procedure and was

diagnosed with post-ERCP gastritis and given intravenous administration of a proton pump inhibitor (PPI) to suppress gastric acid. Four days later the patient was found dead. If the ERCP report had stated that a sphincterotomy had taken place it may have influenced medical staff to undertake a repeat endoscopy, which would have identified bleeding. This was graded very poor care.

For case RCP23, some of the six images indicated that the clinical endoscopist instrumented the pancreatic duct several times, and yet this was not documented in the ERCP report. This would have increased the risk of pancreatitis in this patient. The nursing records noted that sphincterotomy was performed, but this was not mentioned by the clinical endoscopist in the ERCP report. This increased the risk of bleeding in this patient, who was coagulopathic and had grossly abnormal clotting around the time of the ERCP. This was a high-risk case and the opportunity to reduce the risk was not taken.

Case RCP26 was another example where the patient's increased risk was not actively managed. This patient was fit and healthy, however they were noted to be hypotensive (low blood pressure) before the ERCP. The clinical endoscopist was made aware but was recorded as not being concerned. Images taken during the procedure indicated a shadow that the review team described as a 'sail sign', possibly indicating air under the diaphragm and liver. The clinical endoscopist did not refer to this sign or the shadow shown on the images. This was graded very poor care.

Uncertainty over multiple ERCPs

Some ERCP reports failed to reference that a previous ERCP had taken place or make clear how the subsequent ERCP sought to build on previous therapeutic approaches (RCP4, RCP7). The review team observed that there was often no x-ray image provided to check completion of the procedure (RCP3, RCP18). This was important as there were several instances where the ERCP appeared to have been incomplete in terms of removal of stones. On occasion, the review team found the clinical endoscopist's report to have been misleading in stating that an ERCP had been completed successfully when this appeared not to have been the case. For example, for case RCP5 the clinical endoscopist recorded that an ERCP in [*mm yyyy*] had been successful at clearing stones from the common bile duct. However, an ultrasound a fortnight later showed two stones remained in situ. A further ERCP took place [*weeks later*], the clinical endoscopist reported extracted fragments and a large amount of reflux food residue, despite the ultrasound identifying two stones. The review team questioned whether the endoscopist was trying to justify having reported that the first ERCP had been successful in clearing the stones, when this appeared not to have been the case.

Case RCP6 concerned a patient who had three ERCP procedures to remove a stone in the common bile duct. The stone could not be removed during the first ERCP. The patient developed pancreatitis following the second ERCP and had to wait a further six months before a third ERCP removed the stone. The patient had further pancreatitis and two months later, received a surgical procedure to remove the gall bladder. The review team could not understand why purastat (an agent to manage bleeding during endoscopy) was used in this patient during the third ERCP, which indicated a problem during the procedure. The ERCP report lacked detail to understand what had taken place.

Lack of prophylaxis

There was no documentation across the cases to indicate that rectal NSAIDs were used as a prophylactic therapy to reduce the risk of pancreatitis in any patients, including patients who were at high risk of pancreatitis (RCP1, RCP19).

Case RCP19 concerned a patient who died from PEP and covid. The patient had an increased risk of pancreatitis due to a previous admission with epigastric pain, where pancreatitis was recorded as having been suspected. An image seen by the review team suggested that the patient's bile duct was slender, which further increased the risk of pancreatitis. It was not evident that the clinical endoscopist

administered prophylaxis to manage this increased risk. The image indicated that the clinical endoscopist had not fully inserted the wire into the bile duct before inserting dye, which would also increase the risk of pancreatitis.

Sedation

An ERCP often requires more sedation than for other endoscopic procedures. However, a recurring theme was the amount of sedative the clinical endoscopist used for ERCP (RCP1, RCP9, RCP12, RCP15, RCP24). For example, in case RCP24, relating to a female patient [*age redacted*], the clinical endoscopist administered 8.5mg of midazolam and 150mcg of fentanyl, which the review team considered excessive and almost amounted to deep sedation. Despite the high level of sedation, the patient in case RCP24 was noted to have been awake during the procedure and could recall what happened (referring to stents 'snapping'). The patient was said to have become distressed and tried to get up during the procedure. The patient later declined a further ERCP. In case RCP9, relating to a female patient [*age redacted*], the clinical endoscopist administered 9mg of midazolam and 175mcg fentanyl. In case RCP12, the clinical endoscopist used 8mg of midazolam and 75mcg of fentanyl in a female patient [*age redacted*] ([*mm yyyy*]), who was noted to be receiving an intravenous morphine pump prior to the procedure. A nursing entry indicated that the endoscopist was *'not overly concerned'* about this. However, the review team believed there was a risk of respiratory arrest in this patient.

Some older patients also received excessive levels of sedation. Case RCP15 concerned an elderly and frail patient who was documented as being confused. The patient was given 6.5mg midazolam and 100mcg fentanyl. The patient was noted as being agitated at the start of the procedure and further sedation was given. The three images seen by the review team indicated that the patient was unable to keep still during the procedure. There was no documentation to indicate that consideration was given to abandoning the procedure.

Some of the sedation levels were thought to have been recorded inaccurately. For example, in case RCP3 it was recorded that 40mg of midazolam had been administered to the patient. The review team assumed this was an error, as it would have been a fatal amount, and that 4mg should in fact have been recorded.

ERCP technique and approach

In several cases, the review team expressed concern that a partially covered metal stent was used when a fully covered or plastic stent would have been more suitable (RCP1, RCP4, RCP10). In case RCP10, the patient was stented with a partially covered stent before histology results had been obtained. The significance of this is that a partially covered stent is not removable and was placed in this patient who might have required a repeat procedure or, if malignancy was detected, for the stent to be removed. Similarly, in case RCP22, the review team was critical of the clinical endoscopist's decision to use a partially covered stent in a patient without a histological diagnosis. The clinical endoscopist documented taking biopsies from the mid common bile duct, however the biopsy report referred to the sample collected representing 'mucosal villi', which would indicate that the samples contained duodenal tissue.

In case RCP12, the clinical endoscopist used a fully covered metal stent, which the review team considered unnecessary as the plan was to remove the stent at a second procedure (making a plastic stent a more suitable option). At the second ERCP to remove the stent, the clinical endoscopist discovered that the stent had migrated. The procedure was unnecessary, and the patient should not have been cannulated; the patient should have been screened to check the placing of the stent before undertaking ERCP.

Case RCP14 was graded very poor care under this heading. The review team questioned the type, size and positioning of the stent used for this ERCP (an 8cm partially covered stent was used and the review team believed an uncovered or plastic stent should have been used to support drainage). The ERCP report lacked detail: nursing records indicated that a sphincterotomy was performed and a metal stent was inserted and

to see the ERCP report for details, but these details were not contained in the report. The review team observed from the images that the pancreatic duct had been filled with contrast dye. This would require a large volume of dye, which would increase the risk of pancreatitis. Prophylaxis would be needed to manage this risk and it was not evident this happened. The patient developed acute pancreatitis following the ERCP and died of multi-organ failure 20 days later.

Case RCP16 also concerned a patient who was confused, such that they were unable to give informed consent to the ERCP. The patient was given 6mg of midazolam and 150mcg fentanyl. The ERCP had to be abandoned as the clinical endoscopist noted they were unable to get into the common bile duct and could not place a stent to relieve the patient's jaundice. The reason why the endoscopist was unable to enter the bile duct or place a stent was not explained. The images taken were of very poor quality. The review team concluded that this had been very poor care.

The review team was critical of the clinical endoscopist's decision to undertake sphincterotomy in a patient with a permanent pacemaker (RCP17), without taking steps to turn off the pacemaker during the procedure. Every unit should have a policy on how to manage patients with a permanent pacemaker – reference by nursing staff to a pacemaker form indicated that the hospital had a policy but the clinical endoscopist decided this did not need to be acted upon.

Case RCP20 was graded very poor care as the images taken during the ERCP compounded concerns regarding this patient's frailty and deranged bloods (increasing the risk of complications), by indicating that the patient was too unfit to get on their front for the procedure (as is normally required). The clinical endoscopist performed a sphincterotomy, which the review team believed this patient was too unwell for. The patient had a fatal GI bleed four days later.

Lack of transparency

In case RCP25, the patient was later found to have perforation of the duodenum. Perforation was a risk with the technique used for this procedure, which involved sphincterotomy, balloon trawl and removal of stones. nursing records indicated that the clinical endoscopist undertook a pre-cut (a free hand cut) using a needle knife, which increases the risk of perforation; the clinical endoscopist's record of the procedure made no mention of a pre-cut. The review team questioned a lack of transparency by the clinical endoscopist regarding the approach taken during the procedure, which undermined the ability of staff to proactively manage known risks and respond to post procedural complications.

Another case raised questions regarding transparency and led the review team to question whether the clinical endoscopist was demonstrating a lack of honesty in reporting the ERCP. Case RCP8 concerned a patient who needed a repeat ERCP due to the size of two stones. Records completed by a member of the nursing staff detailed that a hole appeared in the common bile duct, indicating a perforation. The clinical endoscopist placed a plastic stent. No adverse event was recorded in the ERCP report, which gave the clinical endoscopist's printed name but was unsigned. The patient was later readmitted to hospital with a perforation. The review team questioned whether the clinical endoscopist recognised during the procedure that there was a perforation or failed to observe the perforation and yet the nurse in the room did. The review team graded this very poor care.

Supervision of trainees

In case RCP11, it appeared that the clinical endoscopist supervised a trainee to undertake the ERCP procedure. The ERCP documented the successful placement of a stent within the bile duct yet following an emergency readmission several hours after the procedure, the stent was discovered within the duodenum. The stent appeared to have migrated into the duodenum. The review team considered it to have been poor care for a stent to migrate so soon after the procedure and questioned the arrangements in place for supervision by the clinical endoscopist.

6.1.5 Recovery following the ERCP

The review team was asked to consider evidence relating to patient recovery following the ERCP. The ratings were as follows:

- 0 cases were rated excellent care
- 5 cases were rated good care
- 5 cases were rated adequate
- 8 cases were rated poor care
- 7 cases were rated very poor care

For several cases, no concerns were identified regarding recovery following ERCP (RCP1, RCP2, RCP3, RCP4, RCP10). Nursing recovery documentation was observed to be good, supported by a high standard of care on the wards. Other cases were graded adequate (RCP5, RCP6, RCP13, RCP20, RCP23), including case RCP6 concerning a patient who had two episodes of PEP.

Patient discharged too early

Where cases were graded poor care (RCP11, RCP12, RCP24) or very poor care (RCP8, RCP19, RCP26) under this heading, it often reflected concerns that the patient was discharged too quickly after the ERCP. For example, in case RCP8, the patient was discharged home at 13:30 and reattended the hospital at 18:00 with vomiting. The patient should not have been discharged so soon, particularly given an entry made by a nurse present during the ERCP documenting a hole in the common bile duct. This should have made staff alert to the possibility of perforation. Similarly, in case RCP17, the patient had a high NEWS[xxiv] which was discussed with the clinical endoscopist, who was recorded as planning to review the patient. It was not evident that the endoscopist reviewed the patient in recovery and they were transferred back to the ward. The patient arrested on the ward and died.

The patient in case RCP26 was discharged within two hours of the ERCP; having left the endoscopy room at 11:00, the patient called the hospital at 13:07 in pain. The clinical endoscopist advised the patient to take their own analgesia at home. The review team found that the patient should have been invited back to hospital to have a CT scan, made nil by mouth, and given intravenous antibiotics. This patient was readmitted the day following ERCP, deteriorated further and died of sepsis a month later.

The patient in case RCP19 deteriorated rapidly post discharge home. The ERCP took place at 10:00. At 11:15, an entry indicated that the patient was off the trolley, sat in a chair and alert. At 15:00 the patient contacted the hospital with pain and was readmitted at 17:00.

The review team observed that other centres monitor patients post ERCP for at least four hours. In case RCP11, the patient recovered well and appeared to have been discharged by a student nurse approximately an hour after the procedure. It was not evident that the patient was expected to wait in recovery for a set period. In case RCP24, the patient received heavy sedation during the ERCP (8.5mg of midazolam and 150mcg of fentanyl), which took place between 09:32 and 10:36. At 13:45 the patient went home. It was not documented that the clinical endoscopist reviewed the patient prior to discharge.

In case RCP12, the patient was discharged home within three hours of the second procedure ([*mm yyyy*]) and within 1 hour of having a NEWS of 7 (high risk).

[xxiv] National Early Warning Score https://www.england.nhs.uk/ourwork/clinical-policy/sepsis/nationalearlywarningscore/

The review team observed that the clinical endoscopist often wrote *'treat as gas'* (i.e., treat as gastroscopy) on the post procedure form as an instruction to nursing staff. This suggested they considered ERCP procedures had a risk profile like gastroscopy, which is not the case, and implied a level of disregard for the potential seriousness of events following ERCP. The review team was critical of this approach as it failed to reflect the specific and distinct nature of ERCP.

Poor decision-making

In several cases, decision-making around recovery was found to be poor (RCP7, RCP12, RCP14, RCP15, RCP16, RCP18) or very poor (RCP22, RCP25). In case RCP7, the recovery nurse asked the clinical endoscopist to review the patient after the patient's NEWS increased to 8 (high risk). The clinical endoscopist reviewed the patient and was not overly concerned, however the nurse remained concerned and informed the sister and the rest of the recovery team, before escalating the patient to the critical care team for advice. This suggested a lack of confidence in the assessment by the clinical endoscopist.

In case RCP14, the immediate post recovery care was poor. The patient was noted to have pain in recovery and yet was transferred back to the ward. The review team believed this was an indication that the patient was developing pancreatitis and they should have been given more intravenous fluid and proper pain relief. The patient developed severe pancreatitis and renal impairment and spent 19 days in intensive care before dying of multi-organ failure. Intensive care was observed as being exemplary.

In case RCP15, there was a lack of detail in the ERCP report to direct recovery, such as post procedure observations and the patient's nil by mouth status. In case RCP16, the patient returned to the ward still very sleepy and without evidence of an assessment of respiratory compromise. In case RCP18, the patient's haemoglobin dropped; this patient was taking warfarin and the clinical endoscopist had not sought to understand their INR on the day of the procedure.

Case RCP22 was graded very poor care for recovery because whilst the initial recovery was appropriate, the patient began to deteriorate and vomit brown material. The review team criticised the decision to treat the patient as if they had post ERCP gastritis and believed the patient should have been offered an endoscopy to establish the source of internal bleeding. The patient was found collapsed and dead four days after the ERCP.

Case RCP25 was graded very poor for recovery because when the patient developed pain immediately after the procedure, the clinical endoscopist advised that it was normal pain and to give diclofenac and discharge the patient. The recovery nurse decided to continue to monitor the patient in line with the matron's instructions and requested review from a surgical registrar. The gradings in this case reflect the decision making by the clinical endoscopist, not the recovery nurse who demonstrated a high standard of care in acting in the patient's best interest.

Case RCP9 was graded very poor care for recovery as the clinical endoscopist failed to demonstrate any inquiry into the severe pain the patient experienced after the procedure or investigate whether this could be a complication of the sphincterotomy performed during the ERCP. Once the patient was transferred back to the ward, staff there managed effectively to control the pain.

6.1.6 Follow up of the patient

The review team was asked to consider evidence relating to follow up of the patient following ERCP. The ratings were as follows:

- 0 cases were rated excellent care
- 3 cases were rated good care

- 4 cases were rated adequate
- 4 cases were rated poor care
- 2 cases were rated very poor care
- For 12 cases it was not applicable to grade this phase of care, as sadly the patient died and therefore follow up was not relevant (RCP13, RCP14, RCP15, RCP16, RCP17, RCP18, RCP19, RCP20, RCP22, RCP23, RCP26) or follow up was undertaken by other clinical departments (oncology and palliative care, in case RCP9).

In three cases, follow up after the ERCP was good (RCP1, RCP2, RCP10); in one case it involved referral to Sheffield Teaching Hospital. In other cases, follow up was harder to identify (RCP3) or considered adequate for the case (RCP7, RCP8, RCP11).

Where cases were graded poor care under this heading, it reflected that follow up was not arranged when it should have been, for example, because the ERCP had been incomplete (RCP5), or follow up was not timely (RCP12, RCP24) or should have involved earlier consideration of surgical options (RCP6, RCP24).

Where cases were graded very poor care under this heading, it reflected:

- that a patient was lost to follow up for five months and the purpose of a second ERCP and approach to stenting was unclear (RCP4)
- a case where the clinical endoscopist said no follow up was required despite the patient showing early signs of complication (RCP25).

6.1.7 Communication with colleagues

The review team was asked to consider evidence relating to communication by the clinical endoscopist with colleagues. The ratings were as follows:

- 0 cases were rated excellent care
- 1 case was rated good care
- 3 cases were rated adequate
- 13 cases were rated poor care
- 8 cases were rated very poor care

Limited evidence of multidisciplinary discussion

The single case graded good care under this heading (RCP10) reflected that MDT discussion took place. The ERCP was timely, for an appropriate reason, and there was documentation to indicate that appropriate discussion took place.

Discussion between clinicians was documented in case RCP1, however it was graded adequate under this heading (and not good care) because this discussion took place after the ERCP. In case RCP2, also graded adequate, the records indicated the involvement of a clinical nurse specialist (CNS) and the records contained a well-documented summary of surgical assessment of the patient for the GP. The grading of adequate for case RCP13 reflected evidence of communication between the clinical endoscopist and a physician at the centre that referred the patient to Rotherham.

There was evidence of MDT discussion in case RCP18, however this patient had several health issues and the review team believed that the MDT should have recommended a biliary stent only if the patient's symptoms required this. The clinical endoscopist went ahead with ERCP without considering the patient's other issues (for example, not taking the patient's INR, despite the fact that they were on warfarin) and the

patient died two days after the procedure. The review team considered this to have been poor care in terms of communication with colleagues.

Absence of communication between clinical endoscopist and colleagues

Cases were most likely to be graded poor care or very poor care under this heading. This reflected that the review team was unable to identify evidence of interactions between the clinical endoscopist and clinical colleagues, or of any MDT input into the decision to undertake ERCP (RCP3, RCP5, RCP15) or after the procedure, including when the patient deteriorated (RCP7, RCP9, RCP12, RCP20).

In case RCP11, the review team was unclear of the position of the person who performed the ERCP under the supervision of the clinical endoscopist; they were assumed to be a trainee. There were no entries in the clinical record to indicate the supervisory arrangements in this instance or whether these had been explained to the patient as part of the consenting process. In case RCP16, there was involvement of an oncologist and palliative care doctor and good documentation of liaison with a hospice team, however it was not evident that the clinical endoscopist participated in any of these discussions, despite being the person taking responsibility for the ERCP. This was also the case for RCP19.

Case RCP17 was graded poor under this heading as the clinical endoscopist appeared to disregard important information communicated by nursing staff relating to a patient's permanent pacemaker. Nursing staff questioned whether a permanent pacemaker form should be completed and the clinical endoscopist was said to be unconcerned for this to happen.

Lack of discussion of alternative options

In case RCP25, the clinical endoscopist decided to bring the patient back for a second ERCP in six months' time, after the first ERCP failed successfully to remove large stones. There was no documented discussion between the clinical endoscopist and colleagues regarding whether surgical options should be considered for this patient, given their age, sex, and the size of their gall bladder stones. In the event, the patient cancelled the second ERCP on the day and pursued surgical options.

Case RCP6 concerned a patient in their 40s, who had one gall stone. The clinical endoscopist undertook three ERCPs to remove the stone and the patient experienced PEP after the second ERCP and was queried to have pancreatitis again after the third procedure. The review team concluded that there should have been discussion with surgeons regarding surgical options after the first ERCP, given the patient's age, sex, and the difficulty experienced at that first ERCP. This was graded very poor care.

Lack of communication undermined management of complications

Case RCP23 was graded poor as the clinical endoscopist had entered minimal information in the ERCP report and did not reference a sphincterotomy that took place, which would have been relevant for colleagues in managing the fatal complications this patient went on to experience. A similar criticism was made in case RCP22, where there was no evidence that the clinical endoscopist discussed the ERCP procedure with colleagues (there was no reference to a sphincterotomy in the ERCP report) or the fatal complication the patient experienced (no repeat endoscopy was done to explore bleeding). This was graded very poor care.

Case RCP8 was graded very poor care under this heading because the clinical endoscopist had not signed the ERCP report and indicated no adverse event, despite a nurse documenting that a hole had appeared in the common bile duct. This raised questions regarding the clinical endoscopist's alertness to an adverse event and interactions with the nurse in the endoscopy suite.

Case RCP14 concerned a patient who developed acute pancreatitis the day after an ERCP. The records indicated that an upper GI MDT was mentioned after the ERCP and after complications occurred. This

patient had a proximal stricture in the bile duct, which was a potentially curable condition and surgical resection, or drainage, might have been better options. This was graded very poor care.

In case RCP25, when the patient developed pain immediately after the ERCP, the clinical endoscopist advised a nurse in recovery that they could prescribe diclofenac and they were happy for the patient to be discharged. The nurse did not follow this advice and continued to monitor the patient in line with instructions from the matron and requested review of the patient by a surgical registrar. The review team praised the actions of the nurse, which contrasted with the very poor care by the clinical endoscopist. There was no documentation to indicate discussion between the clinical endoscopist and colleagues regarding the complication experienced by the patient within a couple of hours of the ERCP. There was documented discussion between intensive care staff and clinicians at Sheffield, but no evidence of involvement by the endoscopist who performed the procedure.

6.1.8 Interactions with patients and their family

The review team was asked to consider evidence relating to interactions by the clinical endoscopist with the patient and family members. The ratings were as follows:

- 0 cases were rated good or excellent care
- 4 cases were rated adequate
- 16 cases were rated poor care
- 5 cases were rated very poor care

Interactions by ward staff

The review team observed good interactions across several cases between ward staff and patients and family members. The same applied to interactions with intensive care staff. Good practice was not identified from the records with respect to the ERCP procedure.

Where cases were graded adequate under this heading it reflected interactions between the patient and other clinical staff, including an upper GI nurse (RCP1), and the ward team (RCP2, RCP10, RCP11). There was no evidence of interactions between the clinical endoscopist and the patient or family members in these cases.

Lack of evidence of interactions by clinical endoscopist

Cases were most likely to be graded poor care, which reflected a lack of evidence to demonstrate interactions between the clinical endoscopist who performed the ERCP and the patient and their family members (RCP3, RCP4, RCP5, RCP6, RCP7, RCP9, RCP12, RCP13, RCP18, RCP19, RCP20, RCP23). For example, in case RCP23 there was well documented discussion on the ward with family members regarding end-of-life care, but no documented interactions with the clinical endoscopist. In several cases, there was no documented communications by the clinical endoscopist when the patient deteriorated, and complications occurred or were a possibility. For example, case RCP20 concerned a patient with a high risk of bleeding, who died from a post ERCP upper GI bleed four days after the procedure. The review team graded this very poor care as there was no documented evidence that the clinical endoscopist spoke to relatives when the patient deteriorated or to indicate that any duty of candour discussion took place.

Lack of evidence of communication after incomplete ERCP

A recurring theme was the absence of documented discussion by the clinical endoscopist with patients after an initial ERCP and before other ERCPs took place. For example, for case RCP5, the first ERCP to remove two stones in the common bile duct was incomplete; the patient returned with symptoms and had to undergo a second ERCP. The clinical endoscopist did not document any discussion with the patient to indicate any explanation provided to the patient regarding the first ERCP or the requirement for a repeat

procedure. The clinical endoscopist undertook three ERCPs on the patient in case RCP6 and did not document discussion with the patient regarding potential surgical solutions or referral to another centre.

In case RCP16, the patient's wife was keen to discuss the ERCP procedure and an attempt was made to contact the clinical endoscopist, however they were scoping at the time. This patient was confused and unable to give informed consent, making discussion with the patient's wife particularly important. It was not clear from the records whether the clinical endoscopist met with the patient's wife, although the wife's concerns regarding the procedure were documented. The patient died within five days of the ERCP, and the review team would have expected well documented discussion with the patient's wife to demonstrate that the best interests of the patient had been fully considered.

For case RCP24, the review team did not identify any documented discussion between the clinical endoscopist and patient before the ERCP, or after the incomplete procedure regarding next steps and other treatment options. The clinical endoscopist recorded that the patient expressed anxiety whilst waiting in the hospital car park for the repeat ERCP and withdrew from having the procedure.

Lack of transparency when complications occurred

Several cases gave rise to concern that the clinical endoscopist had not provided a clear explanation to the patient or family members regarding complications. In some instances, the review team questioned whether the lack of transparency might indicate potential probity issues.

Case RCP8 concerned a patient who suffered a perforation during an ERCP procedure. A nurse present recorded that there was a hole in the common bile duct. The clinical endoscopist did not refer to a hole in the ERCP report. The records documented good ward discussion after the complication, however the records did not indicate any interactions between the clinical endoscopist and the patient or family members regarding the complication. Similarly, case RCP14 concerned a patient who developed acute pancreatitis after an ERCP and died. There was well documented discussion between intensive care staff and the patient's husband, but it was not evident that the clinical endoscopist discussed the procedure and the complication with the patient or their husband. Case RCP22 was another example where the review team was unable to identify evidence to demonstrate discussion by the clinical endoscopist with the patient when they became unwell soon after an ERCP. This was compounded by an omission in the ERCP report completed by the clinical endoscopist that sphincterotomy was performed (a nursing entry recorded that sphincterotomy took place), which increased the risk of bleeding and could have redirected efforts to manage the patient's complications differently. The records did not indicate whether the patient was asked whether they were prepared to be re-scoped to identify internal bleeding.

Two cases were graded very poor care under this heading due to an apparent absence of documented discussion by the clinical endoscopist when complications occurred. Case RCP25, concerned a patient who suffered a duodenal perforation following ERCP. The review team did not identify any documentation to indicate that the clinical endoscopist discussed the complication with the patient. The review team would have expected the individual who undertook the ERCP to have seen the patient to explain what had happened. The absence of evidence to demonstrate this was graded very poor care. Similarly, case RCP26 concerned a patient who experienced pain soon after an ERCP, was advised by the clinical endoscopist to take analgesia at home but deteriorated and was readmitted to hospital. Perforation was suspected and the patient died. The review team did not identify any documentation to indicate that the clinical endoscopist discussed the complication with the patient or the patient's husband, who was documented by other staff as having been very angry. In contrast, documented interactions by intensive care staff were very good.

Concerns regarding capacity

Two cases (RCP15, RCP17) were graded very poor care under this heading as, in both cases, the patients were documented as being confused and yet no capacity assessment was undertaken and there was no evidence of interaction between the clinical endoscopist and these patients before the procedure to establish that the ERCP was in the patients' best interests.

6.1.9 Clinical record keeping

The review team was asked to consider evidence relating to clinical record keeping. The ratings were as follows:

- 0 cases were rated good or excellent care
- 2 cases were rated adequate
- 15 cases were rated poor care
- 8 cases were rated very poor care

Case RCP2 was graded adequate for record keeping. Whilst a high standard of record keeping was observed in the ward notes and for patients admitted to intensive care, deficiencies were identified in the ERCP reporting. The ERCP report contained inconsistencies, for example, stating that the procedure did not involve entering the common bile duct, when clearly this happened, and stating that pathology samples were not taken, when the aftercare notes indicated that samples were taken.

For case RCP13, a grading of adequate reflected that the records enabled the review team to follow each stage of the patient's care.

Cases were most likely to be graded poor care or very poor care. These gradings reflected a range of deficiencies in the case records, including:

- the absence of documents articulating clinical decision making (or who the key decision maker was) regarding a plan for the patient (RCP3, RCP6, RCP26)
- inconsistencies between the ERCP report and other entries in the patient record, including over the levels of sedation used (RCP11) and whether a sphincterotomy had taken place (RCP9, RCP14 and RCP22)
- a lack of transparency regarding the completeness of the procedure (RCP5, RCP19, RCP22, RCP23, RCP24, RCP25) or failure to reflect the actuality of the procedure (RCP8, RCP14, RCP19)
- omissions in the ERCP report (RCP1, RCP15, RCP16, RCP17, RCP18) or reference to previous ERCPs (RCP4, RCP7), or the absence of any documented entry by the clinical endoscopist relating to complications associated with the ERCP (e.g., RCP20).

For example, case RCP14 concerned a patient who developed acute pancreatitis after an ERCP and died. The ERCP report did not reflect the approach taken to the procedure (nursing documentation recorded that a sphincterotomy was performed, however this was not mentioned in the ERCP report). Case RCP4 was graded very poor care for record keeping as the first ERCP report was hard to follow and the second ERCP report made no mention of the previous ERCP.

6.2 Terms of reference 2 – ERCP service design

To review the current ERCP service design for the delivery of care. Consideration will be given to protocols and pathways, facilities, links with other centres, capacity, activity and workload. This will take account of performance against national audit data and outcomes.

6.2.1 Service arrangements pre-July 2021

6.2.1.1 Documentation review

Gastroenterology GIRFT implementation Group: Action Log – 41 actions; 2 completed; 18 were awaiting an update; the rest were ongoing. Due dates were 2021.

A document titled *Rotherham General Hospital - Endoscopist Competency Levels*, indicated that a single clinical endoscopist was the only staff member with competency to undertake ERCP. This individual was also competent to undertake gastroscopy, flex sig [sigmoidoscopy[xxv]], colonoscopy. A note on this document next to the clinical endoscopist's name reads: *'More uppers than colons – save space for therapeutic'*.

A document detailing the arrangements for clinics that support the service (document 2.7) indicated that the ERCP service took referrals from two main sources – inpatients presenting with a diagnosis for which they would benefit from an ERCP and from general surgery outpatient clinics. The only clinic supporting the ERCP service would be the endoscopy pre-operative assessment screening, which is a series of standardised questions asked by the service to all patients coming into endoscopy. This form of pre-procedure assessment was introduced around the time the service was suspended.

Waiting times for endoscopy were detailed in the Trust documentation as follows:

		Jul-19		Jul-20		Jul-21	
		Patient's waiting <6 weeks	Patient's waiting > 6 weeks	Patient's waiting <6 weeks	Patient's waiting > 6 weeks	Patient's waiting <6 weeks	Patient's waiting > 6 weeks
Endoscopy	Colonoscopy	247	0	239	290	200	0
	Flexi sigmoidoscopy	85	0	87	155	72	0
	Cystoscopy	123	0	51	57	61	0
	Gastroscopy	292	0	293	415	271	0
	Total	747	0	670	917	604	0

Minutes of the combined endoscopy governance and user group meeting held on 16 September 2020 detailed that during COVID-19, the upper GI bleed out of hours service was outsourced to Barnsley but had at that point been brought back in-house. The meeting discussed current service provision out-of-hours and it was felt to be unworkable as the rota was being covered by three colleagues. The endoscopists had been approached regarding joining the rota and covering on-calls and one confirmed they were willing to continue to cover the rota provided they were rostered for the days they normally worked. The clinical endoscopist who performed ERCP confirmed that they were willing to continue covering this service whilst expressing concern regarding possible staff fatigue. It was agreed that this should be added to the risk register.

[xxv] A sigmoidoscopy is a diagnostic test to check the lower part of the colon or large intestine.

6.2.1.2 Comments from interviewees

i. How the single operator service came about

Several interviewees highlighted a perception that the Trust previously had an extremely successful gastroenterology department – *'one of the best gastroenterology departments for many years'*, was how one interviewee described it. ERCP had been a single-handed service according to the account of one interviewee, who recalled that, since at least 2015, a single gastroenterologist undertook ERCP.

The review team was informed that the Trust lost all its gastroenterologists in quick succession, following a review into centralising gastroenterology and stroke services. Since that time, the Trust had relied on locum gastroenterologists and lacked a constant ERCP provider. One account was that gastroenterology was led mainly by upper GI surgeons at the Trust. Endoscopy sat within the division of surgery at the Trust.

Following departure of the substantive gastroenterologists, surgeons from Sheffield Teaching Hospital attended the Trust every Wednesday to undertake ERCP for Rotherham patients (estimated to be approximately three or four ERCPs per week). If an ERCP was needed outside of the Wednesday in-reach, the patient would be transferred to Sheffield. This arrangement was reported by some interviewees to have put a strain on the Sheffield surgeons.

Only a few interviewees could speak to the events that led to the development of a single operator ERCP service, provided by a non-medical endoscopist. Many of the senior leaders in place at the time of the review were relatively new to the Trust. However, the review team was able to interview two general surgeons who were said to have led moves to reinstate the ERCP service following the departure of the gastroenterologists.

The divisional director for surgery at the time was approached by a radiology manager at Sheffield Teaching Hospital, who was reported to have suggested that a clinical endoscopist at Sheffield Teaching Hospital was undertaking ERCP and interventional radiology procedures independently and might offer a potential solution for Rotherham. The Trust convened an interview panel – described by one interviewee as a *'standard medical panel'* – comprising a representative of the then medical director, in addition to consultant surgeons, representatives from radiology and from the chief nurse's office. One interviewee reported that the clinical endoscopist came with references that spoke to their technical competence. Another believed the clinical endoscopist had been *'heavily mentored'* and trained by surgeons in Sheffield and described their CV as *'very good'*, highlighting JAG accreditation and that the clinical endoscopist was a JAG trainer in ERCP. The clinical endoscopist was offered, and accepted, a position as consultant nurse at the Trust.

The clinical endoscopist provided details of their background and training to the review team in interview. Having trained in the armed forces, the clinical endoscopist took a position at Sheffield Teaching Hospital in endoscopy. After two years, they were invited to undertake interventional radiology and underwent what was described as a *'structured plan for three years'* undertaking interventional radiology in the non-vascular sector, including upper and lower GI stenting, nephrostomies, and drains. Following this, under the guidance of a general surgeon, the clinical endoscopist undertook training in ERCP. They were signed off to undertake ERCP independently in 2011; they claimed to have been *'trained to level 4'*. The clinical endoscopist undertook ERCP in Sheffield until 2016, while continuing to be based in the radiology department. They were said to have undertaken between 200 and 400 ERCPs per annum in Sheffield. The clinical endoscopist was said to have been active in training other clinicians in diagnostics and therapeutics, teaching ERCP *'on a national basis'* until October 2021.

Senior leaders within the Trust highlighted the fragility of the service due to the reliance on a single operator and recognised how unusual it was to have a non-medical endoscopist provide the ERCP service single-handedly. Others appeared less concerned by the uniqueness of the arrangement, emphasising the skill and productivity of the clinical endoscopist, which had enabled the Trust to retain an ERCP service.

The clinical endoscopist's ERCP activity was supervised by two general surgeons, [*subspecialty redacted*], [*a senior member of the surgical hierarchy*] and [*a consultant surgeon*]. Together, they assumed the roles of *'clinical mentors'* to oversee the clinical endoscopist's decision making and accountability. Neither of the clinical mentors were trained in ERCP. There remained no substantive gastroenterologists to support the service. Referral to the tertiary centre at Sheffield Teaching Hospital was thought to offer *'back up'* if there were issues or problems.

Responsibility for the clinical endoscopist's timetable, job plan and contractual commitments rested with the nursing hierarchy, as the clinical endoscopist was employed under Agenda for Change.[xxvi] The clinical endoscopist was line managed by [*a senior member of the nursing hierarchy*], who was said to be responsible for undertaking their personal development review (PDR).

ii. ERCP activity

One account was that the Trust provided *'close to'* 150 ERCP procedures in 2020. Another account was that the Trust performed 333 ERCPs between 2019 and 2021.

The clinical endoscopist was contracted to provide ERCP and other endoscopic services at the Trust. They had two weekly lists – Wednesday and Friday mornings. Another account was that the Trust had a four-day ERCP service – Tuesday to Friday, with a dedicated ERCP on Wednesday mornings, and a surgical list for endoscopy on Wednesday afternoons and all-day Friday.

The clinical endoscopist was said frequently to pick up additional lists. The review team was informed that, on average, the clinical endoscopist would undertake four or five lists, and additional weekend lists. There was said to be some discrepancy between the clinical endoscopist's understanding of the number of lists they should be doing and the Trust's planning in this regard, and over the way lists should be offered equitably to staff and the pay rate attached to additional lists.

Interviewees expressed uncertainty regarding the gastroenterology out of hours rota and the cover provided by the clinical endoscopist to this rota.

iii. Interventional radiology

The clinical endoscopist had been appointed to undertake interventional radiology, in addition to ERCP, and was initially given one slot a week to undertake interventional radiology procedures in the angiography suite. This arrangement fell apart for several reasons, including the following: that the clinical endoscopist was said to have mislead staff by introducing themself as a *'consultant interventional radiologist'*; that the clinical endoscopist was said to have continued with attempts to place a stent when the supervising interventional radiologist said multiple times to stop; that the clinical endoscopist failed to document the dosages of midazolam and fentanyl administered; that the clinical endoscopist was said to have placed colonic stents in the angiography suite, which was meant to be reserved for sterile insertion only.

[xxvi] The NHS terms and conditions of service (Agenda for Change) applies to all non-medical NHS staff. The NHS terms and conditions of service (NHS TCS) do not apply to doctors, dentists, and those employed on Very Senior Managers contracts (VSM).

These issues reinforced anecdotal concerns said to have been raised by radiology staff at Sheffield Teaching Hospital regarding the clinical endoscopist. There was a breakdown of relationship between the clinical endoscopist and the radiology department and the clinical endoscopist ceased to undertake interventional radiology procedures at the Trust.

iv. Wider scope of practice

The Christie NHS Foundation Trust

In 2018, the clinical endoscopist began working at The Christie NHS Foundation Trust ('The Christie') in Manchester on Mondays, under the agreement of the then divisional director for surgery at the Trust. One account was that the clinical endoscopist's work at The Christie arose from a refusal by the Rotherham Trust's radiology department to allow the clinical endoscopist to undertake interventional radiology procedures. The clinical endoscopist was said to have expressed concern about becoming deskilled from an interventional radiology perspective and that The Christie had offered the opportunity to undertake interventional radiology procedures. Another account was that the clinical endoscopist had a lengthy association with The Christie, reflecting their background with the British Society for Interventional Radiology, and that they were invited by the hospital to streamline its service. The clinical endoscopist did not undertake ERCP at The Christie, according to one account.

[*A senior member of the surgical hierarchy*] was said to have agreed to this arrangement on condition that the clinical endoscopist met their contractual obligations to the Trust. The arrangement with The Christie was considered by the [*senior member of the surgical hierarchy*] to have been *'extracurricular'* and no paperwork was generated within the Trust to confirm the Trust's expectations. The absence of a documentary trail had created difficulties for newer managers who sought to establish the parameters of the agreement with The Christie and mechanisms for reimbursement to the Trust. It appeared that The Christie did not pay the clinical endoscopist for their activity on Mondays.

Northern Lincolnshire and Goole NHS Foundation Trust (NLaG)

NLaG was reported to have sought the Rotherham Trust's help in managing a backlog of endoscopy procedures. The clinical endoscopist was one of two or three of the Trust's endoscopists who undertook weekend lists under a service agreement between NLaG and the Trust. NLaG was also reported to have had problems with its ERCP service; its operatives were said to be *'level 1 or 2'* and lacked the expertise to undertake *'level 3 or 4'* cases. One account was that the clinical endoscopist was asked to provide training and support. Initially, an arrangement was agreed whereby NLaG patients would attend the Rotherham Trust for ERCP. Sometime later, an upper GI surgeon from Lincolnshire attended the Rotherham Trust to undertake training in ERCP under the clinical endoscopist. This required the clinical endoscopist to attend NLaG on an ad hoc basis. The review team was unable to establish the dates associated with these events, however they were thought to have taken place prior to the COVID-19 pandemic and it was thought that the clinical endoscopist had not worked at NLaG on behalf of the Trust since November 2020.

No private work is undertaken at the Trust and staff were unaware of any private activity undertaken by the clinical endoscopist in a personal capacity.

v. Suspension of the ERCP service

The review team was informed that, in May 2021, senior managers began to raise questions regarding the ERCP service and whether patients were coming to harm. There were concerns over serious incidents relating to ERCP and a belief that root cause analyses were not effectively identifying the underlying causes. Concerns raised by a JAG review regarding the single operator service. Some within the Trust were said to be dismissive of these concerns. *'Individuals have been supported and protected, and that's led to some of this'*, said one interviewee.

Three surgeons reviewed a selection of cases associated with serious incidents, including two cases that were undergoing investigation by the Coroner. The surgeons were said to have identified issues regarding consent but did not believe there was a case for stopping the service.

In the following months, further concerns were raised with the senior leadership team and a cluster of serious incidents led to the decision by senior staff within the Trust to suspend the ERCP service. One interviewee said: *'in April/May 2021, the lid started coming off'*. Some of the cases that led to serious incidents were undergoing coronial investigation. The service was suspended in July 2021. The decision to suspend the ERCP service was communicated to clinical leads for onward dissemination to their clinical teams.

The review team was informed that the general surgeons were not supportive of the decision to suspend the service. However, some interviewees said they had never been told the reason why the service was withdrawn and were left feeling *'in the dark'* about it.

One interviewee reflected that the Trust had put itself in *'a very unique and perhaps wrongful position'* to appoint a single operator to undertake ERCP and that it was *'debatable'* whether the level of supervision was adequate. This interviewee believed colleagues had not been sufficiently prescriptive in terms of the parameters of practice for the clinical endoscopist, particularly with respect to high risk, high complexity cases.

The clinical endoscopist was also suspended from the Trust in July 2021 and a referral was made to the NMC, which was said to relate to non-clinical issues. The NMC subsequently imposed an interim suspension order.

6.2.2 Service arrangements since July 2021

6.2.2.1 Documentation review

A document titled 'STANDARD OPERATING PROCEDURE (SOP), Process for ERCP Procedures at Rotherham NHS Foundation Trust. Draft, version 2 (May 22). *[Not yet ratified]'* stated:

> *'Following concerns regarding the outcomes of ERCP procedures undertaken at the Trust (due to fatalities following procedures) the decision was made to cease all ERCP procedures in July 2021. During this period, patients requiring this procedure were transferred to Sheffield Teaching Hospital. This carried with it risk of harm to a cohort of patients who are already frail. To serve our patient population more effectively and safely, we need to reintroduce the provision of ERCPs at Rotherham, and will do this with the support of colleagues and services both internally (General Surgery, Radiology, and Endoscopy) and externally at Sheffield Teaching Hospital.'*

This document indicated that future ERCP procedures would be undertaken by the following: consultants from Sheffield Teaching Hospitals NHS Foundation Trust or Barnsley Hospital NHS Foundation Trust, and consultants or non-medical endoscopists from the Rotherham Trust. At the time of the review an agreement was in place with Sheffield Teaching Hospitals to support ERCP lists at the Trust extra contractually. The SOP indicated that there was no obligation for Sheffield Teaching Hospital to cover the list should a list be cancelled and that if a list was cancelled at short notice the responsible consultant at Rotherham Trust would be informed so urgent patients could be reviewed and, if appropriate, discussed with Sheffield Teaching Hospitals if urgent enough to warrant transfer to Sheffield for an ERCP.

6.2.2.2 Comments from interviewees

Since the decision was taken to suspend the ERCP service, all patients requiring ERCP had been transferred to Sheffield Teaching Hospital. Local GPs were said to have encouraged gastroenterology patients to Sheffield instead of Rotherham for some time, as the service at the Trust was considered *'patchy'*.

A good relationship was reported with the hepatopancreatic biliary (HPB) surgeons at Sheffield who provided the ERCP service, together with gastroenterologists. Nevertheless, the arrangement was thought to be less effective than when ERCP was provided in-house and the transfer of patients to Sheffield was attributed with causing delays in the provision of care.

Several interviewees emphasised an imperative to re-establish the ERCP service at the Trust. Some believed the clinical endoscopist should resume provision of the service if they were deemed to be safe. Some articulated an ambition that colleagues at Sheffield Teaching Hospital should continue to support the ERCP service at Rotherham. Others maintained that Sheffield was reaching capacity for several services and believed that partnership working with another hospital would offer a more sustainable model for the future.

At the time of the review, the Trust had recruited an upper GI surgeon and a gastroenterologist, both able to undertake ERCP. Once these new clinicians begin in post, the intention was for the ERCP service to resume on a different footing and to cease to be a single operator service. Efforts had been underway for several years to foster collaborative working with Barnsley Hospital NHS Foundation Trust and a joint interim chief executive was in post at the time of the review. A joint service had been confirmed, with a joint programme manager. Three joint substantive gastroenterologists were to begin in post in September, one of whom was reported to be trained in ERCP.

In total, it was anticipated there would be 2.5 WTE gastroenterologists and the upper GI surgeon undertaking ERCP. The review team was informed that the intention was to develop an upper GI unit, of which ERCP would be a critical element.

6.2.3 ECRP pathway – decision to undertake ERCP

6.2.3.1 Documentation review

The unratified SOP for ERCP procedures at the Trust, dated May 2022, outlined the core members for the ERCP MDT, as follows: upper GI consultants, consultant radiologists, the clinical endoscopist, gastroenterology consultants, and two HPB consultants from Sheffield Teaching Hospital. The MDT was detailed as happening on Tuesday mornings for an hour (10:30 – 11:30). The SOP indicated that the Sheffield consultants would *'validate the ERCP outcomes when they attend to do the list at [the Trust] if they have been unable to attend the MDT'*.

The SOP included a section on Stage 2 – Validation at MDT, which set out:

- the process for preparing cases for discussion at ERCP MDT meetings (expected to be held on Tuesday's at 11:30)
- that cases discussed within the MDT will either be processed for ERCP or rejected and what should happen if a decision is made not to proceed with an ERCP, as well as for patients deemed appropriate to proceed to ERCP.

The SOP also outlined the indications for ERCP and that it was not indicated for use as a diagnostic procedure. The SOP also detailed absolute and relative contraindications for ERCP.

6.2.3.2 Comments from interviewees

Interviewees gave two accounts regarding MDT discussion of ERCP cases.

The first account was that prior to early 2021, there was no structured MDT discussion of cases requiring ERCP. In 2020, an audit of ERCP cases led to the decision to introduce a formal MDT process, which began in early 2021. The new MDT arrangement was said to involve [*a consultant surgeon*], radiologists and sisters from the endoscopy unit. The clinical endoscopist presented cases referred for ERCP and where a decision was made to proceed for ERCP, an electronic request would be generated, the clinical endoscopist would list the case and request further investigations, as required. This was described as a formal discussion, which was documented, with minutes sent to the referring consultant. In response to observations from the review team that they had not been able to identify evidence of the MDT process in the clinical case records, this interviewee explained that it reflected that the MDT decisions were communicated by email to the referring consultant and would not therefore be visible in the patient record. Plans were mentioned for administrative support to write to the referring consultant following the MDT discussion and to copy the letter to the patient's GP.

The second account was that prior to October 2020, referrals for ERCP came by email, letter or referral form; benign cases would be reviewed by the clinical endoscopist, who would proceed with ERCP or pass back to the referring consultant any cases that lacked sufficient imaging, and only palliative or cancer cases would be referred to MDT. From October 2020 onwards, all ERCP referrals had to be made via an electronic referral form. Benign cases would be listed if the clinical endoscopist considered these were appropriate and cancer cases would be referred to the cancer MDT and reviewed by Sheffield as the tertiary centre.

One interviewee emphasised the need to ensure that the MDT was comprised of people able to provide a balanced view and to not just formalise a decision that was already made. The clinical endoscopist was said to have a reputation for being eager to undertake ERCP, which was not always balanced against whether this was in the best interests of the patient.

6.2.4 ECRP pathway – pre procedure

6.2.4.1 Documentation review

The unratified SOP for ERCP procedures at the Trust, dated May 2022, outlined the pre procedure pathway for ERCP, as follows:

> *'Endoscopy nurses will undertake pre-assessment checks before the procedure date, and arrange for up to date bloods investigations (FBC[xxvii], U&E[xxviii], LFTs[xxix] and Coagulation profile[xxx]) / covid swabbing as required. Patient will be sent the appropriate information leaflet and appointment letter. If there are any abnormalities in the pre-assessment checks, these will be flagged responsible UGI [upper gastrointestinal] consultant as required.'*

6.2.4.2 Comments from interviewees

No comments were received from interviewees regarding pre assessment of patients for ERCP.

[xxvii] Full blood count
[xxviii] Urea and electrolytes, to assess kidney (renal) function and electrolyte balance
[xxix] Liver function tests
[xxx] A group of tests to screen for abnormal blood clotting

6.2.5 ECRP pathway – procedure day

6.2.5.1 Documentation review

The unratified SOP for ERCP procedures at the Trust, dated May 2022, outlined ERCP procedure day, as follows:

- *'Patient will be admitted to the Endoscopy Unit, pre assessed and consented in the unit if not already done.*
- *Patients who have been admitted through endoscopy will be transferred to radiology assisted by endoscopies dedicated porter by walking if the patient is able to walk 100 yards without aid or wheelchair. Patients admitted through the inpatient route will be fetched by endoscopies dedicated porter in their bed which will be stored in radiology until they are taken back to the ward in it.*
- *IV*[xxxi] *antibiotics and NSAIDs to be prescribed by endoscopist*
- *ERCP completed with qualified staff to assist*
- *Patients will be transferred safely to Endoscopy unit for further recovery and periodic observations.'*

A document titled 'Facilities' detailed that endoscopy patients resided on the Keppel ward, a 22 bedded elective ward.

The Endoscopy Policy, first issued in 2009 and most recently revised in July 2019 (2.6.3), contained a summary of the consent policy for the endoscopy department, which addressed (amongst other things) issues of capacity, relevant information regarding the intervention, additional procedures and the conditions to be met for consent to be valid. The document also stated:

> *'The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid/informed consent before treatment begins … Clinicians are responsible for knowing the limits of their own competence and advice should be sought from appropriate colleagues when necessary … Taking consent is usually a process and it is good practice to seek well in advance if able. This gives time for adequate information to be given and the patient to ask questions. The clinician should check before the procedure starts that the patient still consents … Written consent merely serves as evidence of consent; if the elements of voluntariness, appropriate information and capacity have not been satisfied a signature on a form will not make the consent valid.'*

The Endoscopy Policy also outlined the complications of ERCP:

> *'Endoscopic retrograde cholangiopancreatography (ERCP) is the most complicated endoscopic procedure performed by gastroenterologists. Whilst it is a very rewarding therapeutic procedure endoscopically it is also the most hazardous. It requires specialist equipment and needs a long learning curve in order to develop competence. The undoubted therapeutic benefits of ERCP in the minimally invasive management of biliary and pancreatic disorders have to be weighed against a high rate of serious complications, when compared with other forms of therapeutic endoscopy. It should be remembered that: People who need ERCP the least are the most likely to develop complications; Avoidance of marginally indicated ERCP is the best away to avoid serious complications.'*

[xxxi] Intravenous – i.e., given within a vein

The *'most common and important complications of ERCP and sphincterotomy'*, as detailed in this document, were: pancreatitis[xxxii], bleeding, cholangitis[xxxiii] / septicaemia[xxxiv], perforation[xxxv], basket impaction[xxxvi]. The overall incidence of complications was said to depend on many factors. An overall complication rate after sphincterotomy of around 5% was quoted (60% mild, 20% moderate and 20% severe). The procedure-related death rate associated with sphincterotomy, whilst initially reported as being around 1%, was stated in the document to be around 0.2% in the latest series. The commonest cause of post procedure death was detailed as being cardiopulmonary[xxxvii], *'emphasising the need for attention to safety careful monitoring of sedation and analgesia during ERCP.'*

The Endoscopy Policy detailed the clinical and laboratory features that indicated post ERCP pancreatitis, why post ERCP pancreatitis happens, grading and incidence, risk factors (including that the risk of pancreatitis is increased after therapeutic ERCP compared with diagnostic ERCP), management, and *'sensible strategies for prevention'*. Prevention strategies included: *'scrupulous basic ERCP technique'*, adequate training and competence of both endoscopist and endoscopy assistants, adequate case volume to acquire experience and maintain competence, avoidance of diagnostic ERCP when alternative and less invasive methods are available, avoidance of cannulation of the pancreatic duct when not indicated, limiting cannulation time to avoid trauma to papilla, limiting injection number and volume of contrast to avoid pancreatic overfilling causing acinarization[xxxviii], selective use of electrocautery current with a sphincterotomy, and use of a stent in the pancreatic duct for sphincter of Oddi manometry or pancreatic sphincterotomy.

In terms of pharmacological prophylaxis, the Endoscopy Policy detailed that *'although a number of therapeutic agents have been assessed experimentally and clinical trials, none have gained universal acceptance'*. The policy detailed agents that have been tried to reduce post ERCP induced pancreatitis and gave an overview of the evidence for each agent. It concluded: *'There is no agent which has gained universal acceptance for use in prophylaxis of post ERCP pancreatitis. The reported promising results with some of the agents described all need confirmation. Whilst some pharmacological intervention may be reasonable in certain patients at high risk of pancreatitis (e.g., somatostatin in young patients with sphincter of Oddi dysfunction), cost effectiveness studies have not yet been performed to justify this practice. The main stay of prevention for post ERCP pancreatitis remains a properly trained and experienced endoscopist using good technique in the setting of an experienced unit.'*

The Endoscopy Policy also addressed post ERCP bleeding – how to recognise and grade it, the reasons why it occurs, management of post ERCP bleeding (including endoscopic therapy), and strategies to prevent this type of bleeding. The policy stated: *'All patients undergoing any form of ERCP should have a platelet count*

[xxxii] Acute pancreatitis is a condition where the pancreas becomes inflamed (swollen) over a short period of time. https://www.nhs.uk/conditions/acute-pancreatitis/

[xxxiii] Cholangitis is inflammation of the bile duct system.

[xxxiv] Septicaemia describes blood poisoning or serious bloodstream infection.

[xxxv] Gastrointestinal perforation occurs when a hole forms all the way through the stomach, large bowel, or small intestine.

[xxxvi] ERCP can remove large stones from a common bile duct. Steps include cutting the sphincter or sphincterotomy. Where stones are too big to pass through the sphincter one approach is to capture the stones in a wire metal basket, which is on the end of a long wire passed through the scope, into the bile duct via the sphincter. Some baskets can be attached to a device known as a lithotripter, which exerts pressure on the basket, squeezing and closing the basket. As gall stones can be semisolid or pliable, the basket can sink into the body of the stone and become impacted on it, which is known as basket impaction. When this happens, specialist equipment is used to cause the basket to fragment to enable it to be retrieved.

[xxxvii] Relating to the heart and lungs.

[xxxviii] Acinarization occurs when the volume of contrast material injected into the pancreatic duct exceeds the ductal capacity.

and INR measured prior to the procedure – preferably within the preceding 24hrs…. It is considered that a platelet count exceeding 50,000 and a normalised ratio and INR of <1.2 is safe for sphincterotomy. There is no data to indicate that patients undergoing stent deployment or exchange alone (without any form of sphincterotomy) are at excess risk of bleeding even when coagulopathy is present.' Sensible precautions before sphincterotomy included: avoiding sphincterotomy in patients with severe coagulation disorders (and to correct these where possible); and to take preventative measures, where possible, in patients with known platelet dysfunction. The policy added that sphincterotomy appears to be safe in patients taking aspirin and NSAIDs within three days pre or post sphincterotomy, although *'some authorities'* recommend their discontinuation where possible. Low molecular weight or subcutaneous heparin or the newer anti-platelet drugs such as Clopidogrel should *'probably'* be stopped prior to the procedure. Warfarin should be discontinued three to five days before planned sphincterotomy. INR should be checked two hours prior to the procedure; if necessary fresh frozen plasma can be used to reverse the anticoagulation. Vitamin K should be avoided if possible, due to the time it takes to re-establish therapeutic anticoagulation following the procedure. The policy stated: *'there is no evidence to guide the timing of re-starting warfarin therapy. Many endoscopists re-start it the same evening or within 48 hours whilst others wait for three days.'*

The Endoscopy Policy addressed post ERCP sepsis – why it happens, classification, incidence, prevention (including prevention with antibiotic prophylaxis) and treatment. It also covered ERCP perforation and impaction of retrieval baskets (including why these complications happen, risk factors, grading, management and prevention).

Regarding anticoagulation for endoscopy, the Endoscopy Policy indicated (p30/31) that ERCP +/- sphincterotomy in the anticoagulated patient was a high-risk procedure, with low thromboembolic risk. The policy advised discontinuing warfarin 3-5 days before the procedure and to reinstitute warfarin after the procedure. Biliary sphincterotomy was categorised as a high-risk procedure, with high thromboembolic risk, and the policy advised discontinuing warfarin 5 days before the procedure and to consider heparin while INR is below therapeutic level.

Regarding sedation, the Endoscopy Policy stated:

- *'a) Dosage of benzodiazepines and opiates should be kept to a minimum to achieve sedation and should be within the manufacturer's guidelines.*
- *b) Opioids should, whenever possible, be given before benzodiazepines and their effect observed before proceeding.*
- *c) Most endoscopic practices recommend that 5 mg of Midazolam should usually be the maximum dose given and that elderly patients are given 1-2 mg initially with a sensible pause to observe effect. Doses in excess of Pethidine 50mg or Fentanyl 100 mcg are seldom required and elderly patients will require dose reduction (usually below 50%).'*

The JAG report of the July 2021 assessment identified from patient feedback that there was a reluctance to use sedation for procedures. The report stated: *'Some patients felt discouraged from the use of sedation and reported more than expected pain during the procedures. The team has identified this shortcoming and have already discussed this internally to ensure that all patients are given the choice to use sedation. This will require a further audit of patient comfort and sedation use to ensure there has been the desired improvement in patient feedback and comfort scores.'*

A patient information leaflet specific to ERCP (2.6.1) produced by the clinical endoscopist in December 2019 and revised in 2020 and June 2021, highlighted the following *'minor potential complications from an ERCP'*: mild discomfort in the abdomen and a sore throat, dental work can be dislodged, mild inflammation of the pancreas, inability to gain access to the bile or pancreatic ducts, irritation to the vein in which

medications were given (uncommon). Possible major complications from having an ERCP were listed as follows: severe pancreatitis (in about one in 500 ERCP procedures), which in very rare cases can be fatal; if sphincterotomy (a small cut in the bottom of the bile duct) is performed, there is a risk of bleeding which, in severe cases, can require blood transfusion, a special x-ray procedure or an operation to control the bleeding; very frail and/or elderly patients can get pneumonia from stomach juices spilling over into the lung (approximately one in 500 cases); perforation in the wall of the duodenum, either as a result of sphincterotomy or due to a tear made by the endoscope (less than one in 750 cases), which may occasionally be fatal; a very rare complication is a reaction to one of the sedative drugs used.

6.2.5.2 Comments from interviewees

Consent for ERCP

The review team was told that consent for ERCP happens on the day of the procedure. This was said to reflect the approach taken by the endoscopy unit for most patients and a lack of understanding of the distinct risks associated with ERCP in comparison with other endoscopic procedures. The Trust was said to allocate 20 to 30 minutes procedural time for ERCPs. Previously, 45 minutes were said to have been allocated. These time constraints were thought to increase pressure on the consenting process.

One account was that patients undergoing ERCP were provided with information regarding the risk of bleeding, perforation and discomfort and these three risks were written on the consent form. The review team heard that requests had been made for stickers detailing the complication rate associated with ERCP to be produced, which could be applied to the standard consent form. One account was that Trust managers had declined this request on the grounds that it was too expensive. The clinical endoscopist was also said to have made this request as a reasonable adjustment specific to a learning difficulty.

ERCP facilities

The review team was informed that, due to the age of the angiography suite, an image intensifier had to be used for ERCPs. The clinical endoscopist was said to have refused to use the image intensifier in the room used by the radiologists and instead asked for the image intensifier to be brought down to the endoscopy suite. From 2020 onwards, every ERCP case was undertaken in the endoscopy suite.

Clinical assessment of patients

Patients with a pacemaker or similar implantable device were reported to be referred to cardiology before ERCP took place. Outpatients taking apixaban (anticoagulation medicine to prevent blood clots) would be relisted as per BSG guidelines; inpatients would be managed by the ward clinical team. For some patients taking warfarin (an anticoagulant to prevent blood clots), the ERCP would proceed using a plastic stent, to facilitate decompression and the patient would be brought back later for a further procedure. The review team was informed that sphincterotomy would not be performed on patients with clotting issues.

Prophylaxis

Interviewees reported that there was no policy of standard prophylaxis to reduce the risk of post procedural pancreatitis. One account was that prophylaxis for pancreatitis was discussed at one governance meeting but was not implemented. Another account was that, shortly before the ERCP service was suspended the decision was taken to use rectal diclofenac (a non-steroidal anti-inflammatory drug) as standard prophylaxis to prevent pancreatitis. The timing of this decision was unclear, however one interviewee believed that there had been insufficient opportunity for the clinical endoscopist to adopt this practice before the service was suspended.

Sedation

The clinical endoscopist was an independent prescriber with respect to endoscopy patients and had been prescribing since approximately 2010/2011. Midazolam and fentanyl were the clinical endoscopist's

sedatives of choice. For elective ERCPs, the usual approach was said to start with 2mg of midazolam and 50mcg of fentanyl, with incremental increases. The starting dose for midazolam for inpatients who were unwell would be less. The clinical endoscopist reported that the average dosage of midazolam used for ERCP was 3.3mg. The dosages documented were said to reflect the amount of sedative given over the whole period of the procedure.

Rate of abandonment
The clinical endoscopist was said to comply with BSG guidance stating that access to the common bile duct had to be above 90%. An audit of 100 cases was reported to have shown that four ERCPs were abandoned. The review team was informed that it was the clinical endoscopist's practice to undertake sphincterotomy on large stones (level 3 upwards) and allow the pancreas to, in the words of the endoscopist, *'calm down'*, before bringing the patient back later for stone extraction.

ERCP reporting
The clinical endoscopist would complete the ERCP report, detailing the reason for referral, any medications, and details of the procedure undertaken.

6.2.6 ERCP pathway – recovery, discharge and follow up

6.2.6.1 Documentation review

The unratified SOP for ERCP procedures, dated May 2022, outlined ERCP Stage 4 – recovery, discharge and follow up. The SOP outlined the expectation that patients would be kept in the endoscopy recovery unit for observations for four hours post procedure and the decision to discharge (if safe to do so) would be taken by the discharge nurse. If the patient was unwell or unfit to be discharged after four hours, the endoscopists who performed the procedure would be asked to review the patient. If this was not possible, the nurse in charge of endoscopy would request an urgent review from the on call surgical registrar or consultant. Patients would be a given post procedure care leaflet and patients requiring follow up (i.e., those with stents, gall bladder stones requiring surgery) would be given a suitable follow up plan with the relevant consultant.

Several patient information leaflets were included in the Endoscopy Policy document (for example, what to expect after gastroscopy; what to expect after colonoscopy; what to expect after sigmoidoscopy). A separate patient information leaflet specific to ERCP was at 2.6.1 of the supporting documentation. This detailed that patients undergoing ERCP will need to stay in the hospital until they are fully awake, *'which usually takes at least one hour'* and that some patients may be required to stay in hospital under observation for four hours if a sphincterotomy is performed.

The Endoscopy Policy also addressed discharge following ERCP and stent insertion (p106 onwards). This included that there should be a minimum of three recorded sets of clinical observations on all sedated patients; that *'the endoscopist is still responsible for the post endoscopy recovery period and should give clear instructions to the recovery nursing staff or ward, especially when an adverse event has occurred'*; that patients usually remain in the department for two hours and are observed for signs of abdominal pain; if there are no adverse effects such as dizziness or faintness, the patient is walked to the seated recovery and given refreshments; prior to discharge the patient should be considered fit if he/she feels awake, is able to walk with minimal assistance and is not experiencing severe abdominal pain. This document had an entry that indicated post procedural information was required from the clinical endoscopist who performed ERCP.

In terms of safe discharge of patients following ERCP and sphincterotomy, the documentation reiterated that the endoscopist was still responsible for the post endoscopy recovery period and should give clear instructions to the recovery nursing staff or ward especially when an adverse event had occurred. Fifteen-minute blood pressure and pulse readings should be taken for one hour, followed by half hourly observations for one hour, followed by hourly observations until discharge. Any drop in blood pressure or complaints of severe abdominal pain should be reported to the endoscopist. The documentation did not specify a time after which discharge may be appropriate but stated: *'the patient may be admitted to the ward for observations overnight and allowed home the next morning.'*

6.2.6.2 Comments from interviewees

Recovery
Patients were recovered following ERCP in the endoscopy department, down a corridor from where the procedure was performed.

There were accounts that nursing staff had raised concerns via Datix regarding the levels of sedation used for some ERCP procedures and the impact on patients in recovery. Concerns had also been raised that the clinical endoscopist had either not responded to a request to review a patient or had been content for a patient to be discharged when nursing staff remained concerned.

A view was expressed that some patients who received ERCP as outpatients should be admitted as inpatients due to their complexity.

One interviewee reported that incidents had arisen in the recovery area, with patients given insufficient time for recovery and having just one set of observations before being discharged or transferred back to the ward. Efforts had been made to improve this aspect of recovery.

Discharge

No comments were received from interviewees regarding discharge.

6.3 Terms of reference 3 – staffing and team working

To review the quality of staffing and team working within the department and to give a view on whether this supports the delivery of high quality and safe care. Consideration will be given to ways of working, clinical leadership, interactions with members of the wider medical team, to include nursing, and job planning.

6.3.1 ERCP practitioner

6.3.1.1 Documentation review

No documentation was identified relating to the ERCP practitioner.

6.3.1.2 Comments from interviewees

The clinical endoscopist was described as *'part of the complexity'* of the ERCP arrangements, with several issues raised regarding their professional conduct.

Some interviewees emphasised the clinical endoscopist's proficiency and skill set. One described the clinical endoscopist as *'a gifted technician'*; another stated they were *'incredibly slick and skilled'*. Reference was made several times to the clinical endoscopist as being *'slick'*. One interviewee was uncertain whether the clinical endoscopist was *'either at the cutting edge or dangerous'*.

The clinical endoscopist was thought by some to have a good understanding of which patients required ERCP and which did not. These interviewees highlighted the clinical endoscopist's experience in endoscopy and interventional radiology. The clinical endoscopist was said to have performed *'all the stenting'* and to have been *'fundamental'* in developing upper GI stenting within the Trust. One interviewee said that the clinical endoscopist *'had a fantastic work ethic and wanted to get through loads of cases, whether endoscopies or ERCPs'*. None of the interviewees was able to attest to the clinical endoscopist's skill at performing ERCP. Some could speak to the clinical endoscopist's skill in undertaking endoscopy and colonoscopy. The clinical endoscopist was observed as being somewhat *'aggressive'* at times and one interviewee reflected that they had undertaken procedures that, with hindsight, they should not have done. Several interviewees remarked that the clinical endoscopist was *'very willing'* to undertake extra work, although one observed that they sometimes undertook procedures quickly and *'edged towards rushing'*, which was thought to comprise the clinical endoscopist's clinical judgement and even patient safety.

The clinical endoscopist was thought by many interviewees to be profoundly self-confident and interviewees surmised that this made the clinical endoscopist reluctant to seek help from others external to the Trust with expertise in performing ERCP. The clinical endoscopist informed the review team that they would take any concerns regarding a patient to the surgeon under whom the patient was admitted and would discuss any worries with the tertiary centre if needed. The clinical endoscopist maintained they did not feel isolated in their role at the Trust and emphasised their links with colleagues at other centres as well as with the surgeons within the Trust.

Some interviewees described the clinical endoscopist as having a tendency to be autocratic, with a brusque manner and could come across, as one described, *'as a bit bullish and pushy'*. This interviewee considered this may have reflected the challenges in trying to establish oneself in a new place, with a new practice.

One interviewee described the clinical endoscopist as willing to discuss clinical cases internally, describing them as *'very approachable and willing to listen'*. However, this same interviewee highlighted an example where the clinical endoscopist had been reminded of the importance of reviewing patients with deteriorating observations on the request of recovery staff, and said that a Datix submitted after this reminder had been given demonstrated that the clinical endoscopist had failed to respond to a request to review a deteriorating patient. This account was reinforced by that of another interviewee who described the clinical endoscopist as *'a very difficult person to give direction to'*. This interviewee maintained that they would offer advice and guidance to the clinical endoscopist, which was not always followed and meant the clinical endoscopist had to be *'more forcibly directed'*. An example was given of the clinical endoscopist overloading lists and this issue was raised with the clinical endoscopist several times before it was addressed. There was a sense that if the clinical endoscopist were to return to practice, far greater levels of supervision and direction would be required. One interviewee said: *'we'd need to micro-manage [their] workload and not allow [them] to dictate that'*.

A reported failure to act on requests to review patients was said to have created a *'fraught'* atmosphere amongst the nursing team. One interviewee said that some nursing staff considered the clinical endoscopist to be *'maverick'* at times and would discharge patients about whom they had concerns. Some nurses were said to find it stressful working with the clinical endoscopist in the endoscopy room, mainly due to concerns over the levels of sedation used. The review team heard that nursing staff had on occasion been reduced to tears because they did not want to work under the pressure of being with the clinical

endoscopist and were even frightened for their own registration. The clinical endoscopist was said to undertake seven ERCPs on a list, one after the other, and staff in recovery were said to have expressed anxiety that they did not have the resources to cope with this throughput of ERCP patients, alongside other patient cohorts.

Some accounts were that the clinical endoscopist circumvented established pathways. For example, the clinical endoscopist was said to have advised staff that if a patient had a GI bleed during the night, staff could call the endoscopist on their mobile and they would come into the hospital to place a stent in the patient. This was despite an established pathway for patients to be transferred to Barnsley in the event of a bleed during the night. The clinical endoscopist was said by some to be convincing, or what one described as *'compelling'*, in advising staff on the management of patients.

Issues had been raised concerning patients being listed without sufficient information and this was thought to have led to the requirement for a formal MDT discussion of cases.

One interviewee reported that they had observed the clinical endoscopist communicating effectively with patients. Other interviewees had not observed interactions with patients, but equally did not believe this was an area of concern. However, there were several accounts that the clinical endoscopist had introduced themself in such a way that did not make clear their role as a nurse consultant and implied they were medically trained. This was said to have led to confusion amongst patients, as well as doctors and other clinical staff. Senior leaders were said to have discussed this with the nurse endoscopist at length.

A specific incident was highlighted in the endoscopy suite regarding a visiting gastroenterologist. This doctor was said to have experienced difficulty in placing a stent and abandoned the procedure, with a plan to obtain a different type of stent and arrange for the patient to return on a separate occasion. The clinical endoscopist was said to have informed the patient that they would undertake the procedure. This was said to have caused significant upset that the clinical endoscopist had overstepped a professional boundary and undermined a colleague. When challenged about the incident, the clinical endoscopist was said to have focused on the type of stent used and appeared to have overlooked concerns raised regarding professional behaviours with colleagues.

A pattern of resistance to critical feedback or challenge was highlighted. Some interviewees described a lack of responsiveness by the clinical endoscopist to concerns from nursing staff regarding patients in recovery following ERCP. The clinical endoscopist was said to have been dismissive to concerns raised by staff that patients had deteriorated. *'When patients had complications there wasn't the due consideration that there should have been that the patient could be seriously unwell'*, said one interviewee. A specific incident was referred to in which the clinical endoscopist was said to have refused to see a deteriorating patient and instead discharged the patient, who soon returned to hospital and died.

Another area of concern highlighted by some interviewees was a lack of transparency regarding the clinical endoscopist's working pattern and hours, and work location. This related to their arrangement with The Christie hospital, a business the clinical endoscopist was said to be involved with but had not declared, and units where the clinical endoscopist undertook teaching and training.

The clinical endoscopist had a period of absence from the Trust, for a year, between 2017 to 2018. [*Redacted to remove personal information which is not relevant to report conclusions*]

[*Redacted to remove personal information which is not relevant to report conclusions*] The review team was informed that the clinical endoscopist had a period of supervised practice before returning to practice as a sole operator.

[*Redacted to remove personal information which is not relevant to report conclusions*]

The clinical endoscopist informed the review team that areas for development in their practice focused upon improving their documentation of consent and writing more clearly. They detailed the requests they had made for pre-printed stickers to use on consent forms. They maintained that they kept up to date by attending JAG events as a faculty member. With respect to complications, the clinical endoscopist reflected that the more procedures they undertook, the more likely complications were to occur. They added that, shortly before the review, a serious incident relating to a suspected perforation confirmed that it was not a perforation relating to the procedure undertaken by the clinical endoscopist.

6.3.2 Oversight of ERCP practitioner

6.3.2.1 Documentation review

Document 3.3 detailed staff appraisal dates and indicated that the last appraisal date for the clinical endoscopist was 02/02/20.

An email on 08 July 2022 confirmed that the [*senior member of the nursing hierarchy*] had some recollection of appraisals with the clinical endoscopist, however no formal appraisal documentation, paperwork or PDPs were held on file. This email detailed that the clinical endoscopist was *'always line managed within the Division but because of [their] registration being within nursing, it was always felt to be appropriate to have nursing involvement in the PDR process.* [*Redacted*] *… this has therefore always sat with the* [*senior member of the nursing hierarchy*]*. This enabled input from a professional nursing input [sic] to be given but the* [*senior member of the nursing hierarchy*]*'s have had limited ability to set clinical objectives. There have been three* [*senior member of the nursing hierarchy*]*'s during this time.'*

An appraisal meeting with the clinical endoscopist took place on 29 November 2018. This was attended by the [*consultant surgeon*], the [*senior member of the nursing hierarchy*] and another member of staff. The email stated the following of this meeting: *'Although we reviewed progress over previous year and identified some objectives for the coming year, the conversation was dominated by some challenges being encountered within the Radiology Dept linked to a clash with a specific individual. This was clearly having a significant impact on [the clinical endoscopist's] working practice.'*

A further appraisal *'conversation'* took place on 05 February 2020, between the clinical endoscopist, the [*consultant surgeon*], and the [*senior member of the nursing hierarchy*]. The email stated the following of this conversation: '*Identified that previous issue [sic] in Radiology were no longer an issue. Discussion was held about requirement to support external contract at Christie's to maintain skills. The objective I identified was in relation to the wider nursing agenda and an ask for [the clinical endoscopist] to participate in supporting nursing through attendance at the Nurse Consultant meeting and participating in teaching.'*

6.3.2.2 Comments from interviewees

Interviewees confirmed the arrangements for appraisals and line management detailed in the documentation. A recurring theme was that the clinical endoscopist was, as one put it, *'tricky to manage'*.

The surgical division as described as having a *'robust and positive position'* with respect to appraisals, with 94% of nursing staff completing appraisals in the previous year. Nurse leaders had encountered difficulties in establishing whether the clinical endoscopist had completed appraisal.

The review team was informed that a PDR was due to have taken place around the time that the clinical endoscopist was suspended from the hospital. One interviewee reported that two PDRs should take place – one with the nurse manager (focused on career aspirations) and a clinically-focused PDR undertaken by the two general surgeons providing clinical supervision [*redacted*].

Clinical supervision was provided by two general surgeons – see 6.3.2. An *'unhealthy'* relationship was perceived by some to exist between the two general surgeons and the clinical endoscopist, who were thought to protect each other. *'They definitely pull together'*, said one interviewee.

The clinical endoscopist was perceived to have been strongly supported by the general surgeons as a team. In part this was thought to reflect a willingness by the clinical endoscopist to take on a great deal of endoscopic activity, which released surgeons to undertake other clinical activities. The level of surgical support was said to have made it harder for senior leaders to establish whether the ERCP service was functioning effectively and safely. Some interviewees described a *'venomous'* response from some of the surgical team regarding the decision to suspend the ERCP service and a lack of understanding for the decision.

6.3.3 Clinical leadership of ERCP service

6.3.3.1 Documentation review

No documentation was identified relating to clinical leadership of the ERCP service.

6.3.3.2 Comments from interviewees

The clinical lead for the endoscopy service at the time of the review was [*consultant surgeon*], who had been a locum with the Trust since [*yyyy*] and prior to that an associate specialist surgeon (SAS). This individual had been *'stepping up'* as a consultant general surgeon, including participating in the emergency general surgery rota, for nearly 14 years.

6.4 Terms of reference 4 – governance arrangements

To review the quality of clinical governance arrangements currently in place to support and maintain oversight of the service. Consideration will be given to raising and responding to concerns, audits, clinical incident reporting, and reviews of mortality.

6.4.1 Governance arrangements

6.4.1.1 Documentation review

The unratified SOP for ERCP procedures at the Trust, dated May 2022, detailed that the ERCP service clinical lead *'will be responsible for matters relating to governance and will carry out annual audits on:*

- *Referrals and indications for ERCP*
- *Time to ERCP*
- *Consent for ERCP*
- *ERCP outcomes – complications including deaths'*.

The SOP also indicated that there were no plans to utilise the Trust's ERCP lists for training.

The review team received the following general surgery governance meeting minutes: 11.06.19, 10.07.19, 15.08.19, 16.09.19, 15.10.19, 13.11.19, 12.12.19. The clinical endoscopist was not an attendee at these meetings, according to the attendee lists. Three sets of minutes from meetings held in 2019 recorded mortality review of ERCP cases:

- 11.06.19, mortality review of the death of a male patient, aged *[xx]* years, in February 2019. The patient underwent an ERCP and was found to have a duodenal ampullary carcinoma. Conservative treatment was decided upon.
- 12.12.19, mortality review of the death of a female patient in *[mm]* 2019. Following ERCP the patient was diagnosed with pancreatitis and died following critical care input. The minutes recorded: *'No issues with the pancreatitis from the procedure, or the care received after that. There was no clear indication for an ERCP prior to the MRCP report (which said ? Cholangio) and without MDT agreement or discussion with STH for primary resection. PRISM 6 NCEPOD 5 – It was confirmed that [the clinical endoscopist] did ask whether the patient did need an MRCP before he completed the procedure. It was all agreed that an email with a form of clear agreement between the responsible consultant and [the clinical endoscopist], so the agreement is clear. Already escalated as an SI [serious incident].'*
- 15.08.19, mortality review of the death of a female patient aged *[xx]* years in *[mm]* 2019. The patient was minuted as having been *'confused and agitated and too unwell to tolerate ERCP'*.

The JAG report of the July 2021 assessment stated: *'The agenda and minutes of EUG and Governance meetings are well-structured and clearly documented. Areas of improvement were identified from the audits and action plans made for improvements. The attendance at these meetings has also greatly improved from the time of the remote assessment in January 2021.'* However, the service did not meet standard CQ2.1 and the report stated: *'It was identified from the evidence uploaded and interviews that at present the DATIX system doesn't seem to capture all endoscopy-related complications. We discussed the need to educate the endoscopy teams and relevant wards to complete a DATIX form for all endoscopy-related adverse events.'*

The minutes of the endoscopy governance meeting held on 20 January 2022 recorded an action *'to review the ERCP service in view of the unexpected numbers of complications and deaths. This was reported to the Patient safety team. Subsequently the ERCP service in Rotherham was suspended from June 2021.'* Three serious incident investigations were detailed, as follows:

Reference	Details
128559 (HV)	B5 Cardiac Arrest post-ERCP
128314 (DF)	Post ERCP perforation
133402 (VR)	Delayed ERCP now unable to remove stent

This meeting detailed that post ERCP practice had changed to ensure patients remained in recovery for up to four hours with at least three sets of observations, with clearly identified plans for escalation if any concerns arose.

The minutes of the endoscopy governance meeting held on 14 October 2020 detailed the outcome of an inquest into the death of a patient in October 2019 following ERCP. Cause of death was as follows: 1a. Multisystem failure & Sepsis, 1b. Acute Pancreatitis, 1c. Post endoscopic retrograde cholangiopancreatography for mucoele of gall bladder, cholelithiasis and cholangiocarcinoma. The patient developed pancreatitis post ERCP which the minute stated: *'is not in itself significant as the rate of developing this post procedure at TRFT [The Rotherham Foundation Trust] is lower than average'*. The patient died from pancreatitis. The risk of death from pancreatitis was described as *'very low but the correct processes were not followed as it should have been discussed at Sheffield's MDT meeting and the consultant responsible for the decision to undertake the procedure should have been documented'*. Instead, it was discussed with the clinical endoscopist, who organised the procedure. Shared learning was identified as follows: The Trust's failure to adhere to both local and national guidelines in relation to the management of a patient with a common bile duct stricture (no hepatobiliary opinion sought); the clinical teams' very poor record keeping; poor internal communication between the gastroenterology, surgical and endoscopy teams particularly around the decision making to proceed to ERCP; lack of clarity around who was responsible for the patient's management ahead of the consultant formally taking over the patients' care 16 days post admission.

The action plan arising from this learning was for bookings for ERCPS to be made in writing using a specific online form which would be sent to the clinical endoscopist; documentation in notes to be improved with clinician's reason for ERCP; patients to be referred to surgery acutely for opinion and discussion with surgeon to be documented; any suspected stricture to go through upper GI MDT at the Trust and HPB surgery at Sheffield. If a patient required ERCP within 24-48 hours (i.e., the patient had biliary sepsis or jaundice above 200 (as per pancreatic guidelines), staff could contact the HPB on-call. Finally, all ERCP requests were to have a named consultant on Meditech.

6.4.1.2 Comments from interviewees

Interviewees reported that as part of a JAG visit, there had been discussion regarding the risks associated with a single operator service, but no other significant concerns had been raised. Interviewees reflected that they had been swayed by statements that attested to the technical expertise of the clinical endoscopist and their status as a *'level 4 operator'* and accredited trainer.

Several interviewees highlighted a challenge in identifying objective measures to understand how the ERCP service was performing. Personal relationships between some of the general surgeons and the clinical endoscopist were thought to have impacted their objectivity in recognising that there were problems. It was reported that the clinical endoscopist's performance of ERCP was couched in terms of *'everyone gets complications'*, with frequent reference made to the complexity of the patient cohort undergoing ERCP. Interviewees described this as a convincing narrative. A recurring theme was that interviewees felt unable to ascertain whether the clinical endoscopist was competent at ERCP; this was true even for medical and surgical staff, as no-one within the organisation was trained in ERCP and therefore felt unable to provide objective scrutiny to the service. It was only when serious incidents came to light that further inquiry into the service was required, leading to the decision to suspend the service.

The clinical lead for endoscopy had one PA in their job plan for audit and governance. The endoscopy department governance meetings were held every other month and discussed adverse events, morbidity and mortality. The endoscopy user group met in the other month to the governance meeting and was described as more of a business meeting. One interviewee suggested that attendance at endoscopy user group meetings had improved with a change in clinical leadership. Another interviewee observed that discussion of incidents by the endoscopy user group tended to focus on missed pathology, instead of complications.

All endoscopists were expected to Datix 30-day mortality. A serious incident panel met weekly to discuss cases, which were then discussed at the monthly divisional governance meeting and the endoscopy governance meeting every two months. No key performance indicators for ERCP had been collected internally.

Interviewees could not recall any concerns being escalated from department governance or endoscopy user group meetings to the Trust's monthly clinical governance or patient safety group meetings.

6.4.2 Serious incidents, Datix and complaints

6.4.2.1 Documentation review

The documentation contained details of 12 serious incidents; 6 of these related to ERCP (RU00005636, RU00005636 – these incidents had the same number but related to different patients, one male and one female – RU00042070, RU00457936, RU00545974, RU00858063).

The documentation also contained coroner statements relating to cases RCP19 and RCP26.

6.4.2.2 Comments from interviewees

The review team heard of a reluctance within the division of surgery to speak up and raise concerns. One interviewee described governance arrangements as *'loose'*, in an environment where errors and harm to patients was said to sometimes go unnoticed.

Some of the nursing team were said to have raised issues regarding ERCP and the clinical endoscopist, but other interviewees perceived that staff had not had sufficient platform to speak up. The culture of the surgical division was thought to deter nursing staff from voicing concerns. One interviewee relayed that doctors in training had previously referred to a culture of *'toxic masculinity'*. Concerns were also reported regarding attitudes, language and culture between medical staff and some of the nurse endoscopists. A divisional culture review was planned.

Several Datix reports were said to raise concerns regarding levels of sedation used for ERCP. Some held the view that nurse endoscopists within the Trust generally favoured higher levels of sedative than medical consultants. This was thought possibly to reflect that the clinical endoscopist had trained the nurse endoscopists.

One of the problems highlighted by interviewees in trying to establish whether there had been a departure from agreed pathways was that policies and standard operating procedures were not centralised on the Trust's intranet system as they should have been, and some documents sat in personal computer drives. This was said to be an issue across general surgery and endoscopy and not limited to the ERCP service. It had left the organisation without access to key documents or oversight of whether policies were relevant and in date.

The Trust was reported to have a mechanism for ensuring new NICE guidance was circulated to the appropriate clinician. A member of the endoscopy user group was responsible for reviewing all BSG guidance.

6.4.3 Audit

6.4.3.1 Documentation review

The draft SOP outlined the following auditable outcomes for ERCP:

- Success in cannulation of CBD and pancreatic duct
- Success in stone extraction
- Patient comfort
- Complications: pancreatitis, perforation and 30-day mortality
- >90% of ERCPs intended as therapeutic
- Completion of the intended therapeutic procedure at initial ERCP in at least 80% of cases
- Decompression of obstructed biliary systems within 5 working days of first attempted ERCP
- Sphincterotomy bleeding requiring transfusion < 2%
- Perforation rate <2%
- Clinically symptomatic pancreatitis < 5%
- Procedure related Mortality <1%
- Continued antibiotic treatment when obstruction unrelieved in 100% of cases
- Number of procedures performed by each operator.

A document titled *'Post-ERCP pancreatitis (2020). 01/01/20 – 18/11/20, 147 ERCPs'* compared the rates of post-ERCP complications to the BSG JAG standard, as set out in *The Way Forward* standards framework. This indicated that 28/147 patients' results were of *'indeterminate level'* because of uncertain biliary stone size (no MRCP or MRCP inconclusive). The overall complication rate was 10.2% (base 147), with level 2 complications at 8.8% (base 68). No level 1 procedures were included in the sample. The document contained the table below, showing the Trust's complication rate in comparison to the standard rate. Comparisons were also made to other similarly sized centres, across a range of dates (2006 for Scunthorpe and 64% of district general hospitals in 2007, next to data relating to 2020 for the Trust).

Complication	Standard	RGH rate (all procedures)
Perforation	<2%	1.4%
Pancreatitis	<5%	6.8%%
Sphincterotomy bleed requiring transfusion	<2%	Not recorded
30-day mortality	<1%	2.0%
Level 2 complications	<6%	8.8%

The JAG report of the July 2021 assessment indicated that the service had not met standard CQ1.3 or CQ1.5, and stated: *'It is recognised that the amount of audit work required on an ongoing basis to maintain JAG accreditation will require some additional support for the clinical lead. It may be in the form of admin support and also help from other endoscopist colleagues for their lead to help share the burden… The annual JAG audit programme for clinical and non-clinical audits must be clearly set up for the year with named owners and dates.'* The JAG report also required the service to: complete a PCCRC audit covering the period of the previous 12 months; improve the KPIs for most of the endoscopist workforce to ensure they are meeting the minimum BSG/JAG requirements.

The documentation bundle contained details of eight audits, including two specific to ERCP: ERCP outcomes, ERCP consent. The ERCP consent audit was a retrospective review of consent forms of 20 patients who underwent ERCP between January and August 2021. This audit showed that consent forms were often incomplete in terms of the following domains: responsible consultant, patient's printed name, copy given to patients, extra procedures and date of consent.

The ERCP outcomes 2021 audit was completed by the clinical lead for endoscopy, a locum consultant. This detailed 83 ERCP procedures between January and early July 2021. Of these 83, 9 complications were identified (10.8%), which included: 6 cases of pancreatitis (7.2%), 2 cases of perforation (2.4%), 1 case of bleeding (1.2%), 3 deaths (3.61%) and 3 failed procedures (3.6%). This was compared with the JAG standards: <2% perforation, <5% pancreatitis, <2% sphincterotomy bleed requiring transfusion, <1% 30-day mortality.

6.4.3.2 Comments from interviewees

[*A consultant surgeon*] initiated an audit of ERCP 30-day mortalities. The clinical endoscopist provided data to contribute to the audit and the data was validated by the [*consultant surgeon*]. The audit continued for more than a year, until the ERCP service was suspended. The findings of the audit were considered by the general surgery governance meeting. The audit was benchmarked against ERCP mortalities at Sheffield Teaching Hospital: during 2017, the clinical endoscopist did not work in the Trust for a period and patients requiring ERCP were sent to Sheffield. Of these patients, 100 ERCPs had led to three patient deaths. The audit did not involve consideration of complications that did not result in mortality. No external input was sought for the audit from someone trained in ERCP.

It was thought that some of the mortalities within the Trust were not directly attributable to ERCP; one interviewee reported that there were quite a number of complications of pancreatitis, which were thought not to have been a complication of ERCP. Emphasis was placed on the complexity of the cases performed at the Trust, based on the clinical endoscopist's account that cases were of a higher complexity to elsewhere. Cases of perforation were described by this same interviewee as *'slightly more than would expect'*. Three deaths were thought to be related to ERCP, compared with two deaths at Sheffield. The general surgical governance meeting concluded that the mortality rate at the Trust appeared to be *'virtually identical'* with that at Sheffield. Two further deaths occurred after this audit and the ERCP service was withdrawn.

The outcome of the audit was said to be the establishment of a formal MDT process and suggestions to improve the consent process, as the consent forms were observed to be *'illegible'* and often undated (something the clinical endoscopist was reportedly reminded about on several occasions). The governance meeting also recommended routine use of prophylaxis to prevent pancreatitis; there was no follow up to examine whether this happened and the impact it made.

The clinical endoscopist was described by one as an *'aggressive practitioner'*, who was let down by their own judgement and lacked direct supervision of the kind available in Sheffield with an HPB team of surgeons. One interview said that, with hindsight, the clinical endoscopist performed ERCP interventions that should have been referred to a tertiary centre and that parameters should have been agreed at the outset determining what was acceptable to undertake at the Trust.

The clinical endoscopist was said to undertake their own 'mid-term appraisal' of ERCP cases, set against the risk of complications and whether the patient was graded level 1 to level 4.

All the endoscopists were said to undertake audit to ensure they were meeting prescribing thresholds and prescribe in line with BSG guidelines.

In interview, the clinical endoscopist informed the review team that data on the complications associated with ERCP had been inaccurate, as elective cases had been removed. The overall complication rate was said to be 5.9 a quarter.

6.4.4 Continuing professional development (CPD)

6.4.4.1 Documentation review

No documentation was identified relating to CPD.

6.4.4.2 Comments from interviewees

Interviewees believed the clinical endoscopist kept up to date by attending regular meetings and an annual event hosted by the BSG. Reference was frequently made to the clinical endoscopist's status as an accredited trainer in ERCP.

6.4.5 Governance/oversight of activity at other centres

6.4.5.1 Documentation review

No documentation was identified relating to governance arrangements for the service level agreement with NLaG, or the arrangement where the clinical endoscopist undertook interventional radiology procedures at The Christie on Mondays.

6.4.5.2 Comments from interviewees

Interviewees could not speak to the governance arrangements relating to the service level agreement with NLaG, or the arrangement at The Christie.

7 References

[1] https://www.niddk.nih.gov/health-information/diagnostic-tests/endoscopic-retrograde-cholangiopancreatography#:~:text=care%20right%20away-,What%20is%20ERCP%3F,the%20bile%20and%20pancreatic%20ducts.

[2] https://www.nhs.uk/conditions/gallstones/treatment/

[3] https://journals.lww.com/ajg/Abstract/2007/08000/Incidence_Rates_of_Post_ERCP_Complications___A.33.aspx

[4] https://www.cancerresearchuk.org/about-cancer/cancer-in-general/tests/ercp-test

[5] https://pancreasfoundation.org/ercp-endoscopic-retrograde-cholangiopancreatography/

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2697892/

[7] https://www.esge.com/ercp-related-adverse-events-esge-guideline/

[8] https://www.bsg.org.uk/clinical-resource/ercp-the-way-forward-a-standards-framework/

[9] https://www.gmc-uk.org/ethical-guidance/learning-materials/blog---montgomery--judgement

[10] https://www.bsg.org.uk/wp-content/uploads/2019/12/Non-Medical-Endoscopists.pdf

[11] https://www.bma.org.uk/pay-and-contracts/contracts/sas-doctor-contract/sas-doctors-acting-up

[12] https://www.bsg.org.uk/clinical-resource/ercp-the-way-forward-a-standards-framework/

[13] https://www.thejag.org.uk/CMS/UploadedDocuments/Scheme/Scheme5/Guidance/191107%20-%20guidance%20-%20JAG%20quality%20and%20safety%201.0%20final.pdf

[14] National Mortality Case Record Review Programme https://www.rcplondon.ac.uk/projects/national-mortality-case-record-review-programme [Accessed 26 January 2022].

[15] National Confidential Enquiry into Patient Outcome and Death grading system for use by case reviewers http://www.ncepod.org.uk/grading.html [Accessed 26 January 2022].

[16] National Confidential Enquiry into Patient Outcome and Death https://www.ncepod.org.uk/ [Accessed 26 January 2022].

[17] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent

[18] https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf

8 Appendices

8.1 Appendix 1: Documents received and reviewed

Clinical record review
13 randomly selected ERCP cases / 13 index ERCP cases

Service review documentation	
Organisational level information	
1.1	Division of surgery and planned care – management structure
2.3	Map, Level C, Rotherham Hospital
2.3	Site Map 2019
Service specific information	
	The Rotherham Foundation Trust Endoscopy Policy (2009, last review date July 2019)
	STANDARD OPERATING PROCEDURE (SOP): Process for ERCP Procedures at Rotherham NHS Foundation Trust. Draft, version 2 (May 22). *[Not yet ratified]*
2.4	STANDARD OPERATING PROCEDURE (SOP): Process for ERCP Procedures at Rotherham NHS Foundation Trust. Draft, version 3 (March 22). *[Not yet ratified]*
3.0	STANDARD OPERATING PROCEDURE (SOP): Process for ERCP Procedures at Rotherham NHS Foundation Trust. Draft, version 4 (March 22). *[Not yet ratified]*
1.5.1	Gastroenterology GIRFT Implementation Group: Action Log
1.5.2	Royal College of Physicians Joint Advisory Group on GI Endoscopy (JAG) Accreditation report. Date of assessment: 16 July 2021. Date of report: 02 August 2021
2.2	Appendix A – supporting documentation. Facilities.
2.6.1	The Rotherham NHS Foundation Trust. Endoscopic Retrograde Cholangio-Pancreatography (ERCP): Information for patients. Produced December 2019, September 2020, June 2021. Revision due November 2021. Version 4.
2.6.2	The Rotherham NHS Foundation Trust. ERCP discharge advice. 14/09/20.
2.6.3	2019 RDGH Endoscopy Policy. Date issued: July 2009. Last review date: 1st July 2019. Next review date: July 2020.
2.7	Details of the arrangements for clinics that support the service.
2.8	Waiting times for endoscopy.
2.9	ERCP population.
2.10.1	Activity data.
2.12-2.13	ERCP mortality data.
2.15	Patient readmission details July 20-May22.

2.16	Procedure data.
Staffing	
2.1	Rotherham General Hospital – Endoscopist Competency Levels
3.1	Details of staff
3.2	Job plans – for seven surgeons
3.3	Staff appraisal dates
	Email to review team with information regarding appraisal of the ERCP practitioner, 8 July 2022
Governance	
	Post-ERCP pancreatitis. Rotherham General Hospital 2020. Olga White.
	General surgery governance meeting minutes: 11.06.19, 10.07.19, 15.08.19, 16.09.19, 15.10.19, 13.11.19, 12.12.19
4.3	Minutes of the endoscopy governance meeting held on 20 January 2022 by teams and in the anaesthetic seminar room
4.3	Endoscopy governance minutes – 12.02.20, 08.04.20, 16.06.20, 16.09.20 (combined governance and user group meeting), 14.10.20, 09.12.20, 13.01.21 (combined), 10.02.21 (combined), 16.06.21,
4.3	Minutes of the endoscopy user group meeting – 10.03.21
4.3	Minutes of the clinical governance and assurance meeting 08.12.21
4.7	Complaints and responses X 10
4.7	Serious incidents – X 12
4.8	Audits X 8
5.3	GMC trainee survey
5.3	TA outlier post spec by Trust Board
	Supporting coroner statements RCP19 and RCP26
Documentation received during or post-review	
6.1	ERCP referral form

8.2 Appendix 2: Interviews

[Interviews were carried out on 7, 8 and 20 July 2022. Names of individuals interviewed have been redacted]

8.3 Appendix 3: Summary of clinical record review gradings

8.3.1 Gradings by phase of care

Phase of care	Very poor care (1)	Poor care (2)	Adequate care (3)	Good care (4)	Excellent care (5)	Not applicable
Assessment of the patient and decision to arrange ERCP	RCP3 RCP17 RCP23	RCP12 RCP14 RCP16 RCP18 RCP20 RCP24 RCP25	RCP1 RCP4 RCP5 RCP6 RCP7 RCP8 RCP11 RCP13 RCP15	RCP9 RCP10 RCP19 RCP22 RCP26	RCP2	
Consenting the patient for ERCP and information sharing regarding risks	RCP15 RCP16 RCP17 RCP20 RCP23	RCP1 RCP2 RCP3 RCP4 RCP5 RCP6 RCP7 RCP8 RCP10 RCP12 RCP13 RCP18 RCP19 RCP22 RCP25 RCP26	RCP11 RCP14	RCP9 RCP24		
Undertaking the ERCP procedure	RCP8 RCP9 RCP14 RCP16 RCP17 RCP20 RCP22 RCP23 RCP26	RCP1 RCP3 RCP4 RCP5 RCP6 RCP10 RCP11 RCP12 RCP15 RCP18 RCP19 RCP24 RCP25	RCP2 RCP7 RCP13			
Recovery following the ERCP	RCP8 RCP9 RCP17 RCP19 RCP22 RCP25 RCP26	RCP7 RCP11 RCP12 RCP14 RCP15 RCP16 RCP18 RCP24	RCP5 RCP6 RCP13 RCP20 RCP23	RCP1 RCP2 RCP3 RCP4 RCP10		
Follow up of the patient	RCP4 RCP25	RCP5 RCP6 RCP12 RCP24	RCP3 RCP7 RCP8 RCP11	RCP1 RCP2 RCP10		RCP9 RCP13 RCP14 RCP15 RCP16 RCP17 RCP18 RCP19 RCP20 RCP22 RCP23 RCP26
Communication with colleagues	RCP4 RCP6 RCP8 RCP9 RCP14 RCP22 RCP25 RCP26	RCP3 RCP5 RCP7 RCP11 RCP12 RCP15 RCP16 RCP17 RCP18 RCP19 RCP20 RCP23 RCP24	RCP1 RCP2 RCP13	RCP10		
Interactions with patients and their family	RCP15 RCP17 RCP20 RCP25 RCP26	RCP3 RCP4 RCP5 RCP6 RCP7 RCP8 RCP9 RCP12 RCP13 RCP14 RCP16 RCP18 RCP19 RCP22 RCP23 RCP24	RCP1 RCP2 RCP10 RCP11			

Clinical record keeping	RCP4 RCP6 RCP8 RCP15 RCP20 RCP22 RCP23 RCP25	RCP1 RCP3 RCP5 RCP7 RCP9 RCP10 RCP11 RCP12 RCP14 RCP16 RCP17 RCP18 RCP19 RCP24 RCP26	RCP2 RCP13			

RCP21 – no ERCP took place; excluded from review

8.3.2 Overall perspective on quality of care

Clinical reviewer's overall perspective on quality of care	
Good practice: a standard you would accept from yourself, your trainees and your institution.	
Room for improvement: aspects of clinical care that could have been better.	RCP1 RCP2 RCP5 RCP7 RCP10 RCP13 RCP24
Room for improvement: aspects of organisational care that could have been better.	
Room for improvement: aspects of both clinical and organisational care that could have been better.	
Unsatisfactory: Several aspects of clinical and/or organisational care that were well below that you would accept from yourself, your trainees and your institution.	RCP3 RCP4 RCP6 RCP8 RCP9 RCP11 RCP12 RCP14 RCP15 RCP16 RCP17 RCP18 RCP19 RCP20 RCP22 RCP23 RCP25 RCP26
Insufficient information available to assess quality of care	

Index cases: RCP14, RCP15, RCP16, RCP17, RCP18, RCP19, RCP20, RCP21, RCP22, RCP23, RCP24, RCP25, RCP26 *(RCP21 – no ERCP took place; excluded from review)*

8.4 Appendix 4: Glossary

A	Acute pancreatitis	Acute pancreatitis is a condition where the pancreas becomes inflamed (swollen) over a short period of time https://www.nhs.uk/conditions/acute-pancreatitis/
	Acinarization	Acinarization occurs when the volume of contrast material injected into the pancreatic duct exceeds the ductal capacity
	Apixaban	Apixaban is an anti-coagulation medicine to prevent blood clots
B	Basket impaction	ERCP can remove large stones from a common bile duct. Steps include cutting the sphincter or sphincterotomy. Where stones are too big to pass through the sphincter one approach is to capture the stones in a wire metal basket, which is on the end of a long wire passed through the scope, into the bile duct via the sphincter. Some baskets can be attached to a device known as a lithotripter, which exerts pressure on the basket, squeezing and closing the basket. As gall stones can be semisolid or pliable, the basket can sink into the body of the stone and become impacted on it, which is known as basket impaction. When this happens, specialist equipment is used to cause the basket to fragment to enable it to be retrieved.
C	Cannulation	Cannulation is a process by which a small plastic tube (a cannula) is inserted into a peripheral vein
	CBD	Common bile duct
	Cholangitis	Cholangitis is inflammation of the bile duct system
	Consent form 1	Consent form 1 captures a patient's agreement to investigation or treatment
	Consent form 4	Consent form 4 is used for adults who lack the capacity to consent to investigation or treatment
	CT	Computerised tomography scan https://www.nhs.uk/conditions/ct-scan/
D	Datix	Web-based incident reporting and risk management software
	Diclofenac	Diclofenac is a non-steroidal anti-inflammatory medication
E	Endoscope	An endoscope is a long, thin flexible tube with a camera at the end) is passed through the mouth down to where the bile duct opens into the small intestine
	EUS	Endoscopic ultrasound (EUS) combines endoscopy and ultrasound to diagnose and treat a range of gastrointestinal problems
F	FBC	Full blood count
G	Gastrointetinal perforation	Gastrointestinal perforation occurs when a hole forms all the way through the stomach, large bowel, or small intestine.
H		
I	INR	INR is a blood test to measure how long it takes the blood to clot.
J		
K		
L		
M	MRCP	Magnetic resonance cholangiopancreatography (MRCP) is a type of magnetic resonance imaging (MRI) exam that produces detailed images of the hepatobiliary and pancreatic systems
N	NEWS	NEWS is a tool developed by the Royal College of Physicians to improve the detection and response to clinical deterioration in adult patients. In December 2017, an updated version of NEWS, NEWS2 was published.
O		
P	PEP	Post-ERCP pancreatitis. Pancreatitis is inflammation of the pancreas

	Prophylaxis	Treatments or approaches to preventing the spread or occurrence of disease or infection
Q		
R		
S	Septicaemia	Septicaemia describes blood poisoning or serious bloodstream infection
	Sigmoidoscopy	A sigmoidoscopy is a diagnostic test to check the lower part of the colon or large intestine
	Sphincterotomy	Sphincterotomy involves cutting the muscle that surrounds the opening of the ducts, or the papilla, using a small wire on a specialised catheter with electric current to cut the tissue.
	Stent	A small tube. In the case of ERCP, the stent is placed in the bile duct to facilitate stone removal or other therapies
T		
U	U&E	Urea and electrolytes, to assess kidney (renal) function and electrolyte balance
V		
W	Warfarin	Warfarin is an anticoagulant used to prevent blood clots. The most common side effect of warfarin is bleeding more easily than normal, and patients require a blood test every 12 weeks to check that they are taking the correct dose of warfarin (the blood test is called the internal normalised ration (INR))
X		
Y		
Z		

8.5 Appendix 5: Letter summarising initial feedback dated 21 July 2022

Dr Callum Gardner FRCP
Medical director
The Rotherham NHS Foundation Trust

BY EMAIL ONLY

PRIVATE AND CONFIDENTIAL

21 July 2022

Dear Dr Gardner,

Royal College of Physicians: The Rotherham NHS Foundation Trust, ERCP service

I am writing to confirm the immediate feedback that was provided to you, Dr Richard Jenkins, interim chief executive, and colleagues, by the review team on 8 July 2022, the final day of the invited review of the Trust's ERCP service.

The review team gathered a substantial amount of information from the interviews and the documentation provided and is now considering this against the agreed terms of reference. The review team summarises its immediate feedback as follows:

1. **To undertake a clinical review of 26 case records of patients[39] who received ERCP between July 2019 to July 2021, to gain an understanding of the pathways and protocols in action.**

During June 2022, in advance of the interviews held with Trust staff, the review team undertook structured judgment review of the 26 case records. The approach taken to this element of the review was described at the feedback meeting and will be explained fully in the review report. One of the index cases had been coded as having an ERCP, however the procedure had not taken place, so this case was excluded from the clinical case record review. The review team's overall ratings for the quality of care provided in the remaining 25 cases were as follows:

- 7 were graded "room for improvement" for clinical reasons
- 18 were graded "unsatisfactory"
- 0 were graded "good practice", "room for improvement" for organisational reasons, or "room for improvement" for both clinical and organisational reasons
- **11 of the 12 index cases reviewed were found to be unsatisfactory**. These index cases included patients who had died following an ERCP and other patient who suffered significant complications. The unsatisfactory grading reflected that several aspects of clinical care were well below what the review team would expect. Only one of the index cases received a different grading, which was room for improvement for clinical reasons.
- **Seven of the 13 cases selected randomly were found to be unsatisfactory**. The remaining six were graded room for improvement for clinical reasons. It is notable that none of the cases selected

[39] 13 index cases and 13 cases selected randomly

randomly were found to constitute good practice. No organisational issues were identified from review of the clinical records.

Several themes emerged from review of the case records, highlighted in our feedback as follows:

Consent:

- ERCP carries a high risk for morbidity and mortality. Gradings of poor or very poor care with respect to consent tended to reflect a lack of documented meaningful discussion by the clinical endoscopist performing the procedure, with the patient, regarding the risks of the ERCP specific to the individual patient, as detailed in the GMC's guidance on consent. The clinical endoscopist's handwriting was often difficult to decipher, making it hard for the review team to establish the exact risks highlighted. A recurring theme related to the patient's capacity to provide informed consent, in the absence of evidence of a capacity assessment. Consent was often taken in the endoscopy suite, immediately prior to the ERCP and the review team was concerned this could create pressure on the patient to consent to the procedure without having time to properly consider the risks.

8.5.1 Undertaking the ERCP procedure:

- The review team observed several deficiencies in the ERCP reports completed by the clinical endoscopist, including insufficient detail to explain the approach taken and the rationale for this. Such details are important to understanding the risk of post-procedural complications. The procedural approach was often badly described, making it difficult for the review team to understand the exact nature of the procedure. Some ERCP reports failed to reference that a previous ERCP had taken place or make clear how the subsequent ERCP sought to build on previous therapeutic approaches. Radiological documentation of the procedure was often of a poor standard. There was no documentation across the cases to indicate that prophylactic approaches were used to reduce the risk of pancreatitis. In several cases, the review team expressed concern regarding stent choice.
- An ERCP often requires more sedation than for other endoscopic procedures, however a recurring theme was the excessive amount of sedative the clinical endoscopist used.
- The lack of detail contained in some ERCP reports surrounding procedural complications indicated a concerning lack of transparency.

8.5.2 Recovery following the ERCP:

- The review team raised concern that many of the patients in the cohort reviewed were discharged too quickly after the ERCP. This was compounded in some instances by a lack of responsiveness from the clinical endoscopist to nursing concerns regarding patients post ERCP with deteriorating observations.

8.5.3 Communication with colleagues:

- There was limited evidence across the 25 cases of any meaningful multidisciplinary discussion. There was a lack of documented communication between the clinical endoscopist and colleagues, including, for example, regarding whether surgical options should be considered. A lack of documented communication was also thought to undermine management of complications.

8.5.4 Interactions with patients and their families:

- The review team observed good interactions across several cases between ward staff and patients and family members. The same applied to interactions with intensive care staff. Good practice along these lines was not identified from the records with respect to the ERCP procedure and there was a lack of evidence of interactions by the clinical endoscopist with patients. In several cases, there was no documented communication by the clinical endoscopist when the patient

deteriorated, and complications occurred. Moreover, the review team observed an apparent lack of transparency regarding complications. Several cases gave rise to concern that the clinical endoscopist had not provided a clear explanation to the patient or family members about complications and in some instances the review team questioned whether the lack of transparency might indicate probity issues.

8.5.5 Clinical record keeping:

- The review team identified a range of deficiencies in the case records, including:
  - the absence of documentation articulating clinical decision making (or who the key decision maker was) regarding plans for the patient
  - inconsistencies between the ERCP report and other entries in the patient record, including over the levels of sedation used and whether a sphincterotomy had taken place
  - a lack of transparency regarding the completeness of the procedure or failure to reflect the actuality of the procedure
  - omissions in the ERCP report or reference to previous ERCPs, or the absence of any documented entry by the clinical endoscopist relating to complications associated with the ERCP
  - imaging documentation of procedures was often of a poor standard.

The report of the review will identify the cases that underpin these themes and provide examples to explain the issues that were identified.

2. To review the current ERCP service design for the delivery of care, including protocols and pathways, facilities, links with other centres, capacity, activity and workload.

A previously mature ERCP service was withdrawn due to a lack of consultant gastroenterology staff. The solution to restore the service, created by [*a senior member of the surgical hierarchy*] and [*a senior clinician*], was to recruit a clinical (nurse) endoscopist into a unique and unprecedented role, by providing the ERCP service single- handedly, without a medical qualification. The appointment was contrary to existing BSG guidance on non- medical endoscopists (2005[40]). The supervision for this novel arrangement was provided by two surgical consultants, neither of whom were trained in ERCP.

Pressure to continue to provide an ERCP service at Rotherham has allowed the situation to continue despite a lack of clear leadership or robust clinical governance processes. It seems there has been an overemphasis on the continuation of the service over patient safety. For several years there has been no ERCP protocol or patient information sheet, although these omissions have recently been addressed.

The report of this review will make suggestions for a complete redesign of the ERCP service, with a move to a medically qualified, consultant-led service (such as by a suitably trained gastroenterologist, upper gastrointestinal or Hepato-Pancreato-Biliary (HPB) surgeon) that places emphasis on teamworking and peer review. The new ERCP service should strictly follow the BSG standards framework *The Way Forward* (2014[41]), which puts quality and patient safety at the heart of the service.

The Trust's strategic focus on partnership working with Barnsley Hospital NHS Foundation Trust, supported by Dr Jenkins role as Interim Chief Executive on a joint basis for both Trusts, offers to establish a sustainable and more clinically robust ERCP service.

[40] www.bsg.org.uk/wp-content/uploads/2019/12/Non-Medical-Endoscopists.pdf
[41] www.bsg.org.uk/clinical-resource/ercp-the-way-forward-a-standards-framework/

3. To review the quality of staffing and team working within the department and to give a view on whether this supports the delivery of high quality and safe care.

As the service was provided by a single clinical endoscopist, comments about his personality and behaviour featured widely in the interviews. Whilst the clinical endoscopist was regarded by some as being technically skilled and knowledgeable ("slick and quick"), the speed at which he worked and made decisions was also a cause for concern. Significant concerns were also expressed about a wide range of professional behaviours, many of which were felt to have had a highly negative impact both on team and collegial relationships, and on patient safety and quality of care. Concerning behaviours included the following:

- working outside professional boundaries and allegedly misrepresenting his position as a nurse consultant, causing patients and colleagues to be misled into believing he was a medical consultant.
- Undermining interactions with clinical colleagues performing interventional procedures, with a specific example of a lack of respect shown by the clinical endoscopist to a visiting gastroenterologist.
- Some nursing staff were said to be 'frightened' of losing their own professional registration if they continued to work alongside, or challenged, the clinical endoscopist.
- A lack of responsiveness by the clinical endoscopist to complications or concerns from nursing colleagues.
- The review team received accounts that the clinical endoscopist had been dismissive of the opinions of colleagues, resistant to following procedures and guidelines, reluctant to accept being managed by senior nurses, and reluctant to abandon clinical procedures despite patient distress or unsuitability to continue.
- There were reports that the clinical endoscopist had claimed to be eligible for levels of remuneration, or complex work patterns, in the absence of evidence of any contractual documentation to confirm such arrangements or how they aligned with the endoscopist's terms and conditions of service (Agenda for Change).
- The clinical endoscopist's excessive prescribing of sedatives for ERCP was felt by the review team to be outside the norms for prescribing sedatives, particularly for older, frail patients.
- The clinical endoscopist described himself as a national accreditor and trainer; the review team found these descriptors to be misleading.

Oversight arrangements for the clinical endoscopist as an ERCP operator have been inadequate. The clinical endoscopist was line managed by the nursing hierarchy, with clinical accountability to two general surgeons (neither of whom performed ERCP). This has clearly been a challenging situation for nursing managers, who have been thwarted in overseeing his performance by a lack of understanding of ERCP. This created an over-reliance on general surgeons to oversee the clinical practice of the endoscopist. These surgeons were said repeatedly to have given assurances that there were no problems, despite being ill-equipped to provide such assurance. The review team has not received evidence of any appraisal documentation and was informed that the most recent appraisal of the clinical endoscopist took place in 2019.

The clinical endoscopist had clinical responsibilities at other hospitals: The Christie NHS Foundation Trust (every Monday), and North Lincolnshire and Goole NHS Foundation (with hospitals in Grimsby, Scunthorpe and Goole). It was not evident that there was any oversight or governance of the clinical endoscopist's activities outside of his employing Trust.

The clinical endoscopist was regarded as aligned with, and heavily supported by, the general surgery team. The review team received accounts suggesting there had been a closing of ranks, and failure to recognise what was happening to patients because of the clinical endoscopist's approach. The extent to which

surgical colleagues supported the clinical endoscopist proved a significant challenge for senior management. Interviewees described a very defensive response from the surgeons which posed a significant barrier to addressing the concerns about the clinical endoscopist's practice.

A new senior leadership team has increased attention on governance and quality improvement. This new team appears to have a good grasp of the issues requiring attention and have plans to undertake cultural work within the division. It is disappointing that the team has met with hostility in trying to re-focus the division more firmly on patient safety.

4. To review the quality of clinical governance arrangements currently in place to support and maintain oversight of the service.

The review team did not receive any evidence to demonstrate robust governance arrangements for the ERCP service. The review team was informed that there had been little administrative support for the governance programme, however the review of cases where patients had come to harm was threadbare, with insufficient evidence to demonstrate learning from incidents. Attendance at departmental clinical governance meetings and the endoscopy user group was reported to have been inconsistent, and relevant clinical practitioners were said to be absent from many morbidity and mortality discussions.

The report of the review will suggest audits that the Trust can undertake to better understand morbidity and mortality associated with ERCP, to provide a dataset that can be monitored over time.

5. Highlight any new area of concern that arises during the ISR.

The governance and oversight of the ERCP service provided by the general surgical team was wholly inadequate. It has raised issues over the governance of the general surgery service and the reporting of incidents, and it is something we feel the Trust should consider further.

Immediate recommendations for patient safety

- The review team has concluded that the isolated practice by a clinical (nurse) endoscopist has not provided for high standards of performance and safety and has instead resulted in a high complication rate for ERCP. Therefore, in line with BSG guidance, the clinical endoscopist should not undertake ERCP in any healthcare institution that provides an ERCP service. The unusual circumstances of a nurse providing interventionist procedures raises the question over whether contact should be made with the Trust's GMC Employer Liaison Advisor, in the absence of equivalent mechanisms for nurse consultants providing therapeutic interventions. The Trust should inform relevant institutions of the concerns raised by this review, to enable them to consider the relevance of the findings to the clinical endoscopist's wider practice.

- The behaviour and performance of the clinical endoscopist suggests that his wider endoscopic practice should be considered further by the Trust. This should include:

    - Review of all ERCP cases performed by the clinical endoscopist between 2017 and suspension of the service (excluding the cases already reviewed), where the patient suffered a potential complication (including post-ERCP pancreatitis (PEP), infection, bleeding, allergic reaction to the sedation or dye, and perforation in the small bowel), as well as all deaths within 30 days of ERCP, to determine whether the ERCP procedure was in line with good practice, and whether the complication was avoidable. The RCP/BSG may be able to assist with this review, if required.

  - Audit of non-ERCP therapeutic interventions undertaken by the clinical endoscopist (for example, ureteric stenting) and all relevant hospitals where these interventions took place. These other interventions should be evaluated against appropriate benchmarks.

- There is sufficient concern within the clinical case review to advise the Trust to re-refer the clinical endoscopist to the NMC for his clinical decision making, conduct and competence.

I hope this letter is clear and helpful in summarising the review team's immediate feedback on these matters at the conclusion of the review visit. The team will now work to prepare and finalise the invited service review report, which will be sent to you as soon as possible.

Yours sincerely,

[*Name redacted*]
Medical Director for Invited Reviews

26 July 2024

Case review of deaths following ERCP in Rotherham General Hospital

Dr John Painter, FRCP

GMC 3286908

Background:

ERCP is an interventional therapeutic endoscopic procedure, there is virtually no clinical justification for a diagnostic ERCP, due to high quality MRCP and CT scan provision.

ERCP is recognised as a high risk therapeutic endoscopic procedure. JAG (Joint Advisory Group for GI endoscopy) training and certification pathway document 2020 quotes risks of complications between 10% and 14%, and risk of death between 0.1% and 1%.

GIRFT Gastroenterology document published March 2021 quoted 30-day all cause mortality following ERCP to be on average 4.2%, range 0% to 8.5%.

Such complication rates are significantly higher than many surgical procedures, such as cholecystectomy.

Many clinicians not directly involved in the provision of ERCPs are unaware of the relative high risks of ERCP, and most are unaware of the surgical alternatives.

Clinical decision making regarding the indication and appropriateness of ERCP can be complex, and requires detailed knowledge of HPB cancer pathways, and detailed knowledge of surgical alternatives for benign biliary disease, especially for common bile duct (CBD) stones.

Many patients are frail and elderly, and careful holistic consideration is required to decide if proceeding with ERCP is their best clinical interests, requiring careful clinical consideration, clear considered communication with patients, and with their next of kin in patients who lack capacity to consent.

17 case reviews were undertaken by Dr John Painter, FRCP, Consultant Gastroenterologist & GIM physician, South Tyneside & Sunderland NHS FT, in post since 01 June 2000.

Dr Painter is Clinical Director for the General Internal Medicine directorate, and Clinical Director for the South of Tyne Bowel Cancer Screening Centre.

Dr Painter performs advanced therapeutic endoscopic procedures, including ERCPs in his trust, mainly situated on the Sunderland Royal Hospital site.

Methodology:

The case review was undertaken with access to the paper medical records for each patient, to the electronic patient record for 16 patients in Meditec, and with access to the electronic endoscopy records, and with access to the electronic radiology records, to access scan results, films for cholangiograms and other radiological investigations.

I set of notes had been lost due to flood damage.

The 17 cases were selected by Rotherham General Hospital, following concerns regarding the perceived incidence of deaths following ERCP, all performed by a specific consultant nurse endoscopist.

The 17 cases represented patients who died shortly after an ERCP, performed by the specific consultant nurse endoscopist.

No other cases were reviewed.

The cases were performed November 2016 and April 2021.

Deaths associated with ERCP:

Deaths directly related to ERCP – 3

2 deaths due to post-ERCP pancreatitis ([redacted]), both cases were discussed with the coroner's office. The latter case is a concern as the pancreatitis was attributed to pancreatic cancer, which is far less likely than being due to the ERCP. This was overlooked on stage 1 & 2 mortality review. The coroner's office decided no need for formal inquests.

1 death due to post-sphincterotomy bleed ([redacted]), transferred to Sheffield, referred to Sheffield coroner, . The outcome of coroner's inquest stated death due to 1a Upper GI haemorrhage, 1b Sphincterotomy for gallstone impaction, 2 Old age and frailty, AF treated with Apixaban

This is a recognised complication of ERCP, it was managed as quickly as possible after re-admission to hospital, rapid transfer to Sheffield regional centre, endoscopic therapy undertaken in Sheffield to stop the bleeding, but unfortunately the patient suffered a cardiac arrest after the procedure and did not survive. The recognition of the complication and intervention were all timely and appropriate, and there is nothing obvious more that could have been done to change the eventual clinical outcome.

Deaths possibly directly related to ERCP – 2

3 deaths shortly after ERCP, 1-3 days ([redacted]), all cases were discussed with the coroner's office. In two cases ([redacted]) the death was not felt to be directly related to the ERCP.

[redacted], case discussed with the coroner's office as the patient died overnight following the ERCP procedure. No inquest was felt to be necessary and the coroner's office agreed for the hospital to release the death certificate. The agreed cause of death was 1a Biliary sepsis, 1b ERCP, 2 Diabetes Mellitus, Hypertension, Myocardial infarction. It remains unclear why ERCP was undertaken as imaging prior to the ERCP showed no clear bile duct pathology.

1 death from biliary sepsis after ERCP ([redacted]) - ERCP reported stones in cystic duct, stent placed in cystic duct, ERCP reported stone in CBD but no stent placed in CBD, after the procedure increasing jaundice and sepsis and died. Unclear if sepsis exacerbated by the ERCP, if the failure to place a CBD stent contributed to increased sepsis, another possibility is that ERCP report was inaccurate and the stent was placed in the CBD, rather than the cystic duct.

Deaths not directly related to ERCP – 12

7 deaths were related to incurable cancer, progression of disease ([redacted]).

5 cases were related to progression of benign disease and frailty ([redacted])

Deaths discussed with the coroner's office, in whom death not directly related to the ERCP procedure - 2

[redacted], case was discussed with the local coroner's office, who felt that no inquest was required and agreed for the hospital to release the death certificate. The agreed cause of death was 1a Cholangiocarcinoma, portal vein thrombosis. The patient died 2 days after the ERCP and insertion of biliary stent to relieve jaundice from the cholangiocarcinoma. There was no clinical evidence of sepsis or pancreatitis or bleeding recorded. Therefore, the subsequent cardiac arrest and death appear to be directly related to the underlying cholangiocarcinoma and portal vein thrombosis.

[redacted], CBD stone cleared during ERCP, clear duct at the end of the procedure. Unfortunately, the patient died of continued biliary sepsis unresponsive to antibiotic and supportive therapy. Case

discussed with the coroner's office, who were content for a death certificate to be released by the hospital. The agreed cause of death was 1a Biliary sepsis, 1b CBD stone.

Comments regarding deaths:

Overall, the known 3 cases of death directly related to ERCP are recognised risks and complications of ERCP.

There are a further 2 cases where the deaths could have been directly linked to the ERCPs, both deaths were due to biliary sepsis.

It is unknown if the rate of death following ERCP is significantly elevated or not, based on these case reviews.

Good clinical governance requires annual recording and review of all deaths related to endoscopic procedures, including ERCP. Such a review performed annually would enable the clinical service to know if there is a true excess in deaths directly related to ERCP, or not, and whether related to any individual ERCP endoscopist.

Continuous annual audit would enable trends to become clear, to see if any potential concerns are real over time, or just statistical variation over time. Continuous audit would facilitate the opportunity to learn lessons for future cases, helping to safeguard both patients and clinicians.

Ideally this should be engrained in the departmental and trust culture and governance procedures.

Indication for ERCP:

Clear indication to consider performing ERCP in 14 patients, in 2 cases concern regarding clinical decision to perform ERCP, 1 case clear indication to consider ERCP, but debateable if a wise holistic clinical decision.

[redacted], patient with pancreatic cancer on CT, jaundice, bilirubin 148 on the day of ERCP. An alternative choice would have been to refer for consideration of fast track HPB surgery as bilirubin below 200, European guidance suggests consider surgery if bilirubin less than 300. No record of discussion with regional HPB cancer surgical team to see if this was a viable option for the patient.

Subsequent MDT reported radiological staging of pancreatic cancer as T2N0M0, so potentially curable disease and for consideration of surgical resection.

Patient died of pancreatitis shortly after ERCP. According to the medical notes, discussed with coroner, and allegedly death attributed to pancreatitis related to the pancreatic cancer – however

far more likely that the pancreatitis was caused by the ERCP procedure – this was not highlighted in the internal stage 1 &2 mortality reviews.

So unfortunately, a patient with potentially curable pancreatic cancer died following ERCP, with no record of consideration of fast track HPB surgery, to avoid the risks of ERCP.

[redacted], patient presented with jaundice, mild delirium with documented retained capacity to consent. Previous ERCPs [redacted] showed no CBD stones. US and CT scans showed mild biliary dilatation, but no stones and no obstructive lesion seen. Bilirubin rising, surgical ward team placed on ERCP list. No clear involvement of the ERCP endoscopist in case selection.

Unclear why listed for ERCP in this circumstance. ERCP showed no stones or stricture, plastic biliary stent inserted in the hope of offering some benefit, not clearly indicated. Patient died overnight following the procedure. The case was discussed with the coroner's office, it was felt that no inquest was required and the coroner's office agreed for the hospital to release the death certificate. The agreed cause of death was 1a Biliary sepsis, 1b ERCP, 2 Diabetes Mellitus, Hypertension, Myocardial infarction.

This was a high risk procedure in frail elderly patient, unclear why the ERCP was performed when the imaging showed no bile duct pathology. It remains open to speculation as to whether the chances of survival would have been greater if the ERCP had not been performed, whether the added stress of the ERCP contributed to his mortality. It is unknown if the patient would have survived or not if treatment consisted of antibiotic therapy and supportive care only. The patient was very frail so there was always a high risk of death even if ERCP not undertaken.

[redacted], frail elderly patient admitted with likely biliary sepsis, no jaundice, US and MRCP suggested small CBD stones. ERCP should be considered in this situation, however, patient very frail, bed bound, appeared stable on antibiotics. Required form 4 consent, appears to have been done by the ward junior doctors. Ward team appear to have listed for ERCP, unclear if ERCP endoscopist actively involved in the clinical decision making. No-one appears to have considered the small stones could pass by themselves, and doing nothing other than supportive care with antibiotics might be the correct level of intervention, and all that was needed. Overall a high risk procedure in a very frail patient.

ERCP performed, no CBD stones found according to the ERCP report, the stones appeared to have already passed spontaneously. Patient developed post-ERCP pancreatitis and died from this.

Comments regarding indication for ERCP:

Throughout the case review, there is very little recorded information of the ERCP endoscopist being directly involved in case selection and determining if the clinical indication to perform ERCP was justified. In a few of the medical records, there is reference to emails between the ward teams (both medical and surgical) and the ERCP endoscopist, but no record of their content, no clear record of what the nature of the emails were.

The impression is that in many cases the clinical decision to perform ERCP was driven by the junior doctor staff on the wards, and to a lesser extent by the consultant staff on the wards, and unclear if ever the ERCP endoscopist.

It is unclear what medical experience and qualifications and expertise was of such junior and senior doctors in relation to understanding the indication for, the limitation of, the alternatives to, and the risks of performing ERCP.

For the purposes of this clinical case review, it is unclear what the professional qualification, clinical experience and clinical expertise was of the consultant nurse endoscopist providing this ERCP service.

It is unclear if the consultant nurse endoscopist had full knowledge and experience to comment on the alternative approaches to biliary disease, such as no intervention, such as watch and wait, such as alternative surgical approaches.

It is unclear who was responsible, namely ward teams or the ERCP endoscopist, to decide if ERCP should go ahead in each clinical case, and who was responsible to clearly determine if the ERCP was indicated, whether all Montgomery principles were accommodated – clearly consider all clinical alternatives, such as no intervention (too frail or watch and wait strategy with repeat imaging for small stones), such as alternative surgical CBD exploration for selected CBD stone disease, such as fast track referral for consideration of surgical resection in patients with potentially curable cancer and lower levels of jaundice.

It is unclear what the professional expectations were between the various ward teams (both medical and surgical), as to the role of the consultant nurse ERCP endoscopist – it is unclear as to who was the senior clinical decision maker, it is unclear if decisions made collegiately, and if so how, and there are no clear records of alternatives being discussed with the patients, or their next of kin.

There are inconsistent records regarding delirium, dementia and capacity to consent in many of the patients. There is no clear record found of clinical assessments of capacity to consent and junior doctors have completed a number of form 4 consent forms. This is not compliant with national best clinical practice guidance to comply with the requirements of the Mental Capacity Act.

ERCP consent:

In most cases there is no clear medical record of direct involvement of the ERCP endoscopist before the procedure, and not all consent forms have the signature of the ERCP endoscopist.

For clinicians undertaking the consent procedure on the wards, one must assume the vast majority of them, if not all of them, do not perform ERCP. Therefore, to comply with national guidance, they would all require formal bespoke training in ERCP consent to perform this.

Such bespoke consent training would need to include understanding indications, alternatives, potential risks, as well as potential benefits, in line with Montgomery principles. There should be a clear governance record of such consent training for all such clinicians.

This would need to be engrained in the departmental and trust clinical governance procedures.

Ideally, active clinical involvement / review of the patient would be undertaken by a practising ERCP endoscopist before the procedure. Ideally, consent for ERCP would be undertaken by an ERCP endoscopist in person.

There are inconsistent records regarding delirium, dementia and capacity to consent in many of the patients. There is no clear record found of clinical assessments of capacity to consent and junior doctors have completed a number of form 4 consent forms. This is not compliant with national best clinical practice guidance to comply with the requirements of the Mental Capacity Act.

ERCP sedation:

In 15 cases, sedation was clearly recorded as being in line with BSG (British Society of Gastroenterology) and JAG (Joint Advisory Group for GI endoscopy) national clinical guidance.

This guidance states that the median dose of midazolam should be no more than 2.0mg in patients aged over 70, and the median dose of fentanyl should not be over 100mcg in patients over 70.

Please note this is median dose and not maximum dose, as often mis-quoted.

In 2 cases, [redacted], the recorded dose of midazolam was 5mg and 3.5mg respectively, and the dose of fentanyl was 100mcg in the first case. There is no clear reason documented for this, as would be good clinical practice. There may well have been good clinical reason to give such doses, possibly given sequentially depending on patient response to initial dose, and dependent on the course of the procedure – but no clinical documentation to record such.

There is no evidence found in the medical or nursing notes to suggest the patients came to any harm from these doses of sedation used.

Comments regarding sedation:

Overall, this case review supports good compliance with the national BSG & JAG clinical guidance regarding the use of sedation. However, this is a very small audit. The clinical documentation needs improving when higher doses used, to record the individual circumstances and clinical justification.

BSG and JAG expect sedation use and dosage should be routinely audited on annual basis for all endoscopic procedures, including ERCP, to ensure good and safe clinical practice by all endoscopists, in line with the national clinical guidance. This should be part of the annual audit cycle for the endoscopy department, as part of their national JAG accreditation requirements.

ERCP technique:

Limited comments can be made regarding technique as this would require direct observation to be more informative.

However, a number of concerns came to light from the case review.

The reporting of the cholangiogram was not always done or clear, and was often lacking in detail. As happens, not all cholangiogram films appear to have been saved to document good positioning of biliary stents etc.

It is unclear if the trust expectation was for the consultant nurse endoscopist to provide the detailed reporting of the cholangiograms or not. This varies in different trusts.

In many trusts, the cholangiograms (static films) are formally reported later by consultant radiologists.

Three cases highlighted debateable use of biliary stents.

[redacted] – ERCP report states a fully covered metal biliary stent was inserted in a patient with incurable metastatic cancer, usual practice would be to insert a partially covered metal stent to reduce the risk of later stent migration. This decision had no actual impact on the patient in question.

[redacted] – ERCP reports stones seen in cystic duct and CBD, not all stones retrieved, plastic stent placed in cystic duct, no stent placed in CBD. Usual practice would be to place plastic stent in CBD to reduce the risk of further jaundice and sepsis. Patient very frail and died subsequently of sepsis. It is unclear if placement of a CBD stent would have helped reduce the risk of death from biliary sepsis, or even if the failure to place a CBD stent increased the risk of death from undrained biliary sepsis. There is a possibility there is a typo in the ERCP report, and the plastic stent was in fact placed in the CBD. This remains open to speculation.

[redacted] – ERCP reported no CBD stones and no stricture seen, but despite this, a plastic biliary stent was placed. It is unclear why, it is unclear what the clinical rationale was at the time, no clear record of the justification for this clinical decision. The patient subsequently died; case referred to the local coroner. The outcome of the coroner review is unknown, so unclear as to the cause of death, and whether the ERCP contributed to this or not, and whether the insertion of the plastic biliary stent contributed to this or not. This is open to speculation.

Additional holistic care comments:

The ERCP endoscopist was not clearly involved in clinical decisions regarding anti-platelet and anticoagulation therapy.

It is unclear if the nurse consultant ERCP endoscopist was clinically qualified to make holistic balanced clinical decisions regarding the relative risks of ceasing anti-platelet and anticoagulation therapy before ERCP, and to determine the timing of recommencement after the procedure, taking into account each individual patient's comorbidities.

There was (and still is) BSG guidance available to support individualised clinical decision making.

The timing of recommencement of anti-platelet and anticoagulation therapy after any therapeutic endoscopic procedure is dependent on the actual therapy undertaken, and any potential procedural bleeding.

There was a clear absence of any clinical advice given by the ERCP endoscopist regarding the timing of recommencement of anti-platelet and anticoagulation therapy after the ERCPs. These clinical decisions appeared to be taken by the junior medical staff on the wards, with no clear senior support documented.

[redacted] – ERCP performed with no record of Clopidogrel medication being stopped or considered being stopped ahead of the procedure – in 2019 national clinical BSG guidance available at that time suggested discontinuation 5 days before the procedure to minimise the risk of peri and post-procedural haemorrhage. This had no actual clinical impact on this individual patient, who died subsequently of an aspiration pneumonia.

Conclusion comments:

The case reviews did highlight significant concerns regarding the delivery of the ERCP service, raising concerns about consent process, case selection, consideration of alternative approaches, unclear who were / are the senior clinical decision makers. There was no consistent compliance with the Mental Capacity Act for assessment and consent approach for patients who lacked capacity to consent.

It is unclear as to the scope of expected clinical practice of the nurse consultant ERCP endoscopist, and whether clinically qualified to comment on alternative treatment options, whether clinically qualified to guide holistic care in terms of not performing procedures, and giving clinical guidance regarding anti-platelet and anticoagulation therapy.

The case reviews showed no prolific questionable clinical practice, most practice was within expected clinical variation.

Departmental and trust wide clinical governance culture and expectations should have ensured annual continuous audit to monitor complication rates and mortality rates for all endoscopic procedures performed by all endoscopists, which would have potentially demonstrated if any real concern regarding mortality rates, when compared to published JAG and recent GIRFT documents quoting national experience and expectation.

The three deaths clearly directly related to ERCP are all recognised potential complications, and individually do not raise any significant concern.

There are four deaths referred to the coroner, the cause of deaths not available for this review, and so no comment can be made if there are any individual clinical concerns arising regarding causality related to the ERCP procedures.

If any further comments are needed, please let me know.

Dr John Painter

Consultant Gastroenterologist

GMC number 3286908

Independent Review of

ERCP practice

At

The Rotherham NHS Foundation Trust

2017-2021

Addendum to Expert Report (dated February 2024)

Dr Jeremy Woodward MA MB BChir FRCP PhD

Consultant Gastroenterologist

Department of Gastroenterology and Clinical Nutrition,

Box 133, Addenbrooke's Hospital, Hills Road

Cambridge CB2 0QQ

Prepared at the request of Ms Angela Wendzicha, Director of Corporate Affairs, The Rotherham NHS Foundation Trust

CONTENTS

Appendices:

1 Updated summary of findings

1.01 I was instructed to carry out a review of 27 individual cases where complications may have arisen as a result of ERCP procedures performed by a consultant nurse endoscopist between 2107 and the suspension of the service in 2021. A further three cases were subsequently identified which are the subject of this addendum to the report that I issued in February 2024. **I have combined the summary of the findings of all the cases in this section.**

1.03 Of the 30 identified cases (between the initial and addendum reports), twenty-eight sets of patient records were available, one of whom did not undergo ERCP. My review is therefore of 27 patients who underwent 47 separate ERCP procedures, including six who underwent two procedures, five who underwent three procedures and one who underwent five separate ERCPs.

1.04 I was able to identify nine individuals who appeared to have experienced complications directly arising from the ERCP procedure including five instances of post ERCP pancreatitis, two perforations and two instances of biliary sepsis, as well as one case in the current addendum where advice regarding stent duration may have contributed to episodes of biliary sepsis. One of the cases of biliary sepsis was fatal and attributable in my opinion to leaving the duct inadequately drained over an 8-month period. One of the perforations occurred in a frail elderly female who was sent home despite feeling unwell after the procedure with inadequate observations having been carried out, and the complication was not detected until the following day.

1.05 I was able to identify instances that I consider to constitute unsafe practice – in one case the use of a very high dose (200mcg) of fentanyl in an 80-year old female prior to commencing the procedure in order to reduce her blood pressure, and in another case where a sphincterotomy was carried out on a patient who had only stopped clopidogrel three days earlier, rather than the recommended 5-7 days by BSG guidelines.

1.06 It appeared to me that the practitioner condoned the use of long-term plastic stents in patients where he had failed to clear the bile duct of stones which is considered unsafe practice except in very frail patients near the end of life. Explant dates for stents were not given and potentially led to further complications.

1.07 There was no documentation to suggest that the practitioner considered the risk of post ERCP pancreatitis or provided patients with pre-procedure prophylaxis and in a number of cases the pancreatic duct was inadvertently cannulated but not stented. Prophylactic measures to prevent or reduce the severity of post procedure pancreatitis have been recommended in guidelines since 2014 and were standard practice at the time of the ERCPs carried out in this review. The apparent failure to have instituted this practice would therefore fall below an acceptable standard.

1.08 In two cases the indication for ERCP was not clear – in neither case did a complication occur. In one case in the **current addendum report** I considered an ERCP procedure not to have been indicated. There was also an attempt to cannulate and stent a pancreatic duct in a patient with

necrotizing pancreatitis. The reason for this was unclear and not recommended by guidelines as it could increase the risk to the patient.

1.09 Although ERCP generally requires high doses of sedation, in the cases reviewed doses were often very high for the age and condition of the patient. There were two patients who required reversal agents and others who experienced hypoxia in the recovery area who did not receive reversal agents. In two cases where the endoscopist was unable to intubate the duodenum (and therefore failed early in the procedure) 100mcg fentanyl was given – and must therefore been given as a large bolus prior to commencing rather than titrating up during the procedure. One of these was an elderly female.

1.10 The majority of patients were given Buscopan at either 20mg or 40mg with no apparent regard to underlying cardiovascular risk, including in the two cases where the endoscopist was unable to reach the duodenum to know whether or not it was actually required (for papillary visualization and cannulation). **In the current addendum report**, one patient received 100mg buscopan but without evidence of adverse effects. In light of MHRA advice, I consider this to constitute unsafe practice.

1.11 The standard of documentation of consent was very poor – consent forms frequently being undated or even unsigned by the endoscopist – and often poorly legible. Whilst there is no evidence on which to assess the quality of discussion with the patient prior to signing the consent form, the poor standard of documentation suggests that there may have been deficiencies in the process of gaining consent for the procedure.

1.12 The documentation of the procedure itself was also inadequate in the majority of cases – standard phrases apparently being used by the endoscopist without alteration, and details such as the means of accessing the duct, the type and dimensions of stents and explant dates from them were frequently omitted. Only in cases where there is a handwritten note by the nurse assisting the procedure (and in one case a 'sticky note' attached to the records) is there evidence of more detail. For instance, the use of a needle knife is not acknowledged in any procedure report by the endoscopist, but three times in the handwritten nurse records. Furthermore, the amount of sedation given during the procedure is frequently recorded differently in the nursing record and the endoscopist's formal report.

1.13 Given the poor standard of documentation (as noted above) by the endoscopist, it is unclear what other relevant details may have been omitted from the reports, especially where there is no handwritten addendum by the nurse assistant.

1.14 In thirteen cases bile duct stones were cleared at first ERCP, but in six cases there was a failure to do so and these patients underwent repeated procedures. BSG standards recommend that stones are cleared in >75% of cases at first ERCP. Given the potential skewed population of the selected cases in this review it is not possible to determine whether or not this standard has been reached. Nevertheless, in one case five ERCPs were required before the duct was cleared which is

inappropriate in my opinion, and in two cases patients were left with stones and stents in their ducts without further follow up as a result of several failures to clear the ducts. Whilst overall there is no evidence to suggest (possibly as a result of poor documentation) inadequate technical performance by the endoscopist, this failure to clear ducts of stones and leaving stents in place would raise this as a possibility.

1.15 The poor documentation may conversely make it difficult to identify good practice. I did notice two instances where practice could be considered good (in the identification of duodenitis and carrying out a CLO test, and in placing a stent rather than carrying out a sphincterotomy on a patient who was still taking clopidogrel).

1.16 Overall I classified 14 cases as 'room for improvement' (often on the basis of poor documentation) and 11 as 'unsatisfactory'. However, within these cases I found evidence of practice that I considered unsafe, and a failure to follow established national or international guidelines with regard to pancreatitis prophylaxis, use of sedation and Buscopan, use of long-term stents in patients with bile duct stones, and procedures in patients receiving antiplatelet agents.

1.17 In my opinion, the service appears to have been established with little understanding of the nature of ERCP which requires clinical decision making before, during and after the procedure, good feedback of complications and learning from careful audit of outcomes, rather than merely technical expertise. As a result, I consider it likely that patients and staff have been exposed to risk.

1.18 In view of my concerns about the appropriateness of the endoscopist's recommendations regarding stents, and in particular the apparent acceptance of long-term plastic stents in patients with residual ductal stones and the failure to recommend explant dates for stents, I suggest that an internal audit be carried out of patients who may still have 'forgotten' stents in place and be at risk of complications as a result. The evidence from the current review would suggest that this audit should extend to patients with metal stents and pancreatic stents placed as well as plastic stents used in patients with incomplete clearance of ductal stones.

2 Introduction

2.01 I am Dr Jeremy Mark Woodward. I am a consultant gastroenterologist at Addenbrooke's Hospital in Cambridge where I was appointed in July 2002. My Curriculum Vitae is included in the appendix. My experience relevant to this case is as follows:

I work as a consultant gastroenterologist in a busy tertiary referral centre with over 20 years of experience as a consultant. I was departmental lead for safety and governance from 2018 to 2022 and specialty lead from 2019 to 2022. I have practised independently in ERCP (endoscopic retrograde cholangio-pancreatography) as a consultant since July 2002 and have trained others in the procedure for approximately 20 years. I have developed a particular interest in pancreatic ERCP and duodenal polypectomy and I provide a regional service for papillectomy. The ERCP service in my Trust is also specialised as a result of being a liver and multivisceral transplant centre.

1.02 My medico legal experience is as follows: Cardiff University/Bond-Solon certificate as expert witness 2010, last update course attended July 2023. I have acted as expert witness in medical negligence (breach of duty and causation, condition and prognosis,) inquests, court of protection and personal injury. I do not select cases on the basis of defendant/claimant representation and the mix is approximately 60% for the claimant. My practice and experience is largely in England and Wales however I have read and I understand the Law Society of Scotland code of practice for expert witnesses and I keep up to date with Scottish case law where there are issues relating to expert evidence - I have acted as an expert witness in Scottish law.

1.03 This is an addendum to the advisory report provided by me in February 2024 as an independent review of the ERCP practice of one individual acting single-handedly at The Rotherham NHS Foundation Trust between 2016 and 2021 when the service was suspended. I have been instructed by Ms Angela Wendzicha, Director of Corporate Affairs at The Rotherham NHS Foundation Trust to review the records of 25 selected individuals who were readmitted or experienced complications following ERCP procedures carried out at the Trust between 2016 and 2021.

1.04 None of the individuals named in this report is known to me personally and I have no vested or conflicted interest in the outcome of this case.

3. Investigation

3.01 The following available documentation has been provided relevant to this case:

a) JAG (Joint Advisory Group on endoscopy) Accreditation report – assessment date 16/Jul/2021; report dated 02/Aug/2021

b) Royal College of Physicians invited service review, 13, 15/Jun/2022; 7,8/Jul 2022, report dated 25/Jan/2023

c) Medical records of 3 individuals from before and after undertaking ERCP procedures.

3.02 The procedures (and patients) selected for scrutiny in this report were those that had undergone ERCP at The Rotherham NHS Foundation Trust between 2017 and July 2021 and had complications and/or had been readmitted within 30 days of the procedure. Twenty-seven patients were originally identified of whom the records for 25 were provided for the purposes of the main report and three additional individuals were identified for the purpose of this addendum report.

3.03 Patients who died within 30 days of an ERCP procedure during the above time period (17 cases) were not included in the current review, these cases having been scrutinised previously.

4 Background to independent review

4.01 In 2015 the provision of an ERCP service in Rotherham Hospital collapsed due to loss of the consultant gastroenterologists, thought to have been due to regional service reconfigurations. The gastroenterology service was staffed by a succession of locum consultants who were not ERCP-trained. The endoscopy department came under the jurisdiction of the directorate of surgery.

4.02 Initially the ERCP service (amounting to 3-4 procedures a week) was run by a visiting endoscopist from Sheffield once a week. However, in 2016 a nurse endoscopist who had been trained in ERCP and other non-vascular interventional radiology procedures in Sheffield was appointed as a nurse consultant to run the service in Rotherham. The service was therefore single handed and supervised by two consultant surgeons, neither of whom carried out ERCP.

4.03 Apart from a break during 2017-2018, the ERCP service in Rotherham continued to be provided by the nurse endoscopist until the service was suspended in July 2021 following a cluster of adverse incidents related to ERCP procedures. During 2017-2018 and from July 2021, the service reverted back to Sheffield.

4.04 A JAG accreditation visit was carried out on 16/Jul/2021 and identified concerns regarding the ERCP service, recommending an independent review by the Royal College of Physicians (RCP). This was carried out in June and July 2022. The RCP invited review considered 13 cases of individuals who died or experienced significant complications after ERCP, and 13 randomly selected cases (every 5th case performed) between July 2019 and July 2021. The RCP invited review recommended that all ERCP cases between 2017 and July 2021 should be scrutinised where the patient suffered a potential complication (including post-ERCP pancreatitis, infection, bleeding, allergic reaction or perforation) as well as all deaths within 30 days of ERCP, in order to determine whether the ERCP procedure was in line with good practice and whether the complication was avoidable. This was the remit of the initial review that I reported in February 2024 and is the remit of the current addendum of three further cases.

5 Findings of the Joint Advisory Group on Endoscopy and the Royal College of Physicians external reviews

5.01 Please refer to my original report of February 2024.

6 Individual cases – summaries and comments

6.01 In providing my opinion of the quality of care provided during and around the ERCP procedures I will use the framework – where applicable – that was used by the RCP visit and the descriptors in the RCP report. The RCP report used structured judgement reviews as a part of a wider remit that included a site visit and interviews with staff to review the whole ERCP service and therefore encompasses some areas that are not pertinent to the current report which is based purely on review of individual case records.

6.02 [redacted] **(JMW26):** A [redacted]-year old female [redacted] who was admitted with acute cholecystitis in [redacted]. At laparoscopic cholecystectomy [redacted], a bile leak from the cystic duct required oversewing. On [redacted] she developed pain and fever secondary to a bile leak.

6.03 ERCP was attempted on [redacted] from 1534 hr to 1635 hr. The consent form is appropriately completed with notification of the potential risks and is signed by the endoscopist. The documentation notes that 5mg midazolam, 100mg Buscopan and 50mg pethidine were administered. The papilla was identified but neither the bile duct nor the pancreatic duct could be cannulated and a precut was made with a needle knife from which bile was seen to be oozing. A further attempt at ERCP was recommended.

6.04 Repeat ERCP was carried out on [redacted]. Again, the consent form is appropriately completed with notification of the potential risks and is signed by the endoscopist. 4mg midazolam, 60mg Buscopan and 75mcg fentanyl were administered. The duct was successfully cannulated and the sphincterotomy enlarged. Initially a 60mm stent and then an 80mm stent was placed to cover the cystic duct origin. Whilst the type of stent placed is not clear from the records, a photograph is present in the records that shows a fully covered metal stent in good position into the duodenum.

6.05 The patient made a subsequently uneventful recovery and returned for removal of the stent by gastroscopy on [redacted] which was carried out successfully with 3.5mg midazolam and 75mcg fentanyl.

6.06 **Comment:** In my opinion, both ERCPs were indicated and I am not critical of the initial failure to cannulate and stent the common bile duct. There appear to have been no issues with consent and the documentation of the procedures was adequate. The delay of over a week before the second procedure was suboptimal and will have contributed to this patient's length of stay, however with a single operator list this will have been unavoidable. Whilst it was probably unnecessary to change the 60mm stent for the 80mm stent (the purpose of stenting is to open up the sphincter rather than to cover the leak itself), I am not critical of the endoscopist for doing so.

6.07 As in previous cases, I am critical of the failure to prescribe or administer rectal NSAID suppository in order to prevent or reduce the severity of post procedural pancreatitis. However, this was without consequence in this case. The dose of Buscopan used was excessive – 100mg in the first attempted ERCP – and such a high dose may have adverse consequences with little additional benefit for the endoscopist. With the exception of this unusually high dose of Buscopan given, I consider both procedures to have otherwise been carried out to an acceptable standard.

6.08 [redacted] **(JMW27):** A [redacted] year old male with a bile leak from the cystic duct stump after open cholecystectomy carried out [redacted]. This man had previously required a cholecystotomy for gallbladder empyema but had no other significant prior co-morbidity.

6.09 ERCP was carried out [redacted]. The procedure note documents that a 6cm fully covered metal stent was placed and that it would require removal in 6 months. The consent form is appropriately completed and signed. There is no record of prophylactic NSAID suppository being given and there is no record of a sphincterotomy being made during the procedure.

6.10 Following the procedure, [redacted] developed post-ERCP pancreatitis that required a stay on the intensive care unit and he was eventually discharged [redacted].

6.11 There is a letter from [redacted], consultant surgeon, dated [redacted] to [redacted] in which he writes that the endoscopy department had been trying and had failed to get in touch with him for removal of the stent.

6.12 The patient was readmitted on [redacted] with gram negative sepsis, thought to be biliary in origin and the following was noted in the medical records:

> Plan was to remove the stent in about 6 months. Pt explained, that [redacted] who placed the stent, reassured him, that this type of stents may remain in situ for years.
> On [redacted] documentation from October 2021, there seems to be a communication with [redacted] in NGH for a stent removal. In this admission the stent is thought to be one of the possible sites of infection.

6.13 He was admitted again from [redacted], and [redacted] with biliary sepsis on each occasion. On the last admission he underwent an MRCP scan that showed debris in the biliary tree and thickening of the bile duct in keeping with cholangitis – he was transferred to a regional unit for removal of the stent.

6.14 **Comment:** Once again there is no evidence of the use of NSAID suppository prior to the procedure and on this occasion the patent did experience post-procedural pancreatitis. Whilst I note that the patient failed to respond to attempts to arrange further endoscopy for removal of the stent, this may have been related to the poor advice given by the endoscopist. To leave such a stent in place for 6 months would be excessive in this setting (the leak should heal within a much shorter period of time and 8-12 weeks would usually be the recommended time frame for stent removal). Whilst based on patient recollection, the advice that such stents 'can remain safely in place for years'

would also be inappropriate. Whether or not this influenced the patient to not respond to invitations to have the stent removed is unclear, however if this were the case then this advice would have contributed to the further three admissions with biliary sepsis over the subsequent year after the procedure.

6.15 On the basis of the above – the failure to use prophylactic NSAID, the inappropriate advice to leave the stent in place for 6 months and not to worry about it if left longer – lead me to consider this procedure as 'room for improvement'. In this case the stent retention resulted in three admissions for management of biliary sepsis, however the extent to which patient factors contributed to the period of stent retention is unclear.

6.16 [redacted] **(JMW28):** A [redacted] year old man [redacted] who was found to have obstructive jaundice thought to be secondary to a common bile duct stricture on CT scan [redacted].

6.17 ERCP was undertaken [redacted] as a day case. The notes of the ERCP procedure state that cytology brushings were taken and a 4cm fully covered metal stent was placed with relief of the obstruction. The consent form for this procedure is not present in the records. The procedure was carried out with 5mg midazolam, 100mcg fentanyl and 20mg Buscopan. There is no evidence of pre-procedural rectal NSAID suppository being given. There is no record of a sphincterotomy being performed. Cytology brushings were reported as benign.

6.18 [redacted] returned later the same day with severe abdominal pain and was admitted into hospital with post-procedural pancreatitis. The course was subsequently protracted with the development of peripancreatic collections, sepsis and pulmonary emboli. [redacted] a further ERCP was undertaken to change the metal stent for a plastic pigtail stent. No records are available for this procedure.

6.19 He was discharged initially [redacted] but readmitted [redacted] with haematemesis and subsequently transferred to the regional centre [redacted] and remained an inpatient there until [redacted] due to complications of the post-procedural pancreatitis.

6.20 **Comment:** The ERCP procedure was appropriately undertaken [redacted] in view of obstructive jaundice. I am unable to comment on the procedure for consent as the consent form is not present in the records. The medications given during the procedure were appropriate. However, there is no record of rectal NSAID being given. I am unable to comment on the ERCP undertaken on [redacted] as there are no procedural records in the notes. There is some evidence to suggest that fully covered metal stents (as opposed to uncovered or partially covered) can lead to post procedural pancreatitis by occlusion of the pancreatic ductal orifice. Many ERCPists (including myself) routinely carry out small sphincterotomies prior to fully covered metal stent insertion, although the evidence is not considered strong enough to support this practice currently in guidelines, and pre-stent sphincterotomy is not recommended in any other settings[1]. However,

carrying out a repeat ERCP one week later to exchange the metal stent for a plastic stent as in this case would be have been highly unlikely to have changed the course of the severe pancreatitis and would merely have exposed the patient to additional risk. I therefore consider the initial procedure to have been satisfactory on the basis of the evidence available with the exception of the use of pre-procedural NSAID, and that the second procedure to exchange the metal stent for a plastic stent was not indicated.

7. Opinion

7.01 My overall opinion is unchanged from my report of February 2024 as a result of analysis of the further cases and I refer to my original findings.

7.02 The additional three cases included five separate procedures of which four were carried out for appropriate indications. Where consent forms were available for review (in three out of five cases) they were completed appropriately and signed by the nurse endoscopist.

7.03 There is no record of pre-procedural NSAID suppositories being given in any of the five procedures.

7.04 Regardless of the failure to administer rectal NSAID, I rated three procedures as being satisfactory and one as 'room for improvement' whilst being unable to comment on the other procedure due to lack of documentation although I considered it not to have been indicated.

7.05 The procedure rated as 'room for improvement' was in the case of JMW27 where inappropriate advice appears to have been given to leave the stent in place for six months. In this case it is also reported that the patient was told that the stent could remain safely in place for years. This is reported by the doctor making the note entry and the quality of evidence is therefore 'heresay' and cannot be relied upon. However, this would be consistent with the endoscopist's approach to stent placement from previous examples and if this were the case it may explain the reluctance of the patient to undergo further ERCP for stent removal, resulting in further admissions being required for biliary sepsis.

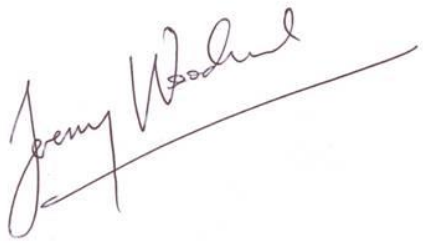
7.07 Combining these outcomes with the initial cases reviewed by me, there were twenty seven (27) individuals, a total of forty seven (47) separate ERCP procedures including six patients who underwent two ERCPs, five patients who underwent three ERCPs and one patient who underwent five ERCPs.

7.08 In total I classified fourteen (14) cases as 'room for improvement in aspects of clinical care' and eleven (11) as 'unsatisfactory' in keeping with the RCP report referenced.

7.09 I note that these procedures added to the list of complications associated with ERCP in this practitioners' workload by two cases of post-ERCP pancreatitis (JMW27 and JMW28). I also consider that there was a material contribution to the biliary sepsis episodes in JMW27.

8. STATEMENT OF TRUTH

I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.



Dr Jeremy Woodward September 2024

References

1. Dumonceau J-M, Andriulli A, Elmunzer BJ et al. Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – updated June 2014. *Endoscopy* 2014; **46:** 799-815

Royal College of Physicians invited review to Rotherham NHS Foundation Trust in June/July 2022

The Royal College of Physicians undertook an invited review to Rotherham NHS Foundation Trust in June/July 2022. Following this review the invited review team provided the following recommendations. Please indicate if these recommendations have been implemented, and which have proved successful or unsuccessful, including details of the actions taken by the Trust.

Implemented (I) and
Successful (S)
Unsuccessful (US)

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
a.	In line with BSG guidance, the clinical endoscopist should not undertake ERCP in any healthcare institution that provides an ERCP service **(0-3 months)**	I/S	Clinical endoscopist not undertaking ERCP in any healthcare institution. NMC interim order of practice currently in place barring endoscopist from ERCP practice. Resumption of ERCP service will ensure procedure is undertaken by Consultant Gastroenterologists. Completed in recommended time frame.
b.	The unusual circumstances of a nurse providing interventionist procedures raises the question over whether contact should be made with the Trust's GMC Employer Liaison Advisor, in the absence of equivalent mechanisms for nurse consultants providing therapeutic interventions **(0-3 months)**	S	Nurse endocopist regulated by NMC so GMC referral not completed. Referral made to NMC. Discussion held with GMC ELA regarding medical staff referred to in report. Completed in recommended time frame.

invitedreviews@rcp.ac.uk | +44 (0)20 3075 1237 | www.rcp.ac.uk/invitedreviews

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
c.	There is sufficient concern within the clinical case review to advise the Trust to re-refer the clinical endoscopist to the NMC for their clinical decision making, conduct and competence **(0-3 months)**	S	Nurse endoscopist referred to NMC. Currently has interim order of practice. Process ongoing. Completed in recommended time frame.
d	The Trust should inform relevant units, both in the public and private sector, where the clinical endoscopist has provided services (ERCP and other interventional procedures) of the concerns raised by this review, to enable them to consider the relevance of the findings to the clinical endoscopist's wider practice **(0-3 months)**	S	Relevant units informed and review of endoscopists wider practice undertaken with support from NHSE North East and Yorkshire. Completed in recommended time frame.
e.	The Trust should undertake internal review of its processes for employing clinicians to ensure that the concerns raised by this review are not duplicated for other staff. This may include ensuring that there are robust arrangements for clinical and managerial oversight of any new appointee, and that there is a clear process for considering any activity undertaken at other healthcare organisations (including governance and financial implications) **(0-3 months)**	S	Medical Staff appointed as appropriate and oversight through performance and appraisal. Appraisal includes activity at other healthcare organisations
f.	The ERCP service should move to a medically qualified, consultant-led service (such as by suitably trained gastroenterologists, upper GI or Hepato-Pancreato-Biliary (HPB) surgeons) **(0-6 months)**	US	Planning in place to resume ERCP service once 2 Consultant Gastroenterologists appointed. Both will be JAG accredited for ERCP. Interim measures remain in place and ERCP service currently provided by Sheffield Teaching Hospital.
g.	ERCP endoscopists should demonstrate that they undertake a minimum of 75 cases per annum, with the aim for a minimum of 100	US	Gastroenterology partnership work with Barnsley NHS Foundation trust and ongoing audit will ensure appropriate number of cases are completed annually.

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
	cases, as per The Way Forward 2014 **(6-12 months)**		
h.	Minimum standards for independent practitioners should be based on intention to treat and include a >=85% cannulation rate of virgin papillae, CBD stone clearance for >=75% of those undergoing 1st ever ERCP, and for patients with an extra-hepatic stricture, successful stenting with cytology or histology where appropriate at 1st ERCP in >=80%, as per The Way Forward 2014 **(6-12 months)**	S	Individual endoscopists will have these KPIs assessed every 6 months in accordance with The Way Forward and JAG recommendations. This will be monitored by the Clinical Lead for endoscopy and the Clinical Lead for Gastroenterology.
i.	Performance criteria should be monitored by a detailed audit and feedback process and incorporated into consultant appraisal, as per The Way Forward 2014 **(12-24 months)**	S	As per h and will be monitored in Consultant appraisal.
j.	The organisation and standards for training for ERCP should follow from the performance criteria detailed under (h), as per The Way Forward 2014 **(12-24 months)**	S	The two consultant Gastroenterologists will have completed training and have undergone supervision and training in ERCP at Barnsley NHSFT as part of the joint gastroenterology working arrangements.
k.	Newly appointed consultants should be mentored to ensure a safe and effective transition from trainee to independent practitioner, as per The Way Forward 2014 **(0-6 months)**	S	Consultants will have both been working at Consultant level and have undertaken ERCP procedures at Barnsley NHS FT prior to the service resuming at Rotherham. Supervision and joint working will continue with Rotherham.
l.	The new ERCP service should strictly follow the British Society of Gastroenterology (BSG) standards framework The Way Forward (201412). This requires the Trust to ensure that, amongst other things, key performance indicators (found in The Way Forward and in JAG Accreditation Programme guidance13) are	S	SOP developed to support the resumption of the ERCP service. This has been developed using The Way Forward standards framework and the numbers will be monitored to assure they are sufficient per facility per year and also per operator per year.

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
	measured and delivered against, and there should be 150 cases minimum per facility per year, with the aim of 200 cases **(6-12 months)**		
m.	The new ERCP service should work collaboratively in a regional hub-and-spoke model, with simple and rapid referral pathways established. Facilities for urgent or emergency ERCP should be available, as per The Way Forward 2014 **(6-12 months)**	S	ERCP service will continue to work alongside Sheffield Teaching Hospital as the tertiary centre for hepatopancreatobiliary service with an MDT approach utilised and facilities for transfer for urgent or emergency ERCP. ERCP lists will take place twice a week at TRFT.
n.	In formalising a SOP for the ERCP service the Trust should refer to the SOP used by Barnsley to ensure a unified approach across the two organisations **(6-12 months)**	S/I	Barnsley SOP used in development of TRFT SOP.
o.	The behaviour and performance of the clinical endoscopist suggests that their wider endoscopic practice should be considered further by the Trust. This should include: a. Review of all ERCP cases performed by the clinical endoscopist between 2017 and suspension of the service (excluding the cases already reviewed), where the patient suffered a potential complication (including post-ERCP pancreatitis (PEP), infection, bleeding, allergic reaction to the sedation or dye, and perforation in the small bowel), as well as all deaths within 30 days of ERCP, to determine whether the ERCP procedure was in line with good practice, and whether the complication was avoidable. The RCP/BSG may be able to assist with this review, if required.	S	a) Review of all cases immediately undertaken to identify deaths within 30 days of ERCP undertaken by the nurse endoscopist. These deaths have been reviewed by an independent Consultant Gastroenterologist to assess whether ERCP was in line with good practice. Interim review received. Review of all ERCP cases has taken place to identify potential complications. These have been reviewed internally by senior clinicians. Cases where the complications were related to the ERCP have been identified and a review of these will be undertaken by an external independent reviewer. This is expected to complete in the next few months. b) non ERCP interventions audited at all relevant organisations and coordinated by NHSE North and North East England

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
	b. Audit of non-ERCP therapeutic interventions undertaken by the clinical endoscopist (for example, ureteric stenting) and all relevant hospitals where these interventions took place. These other interventions should be evaluated against appropriate benchmarks **(0-3 months)**		
p.	The governance arrangements for a single-handed clinical endoscopist providing ERCP were deeply unsatisfactory. As part of their discussions with the GMC employment liaison officer, the Trust should consider whether the two surgeons responsible for overseeing these arrangements fulfilled their duty of care as detailed in GMC good medical practice, Leadership and Management for all doctors. **(0-6 months)**	S/I	Discussion has taken place with the GMC Employment Liaison Officer. An external governance review of the service has been commissioned and the findings of this will be considered with relevant actions taken.
q.	The Trust should review the endoscopic reporting software and its ability to both upload to the National Endoscopy Database (NED), which requires the software to be NED compliant, and to automate audit of all JAG mandated key performance indicators (KPIs), especially those relating to sedation across all modalities and ERCP. There should be at least annual audit of ERCP numbers and outcomes, as per KPIs set out in The Way Forward. Endoscopy reporting software should be NED compliant **(6-12 months)**	S/I	Medilogik Endoscopy Management System has been implemented. This is fully NED compliant and supports all JAG clinical audits.
r.	The Trust should consider how, once its new ERCP service is established, it can support high quality ERCP research, as per The Way Forward 2014 **(12-24 months)**	U	This will be given consideration in due course with support of the joint Gastroenterology service at Barnsley and the Trust Research and Development programme.

Ref	Recommendations (and timelines)	Was it I / S / US?	Action/progress to date
s.	The Trust should share this report with the following regulator(s): Care Quality Commission; Nursing and Midwifery Council **(0-6 months)**	S/I	The report has been shared with the Care Quality Commission and the Nursing and Midwifery Council.
t.	The Trust should share this report with service commissioners and the Integrated Care Board **(0-6 months)**		
u.	The Trust should share this report with JAG on GI Endoscopy; the NHSE/Ixi endoscopy transformation team; and the BSG president and endoscopy committee chair **(0-6 months)**		

Did you find the timescales for each recommendation useful/not useful? Did it assist your healthcare organisation in implementing an action plan?
Click here to enter text.

What do you think the RCP could do to improve the service?
Click here to enter text.

What were the benefits of commissioning this review with the RCP?
Click here to enter text.