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British Society of Gastroenterology Endoscopic Retrograde Cholangiopancreatography (ERCP) Quality Improvement Programme: minimum service standards and good practice statements

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ABSTRACT

In 2014, the British Society of Gastroenterology (BSG) published a standards framework outlining key performance indicators for ERCP practitioners and services. In the last 10 years there have been numerous changes to clinical practice yet there remains considerable variation in service delivery in the UK. In 2021 the BSG commissioned an ERCP endoscopy quality improvement project (EQIP) comprising members from all relevant stakeholding groups. This document draws from the results of a national survey of ERCP practitioners and units performed in 2022/23 supported by detailed stakeholder interviews. These results informed a draft document and series of statements that were revised at 2 group meetings and through several iterations. Each statement was included only after achieving 100% consensus from all participants. This service specification has set out 70 consensus statements covering the patient journey from booking to discharge and follow up, the members of the ERCP team, requirements for continued professional development and clinical governance, equipment and facilities and network provision and MDT working. This document describes the key components of a high quality and safe ERCP Service, seen from the patient's perspective. It provides a detailed template for service delivery that should now be implemented by ERCP practitioners and units through the UK and should be used by ERCP providers and commissioners to benchmark services and guide continuous quality improvement.

INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is one of the highest-risk procedures performed routinely by endoscopists. ERCP services in England were last subject to national audit and survey in 2007.[1] In 2014, the British Society of Gastroenterology (BSG) published a Standards Framework outlining key performance indicators (KPIs) for ERCP practitioners, for service provision and for training programmes.[2] This was followed by a repeat Census in 2016 from 234 ERCP units via the Joint Advisory Group (JAG) Global Rating Scale (GRS) that highlighted significant shortfalls in comparison to the Standards Framework.

ERCP practice has evolved in response to recognition of an ageing population and technical advances. ERCP should almost always be performed with therapeutic intent with safer diagnostic options such as MR cholangiopancreatography (MRCP) or endoscopic ultrasound (EUS) being routinely available, whereas new developments such as intraductal cholangioscopy and therapeutic EUS have expanded the range of available therapeutic options.

The Getting it Right First Time (GIRFT) gastroenterology review identified variations in case selection, access to multidisciplinary teams (MDTs), systems for tracking biliary stent removal and

variation in outcomes related to stone disease and mortality in different Trusts.[3] The document highlighted the need for ERCP MDTs and to consider consolidation of services across centres. Furthermore, a recent draft white paper from National Health Service (NHS) England (NHSE) has stressed the need to enhance quality and organisation of ERCP practice into regional networks and MDT work.

Over the last decade, a number of clinical guidelines and standards have been published by the BSG, National Institute for Health and Care Excellence (NICE) and European Society of Gastrointestinal Endoscopy (ESGE) that have produced a range of recommendations and KPIs related to ERCP, adverse events, safety and common bile duct (CBD) stones.[4–10] These recommendations have not been subject to rigorous implementation and the process by which clinical outcomes and complications data should be collated by Trusts and individuals has not been described.

The most common clinical indication for ERCP remains CBD stones yet duct clearance is variable, with residual stones common and repeat procedures performed more frequently than is recommended. There is also currently no clear guidance on the performance of sphincterotomy and verification of duct clearance.[11–13]

ERCP services, in common with other areas of endoscopy, are under pressure. ERCP is about far more than just the technical skills of the practitioner, requiring referral pathways for complex cases, preassessment of patients, thorough consent, complex clinical decision-making, team-based preprocedural, periprocedural and postprocedural management, systems for managing complications and input from other specialists including interventional radiology (IR). Errors leading to harm can occur at any point in the complex patient pathway.[14] ERCP endoscopists are required to fulfil many roles within gastroenterology, general surgery or radiology and may not have sufficient time devoted to ERCP-specific continuing professional development (CPD) and governance. Patient outcomes may be compromised by outdated equipment and facilities and inadequate access to anaesthetic supported lists.[15] Updated General Medical Council (GMC) and BSG guidance on consent and a recent coroner's inquest into post-ERCP deaths have highlighted the need for robust systems within hospitals to ensure appropriate patient selection and individualised consent.[16–18] It is in response to these multiple drivers that we have set out to describe the components of a high-quality and safe ERCP service.

AIMS

To describe in detail the components of a high-quality and safe ERCP service, seen from the patient's perspective that should be used by ERCP providers to benchmark their own service and act as a guide to continuous quality improvement. Key elements will be incorporated into the JAG GRS. This document maps the patient journey from point of referral to discharge from the endoscopy service and aims to consider all elements of that pathway as well as clinical governance and safety, equipment and facilities. The model identifies key standards that should be met by all providers that offer ERCP to patients.

This document is applicable to all those who are involved in delivering an ERCP service. The service includes the entire patient journey for all patients that are referred for possible ERCP from the point of referral to discharge and it is recognised that some patients may not undergo the procedure due to lack of appropriateness or fitness. Key individuals involved in this service include (but are not limited to) management and clerical staff, nurses (those involved in the procedure as well as preprocedure and postprocedure care), radiographers and medical staff, both endoscopists and supporting specialties. Although extremely important, in this paper, we do not seek to address issues related to workforce planning and training.

METHODS

Following a recommendation from the BSG Endoscopy (BSGE) committee and endorsed by the BSG Executive, an ERCP Project Group was established in 2021 within the BSGE Endoscopy Quality Improvement Programme (EQIP). Following this, a group of stakeholders were invited to form an advisory group (AG). Members of the AG were selected to meet requirements of equality, diversity, geographical variation, surgical, medical and nursing groups and referral/non-referral centres. Patients who had participated in a series of stakeholder interviews were approached and volunteered to participate in the AG.

We took a multimethod approach to understanding ERCP delivery in the UK, involving collecting survey data and conducting discussion groups with, nurses, endoscopists and patients.

Two national surveys of ERCP practice were disseminated by the BSG. These surveys audited current clinical practice and sought to understand variation in practice, process, facilities, resources and adherence to guidelines across ERCP nationally. One survey was targeted at ERCP practitioners (individual) and the other at endoscopy units (organisational) to gain a complete understanding of practice at an individual and unit level. There were nine open-ended response questions related to priorities for service improvement and barriers to change. Descriptive statistics of fixed characteristics were calculated for both surveys. Free-text

Executive Summary

List of statements

Policies

1. Endoscopy units that offer ERCP should have a dedicated written policy covering administrative processes and common clinical scenarios.

Patient Journey

Referral

2. ERCP units should utilise dedicated ERCP request forms that contain a minimum dataset to determine suitability for the procedure. Units should use standardised electronic request forms, but where that is not possible in the immediate future, paper forms should be legible, complete and patient demographics typed.

Vetting

3. Before an ERCP procedure is booked, the referral should be vetted for appropriateness by a member of the ERCP team, with final responsibility for this by an ERCP consultant. Where the information on the request is insufficient to determine appropriateness, further information should be sought from the referrer or the medical records before the procedure is booked.
4. Where the indication for ERCP is uncertain, this should be discussed in a local and/or regional MDT. If a patient attends for ERCP and the indication for the procedure is unclear or may have changed, the procedure should be deferred pending further discussion or investigation.
5. All patients should be assessed for fitness for the procedure and to ensure that the correct blood tests and adjustments to medication have been made. For out-patients this can be via a nurse-led preassessment team. For in-patients, this should be by a ward visit by a member of the ERCP team.

Booking

6. Outpatients should be booked sufficiently early in the day to facilitate same-day discharge.
7. All patients with CBD stones and jaundice should be treated within 72 hours of diagnosis and units should audit their compliance with this.
8. Units should identify the specific waiting times for patients requiring anaesthetic procedures and there should be a process for tracking planned stent removal/exchange procedures with an escalation policy if there are delays.
9. Booking policies should be stated in the unit SOP.

Consent

10. All outpatients having ERCP should have access to discuss the procedure face to face or over the phone with a member of the ERCP team in advance of attending for the procedure. This should be supplemented by written or online material. All in-patients should receive a visit from a member of the ERCP team prior to attending the unit.
11. Despite the often urgent nature of ERCP, units should take steps to adhere to the requirements of unrushed and private consent conversations as outlined in the BSG guidelines on consent.
12. ERCP-trained nurses and other members of the ERCP team can contribute to patient information, assessment and the consent process throughout the patient journey but the final confirmation of consent should be by an ERCP endoscopist.

Case Preparation

13. Careful attention to preprocedure preparation should include reviewing radiology, checking blood results, medication, cardiac devices, ensuring the patient is hydrated with intravenous fluids and that the necessary support specialties are notified in advance of the procedure. Specialist radiological support should be available to review imaging where required.

Patient Safety

14. Before any ERCP list, a full team briefing should occur. This should involve all members of the team (endoscopist(s), nursing team, radiographer anaesthetist) in which cases are reviewed, potential difficulties highlighted and potential equipment (including endoscope) requirements reviewed.
15. Before each ERCP procedure a minimum of a sign-in and time-out should occur that should include all of the basic endoscopy requirements (e.g. identification, consent) but also components specific to ERCP (e.g. clotting, pregnancy checks).
16. Whenever a stent is to be used, there should be a further time-out in which it is checked that the correct stent is being used and is in date.
17. Debriefs should occur at the end of lists and should focus on good practice and discussion about adverse events.

Teamwork

18. A focus on teamwork to foster a welcoming, just and learning culture in the ERCP room should be developed in all ERCP teams. Lists should be booked to avoid fatigue, with the provision of breaks and access to support staff.

Complications

19. Unit policies for prevention and recognition of complications from ERCP should be enshrined in the written unit SOP. A culture of early recognition of complications during and after the procedure should be encouraged and enhanced through team-based training.

Continued

Executive Summary Continued

Recovery

20. Patients should be recovered in a suitable environment, equipped and staffed by nurses trained in recognising adverse events related to ERCP. Four hours is the minimum recommended recovery period, although in some selected cases 2 hours may be sufficient.

Discharge

21. Patients should receive information about their procedure and next steps in a private room once they have recovered from sedation. Written discharge information should be provided that gives advice about ERCP-specific adverse events and how to contact the hospital in the circumstance of developing such symptoms.

Stent Tracking

22. Trusts need to ensure that there is a reliable system in place for tracking patients with stents that require removal or exchange and ensuring that this is performed on time.

The ERCP Team

Nursing

23.Each unit should have a list of nurses whohave received training and are competent to lead an ERCP list. Nurses who lead ERCP lists should receive specialist training in hepatobiliary anatomy, ERCP indications, complications and equipment.
24. ERCP units should identify the competencies, training and credentialing needs (supported by the network) of ERCP nurses and ensure that nurses leading an ERCP room have received appropriate training and been signed off as competent.
25. ERCP nurses should have access to audit and CPD sessions both online and at face-to-face meetings, supported by an appropriate budget.
26. Nurses who lead ERCP rooms should have regular updates on the use of equipment at a minimum every 6 months. A network approach to this should be developed and nurses supported to be released to attend local specialist centres in order to achieve this.
27. ERCP lists should be supported by a minimum of three staff. Two must be registered healthcare staff and 1 must be a registered nurse. One member of staff should be trained in leading ERCP lists.
28. Each ERCP unit should have a named lead ERCP nurse that is responsible for supporting the training and mentoring of other ERCP nurses, troubleshooting equipment problems, ensuring appropriate stock levels and supporting governance processes within the unit.
29. Units should develop and support the expanding role of specialist nursing in ERCP to support patient preassessment and postprocedure care, especially for inpatients.
30. ERCP units should implement nurse preassessment for outpatient ERCP.
31. ERCP networks should identify a lead ERCP nurse to support training and movement of nurses between ERCP units within the network.

Management

32. An ERCP service should be supported by a triumvirate of lead ERCP endoscopist, lead ERCP nurse and a member of the management team who is identified in assuring the quality of the ERCP service.
33. The lead ERCP manager should have roles in waiting list management (and publication), list booking, staffing levels, equipment management and supporting governance and CPD.
34. List numbers and capacity should be monitored and there should be an action plan in the ERCP SOP if numbers fall below a defined level.

Patient

35. Feedback from patients who have had ERCP should be sought and fed back to unit and network governance meetings.

Supporting Specialities

36. Specialist radiological support should be available to review imaging prior to ERCP for all units.
37. Where MDT input is required, radiological and surgical input should be available.
38. Urgent access to acute surgical and IR expertise should be available for all units, either locally or via network pathways, defined in the unit SOP.
39. Anaesthetic support for emergency or clinically unstable cases should be available in all units.

Continuous Professional Development

40. All endoscopists performing ERCP should have adequate time for specific ERCP-related CPD agreed in their job plans, which should include a minimum of 4 hours a month. The content and reflective learning from CPD should be available at annual appraisal.

Continued

Executive Summary Continued

Key Performance Indicators

41. All units providing ERCP must have in place governance arrangements that specifically focus on ERCP practice. This must include a designated medical governance lead with adequate job planned time. This must also include regular and documented review meetings with relevant members of the MDT. The clinical governance arrangements must include as a minimum a retrospective review of:
    a. 30-day complication and mortality rates.
    b. incidents.
    c. complaints and compliments.
    d. risk management.
    e. patient experience.

42. Referral centres should put in place systems that enable M&M reviews of patients who might have experienced readmissions to other units.
43. All units providing ERCP must carry out regular quality and safety audits of the ERCP service that cover the key quality and safety standards outlined in this document.
44. All units providing ERCP must have a designated medical clinical lead for ERCP who is responsible for ERCP service delivery and governance. This role should be supported by adequate job planned time.
45. All units performing ERCP should have an agreed process for determining and addressing endoscopist under-performance or safety concerns.
46. Individual ERCP endoscopists should perform a minimum of 100 procedures per annum and ERCP units should perform a minimum of 200 procedures per annum. Where a unit or individual does not meet the required numbers this should be reviewed by clinical or network leads and written plans developed to correct this.

Equipment and Facilities

47. ERCP should be performed in dedicated fluoroscopy rooms with sufficient space to accommodate the endoscopy, radiology and, where required, anaesthetic teams and their equipment.
48. The ERCP room should be located in a space where there is prompt access to all of the equipment that may be needed during the procedure and which promotes efficient patient flow.

Ergonomics

49. Appropriately sized lightweight leads should be available for all staff participating in ERCP.
50. Room design should allow sufficient space for equipment storage and preparation and should be optimised to minimise musculoskeletal strain on staff participating in ERCP.

Fluoroscopy and Radiation Protection

51. Fluoroscopy equipment used for ERCP should be of sufficient standard that allows real-time analysis of images and visualisation of ductal anatomy to the level required for the procedure.
52. Radiation doses should be recorded for individual procedures, and radiation exposure to staff should be monitored using dosimeters. These should comply with local standards for radiation dosing and protection.
53. All units should provide a radiation safety or equivalent course with attendance mandated for all those working with ionising radiation.
54. Adequate PPE should be provided including eye protection glasses for all procedures.

X-Ray Acquisition

55. Standard images at each ERCP should include a control image, a cholangiogram and a final full abdominal exposure at the completion of the procedure. In addition to this, for cases of stone disease, a further cholangiogram should be taken confirming duct clearance where it has occurred.
56. Further images should be taken to demonstrate pathology encountered and significant events during the procedure.

Duodenoscopes and Accessories

57. There should be a sufficient number of duodenoscopes with adequate processing facilities to reduce the risk of duodenoscope-associated infections and support a full (4 cases) ERCP list without delays due to reprocessing.
58. Staff should be trained to use the available equipment in the unit, especially those items that are used less frequently.
59. Dedicated systems should be available for stock management to ensure continuous availability of all equipment based on the complexity of ERCP being performed in individual units.

Deep Sedation and General Anaesthesia (DS/GA)

60. Access to adequate numbers of DS/GA lists should be available regularly across organisations or networks.

Continued

Executive Summary Continued

61. Patients should be prioritised for DS/GA based on patient tolerance, the complexity of the procedure and patient factors, including the need for emergency ERCP or in unwell patients. If DS or GA are required but not available in the local hospital, facilities should be available to transfer the patient to an organisation that can provide this.

Networks and MDT

62. ERCP services should work collaboratively within a region, health board or integrated care board in a hub-and-spoke model with clear and formalised leadership and terms of reference.
63. Each network should develop and agree a pathway of care encompassing preprocedure, procedure and postprocedure care and data collection.
64. Each network should have a regular MDT to discuss complex or challenging cases, to which all units from the network should have access.
65. Each unit should participate in a network CPD/audit day at least annually. In addition, every unit performing ERCP should have regular M&M/audit meetings that include all members of the ERCP team.
66. Each network should agree formal protocols and pathways for the management of common pancreaticobiliary conditions.
67. Each network should develop and agree cover/backfill arrangements to maximise use of capacity to minimise patient waiting times and travel distance.
68. Each network should develop and agree measures to enable cross unit working of medical and nursing staff to enhance training.
69. Each network should develop and agree in collaboration with regional HPB service criteria a pathway for biliary drainage within 24 hours in urgent cases.
70. Each network should ensure that practitioner and unit annual volume are audited and the minimum numbers of 100 and 200 cases, respectively, is achieved as soon as feasible.

responses were categorised, and the frequency of different reported issues was calculated. Response rates from each survey were high indicating that the data used here are a fair reflection of current practice. All 170 UK endoscopy units identified responded to the survey (100%) and a 74% response rate to the individual ERCP practitioner survey was achieved (389/526 respondents). Selected data from these surveys are reported here to support the statements. Full details of the surveys and comprehensive analysis of the findings will be the subject of further publications in the near future.

In order to understand the factors underpinning the variations identified in the surveys and any concerns stakeholders might have with approaches to standardisation of practice and quality improvement processes, a series of discussion groups were held in summer 2023, in which the key areas examined in the survey were considered by a range of stakeholders with varying experience, specialisms and perspectives. Discussion groups were arranged by specialism (endoscopists, endoscopy nurses and public/patient) and provided a forum to understand the experiences of these individuals; to integrate their perspectives into the EQIP; understand underlying issues which may contribute to some of the survey findings and consider potential strategies to improve practice. As for the surveys, selected results from these discussion groups are presented here while detailed analysis will be subject to future publication.

Following the survey and stakeholder interviews, priorities for a high-quality and safe ERCP service were identified and collated into a draft manuscript and series of statements by the project group. A first draft was shared with the AG in February 2024. Initial feedback was sought via a structured online questionnaire and used to inform a face-to-face meeting, held in London in February 2024. A combination of nominal group techniques and facilitated small group work were employed to determine areas of agreement or disagreement. Where there was disagreement, the statement was amended prior to repeat discussion and ratification at an online meeting with the AG in April 2024 in which all statements were confirmed. Only statements for which there was 100% agreement are included here.

Due to the paucity of high-quality evidence, this is not a guideline; in accordance with limitations to the Grading of Recommendations Assessment, Development and Evaluation approach in this circumstance, we have provided good practice statements rather than recommendations, written from the perspective of what a patient would wish when entering an ERCP service.[19]

KEY COMPONENTS OF A HIGH-QUALITY ERCP SERVICE

Documents and policies

The survey demonstrated that 75% of organisations have written policies and guidelines covering clinical pathways, 68% have processes covering administrative pathways for ERCP, 23% have written policies

on requesting removal of temporary stents, 44% have written guidance that eligible patients undergoing ERCP receive rectal non-steroidal anti-inflammatory drugs (NSAIDs) and 3% have written policies on the insertion of pancreatic duct stents for prophylaxis.

There is, therefore, significant variation and while standard operating policies (SOPs) do not guarantee optimum practice, they should reduce variation in clinical practice, provide clarity of process and transparent assurance to external reviewers of a standard approach within the unit. Lack of SOPs was identified as a key contributing factor in non-procedural patient safety incidents in England and Wales.[14]

While this document outlines the general principles of a high-quality and safe ERCP service, it is recognised that individual units will find their own solutions to each statement. Thus, all units performing ERCP should have a dedicated written policy covering common clinical scenarios and processes. This should include, but not be limited to, vetting for appropriateness, preassessment, consent, safety policies including use of safer surgical checklists and implant time-outs, booking policies, adherence to published ERCP guidelines, prophylaxis against post-ERCP pancreatitis, arrangements for follow-up procedures and stent removal tracking processes. This can be part of the overarching endoscopy policy or separate but should be clearly identified as relating to ERCP practice. Table 1 outlines the recommended components of a unit ERCP SOP.

Statement

1. Endoscopy units that offer ERCP should have a dedicated written policy covering administrative processes and common clinical scenarios.

Patient journey

Preprocedure

Case selection

Referral mechanisms

Booking procedures at the appropriate time and on the correct list is essential to maximise timeliness and efficiency. Delays and errors will occur where the information on the referral is incomplete or illegible.

58% of units receive all referrals on electronic booking forms while the remainder use either paper-based request forms or a combination of the two. There are numerous advantages to electronic request forms including the requirement to complete certain sections, legibility, speed, the presence of an audit trail and moving towards a paperless work environment. There are several applications that can be used for electronic referrals and we recommend that all units move towards one of these.

37% of organisations receive referrals from neighbouring hospitals. This may provide greater challenges in incorporating electronic referrals across different IT networks. Nonetheless, we recommend that networks collaborate to provide digital solutions in the near future.

Where institution of electronic referrals is not immediately possible, requests should be made on standardised ERCP request forms that include all relevant information that permits vetting for appropriateness (see below) such as comorbidities, relevant anticoagulation drugs, American Society of Anaesthesiologists classification, relevant blood results and capacity to consent. Referrals should be rejected if incomplete or illegible and patient demographics should be typed (or patient sticker) to avoid transcription errors. The components of an ERCP request form, which contains what may be considered a minimum dataset to facilitate vetting, can be found in table 2.

Statement

2. ERCP units should use dedicated ERCP request forms that contain a minimum dataset to determine suitability for the procedure. Units should use standardised electronic request forms, but where that is not possible in the immediate future, paper forms should be legible, complete and patient demographics typed.

Vetting for appropriateness and preassessment

After receipt of the referral, procedures are vetted for appropriateness by an ERCP consultant in 85% of units. However, in the remaining 15%, a variety of solutions are employed, including trainees and nurses. The need to avoid assessment of the appropriateness on the day of the procedure is essential to prevent late cancellations, or, worse, proceeding with an unnecessary procedure. This is reflected in recent BSG guidance on consent and a Coroner's inquest in 2021 into post-ERCP deaths criticised a lack of robust auditable vetting pathways.[16 18]

Thus, there must be a system in place that ensures that all patient factors relevant to the clinical indication for, and safety of, ERCP are identified in advance of the procedure and capture what information has been considered as part of this process. Such considerations should include whether the procedure is indicated on clinical grounds, likelihood of success (eg, the presence of altered anatomy) and patient factors such as fitness to undergo the procedure, prior procedures, capacity to consent or the requirement for anaesthetic. Vetting for appropriateness should be performed by someone from the ERCP team who is adequately trained in ERCP and its indications before a procedure is booked. Although this process can be delegated, final responsibility for any vetting decision is with a nominated ERCP consultant. Where this process is delegated, this should be described in the unit ERCP SOP.

A specific situation in which ERCP can be avoided is where bile duct stones have passed. Recent large case

Table 1 Key components of an ERCP unit SOP

Booking policies	Day-case procedures (avoiding overnight admission) Transfers
Waiting list management	Demand vs capacity monitoring Anaesthetic supported cases Repeat procedures Stent removals
Pre-assessment policy	Medical comorbidities Drugs Relevant blood tests Fitness for DS/GA (as required)
Referral policy to local and/or regional MDT	Preprocedure cases for discussion Complications Repeats
Vetting for appropriateness	Person(s) responsible Process for review and documentation
Consent for ERCP	Inpatients, outpatients, transfers Preprocedure information provision Patients that lack capacity
Safer surgical checklists	Team briefing Sign-in/time-out Implant time-outs Debrief
Nursing	Training and competencies Room numbers Recovery and discharge policy
Clinical pathways	Prophylaxis against post-ERCP pancreatitis Common bile duct stones Suspected malignant biliary obstruction (distal and proximal) (Reference to published clinical guidelines) Management of adverse events—access to surgery and interventional radiology
Clinical governance	Audit policy—data collection processes KPI monitoring Complication tracking Readmissions Duty of Candour policy Mortality review process
Ionising radiation	Monitoring/dosimeters Training Personal protective equipment
Stent insertion	Decision regarding permanent versus temporary Removal request and tracking

DS/GA, deep sedation or general anaesthetic; ERCP, Endoscopic Retrograde Cholangiopancreatography; KPI, key performance indicator; MDT, multidisciplinary team; SOP, standard operating policy.

series have demonstrated that where ERCP is delayed 2–7 days after imaging detected stones, these stones will have migrated on up to 22% of occasions, particularly where stones are single and small (<5–6 mm).[20–22] Where there is a reasonable possibility that this may have occurred, or where there is uncertainty on imaging, this should be identified at the time of vetting. Options include performing a check EUS immediately prior to ERCP, although only 37% of units offer this on some or all lists. Lack of available EUS should not, however, deter endoscopists from delaying an elective procedure, for example, to repeat an MRCP or refer to a centre where EUS can be performed.

Some indications for ERCP are uncertain, depend on local expertise or may require referral to a specialist centre. Examples may include hilar strictures, primary sclerosing cholangitis, postsurgical anatomy and large or difficult CBD stones. Wherever the indication is uncertain or may require a referral, the case should be discussed in a local or regional MDT setting. Lack of MDTs for ERCP procedures was identified in the GIRFT report and it is essential that all units have access to a local and/or regional referral MDT.[3]

Many patients requiring ERCP are in hospital. These patients are often under the care of teams who may not be familiar with the demands and risks of ERCP. These

Table 2 Minimum elements of a standardised patient referral form for ERCP

Patient demographics	Typed or patient sticker
Referrer	Designation Contact details
Location	Inpatient Outpatient Transfer
Indication for procedure	
Recent relevant imaging	
Recent relevant blood tests	FBC LFTs Clotting parameters U+Es
Comorbidities	Fitness (eg, ASA, Performance Status, frailty) Diabetes (use of Insulin) Sleep apnoea and respiratory problems Mobility Presence of implantable devices (eg, pacemakers, defibrillators, nerve stimulators)
Drugs	Antiplatelets Anticoagulants Insulin Allergies
Infection control issues	
Consent	Capacity to consent Need for interpreter
Booking information	Priority (urgency) Day-case requirements Need for anaesthetic
Clinical narrative	

ASA, American Society of Anaesthesiologists; ERCP, endoscopic retrograde cholangiopancreatography; FBC, full blood count; LFT, liver function test; U+Es, urea and electrolytes.

patients are frequently sick, frail, have significant comorbidities and are more likely to lack capacity than outpatients. In 29% of units, a consultant routinely reviews inpatients on the ward, whereas in 20% of units, there is no routine process for reviewing patients prior to the procedure. Assessment of fitness for the procedure prior to the patient attending the unit is essential. Thus, it is important that all units institute a system whereby inpatients are reviewed by a member of the ERCP team on the ward prior to attending the department for the procedure.

Patients being transferred from other units pose significant challenges in this respect and units must satisfy themselves that they have sufficient information relating to the patient's indication and fitness for the procedure before transfer. While not commonplace now, the institution of video assessment and consultation of patients in remote units should be considered prior to transfer.

For outpatients, nursing preassessment is important to troubleshoot any problems on the day of the procedure and to make arrangements for the management of coexisting medical conditions such as anticoagulation therapy or diabetes. Preassessment allows the opportunity to ensure that the necessary blood tests (eg, coagulation and renal function) have been checked prior to the procedure. This is currently available in 64% of units whereas this should be universally instituted.

Statements

3. Before an ERCP procedure is booked, the referral should be vetted for appropriateness by a member of the ERCP team, with final responsibility for this by an ERCP consultant. Where the information on the request is insufficient to determine appropriateness, further information should be sought from the referrer or the medical records before the procedure is booked.
4. Where the indication for ERCP is uncertain, this should be discussed in a local and/or regional MDT. If a patient attends for ERCP and the indication for the procedure is unclear or may have changed, the procedure should be deferred pending further discussion or investigation.
5. All patients should be assessed for fitness for the procedure and to ensure that the correct blood tests and adjustments to medication have been made. For outpatients, this can be via a nurse-led preassessment team. For inpatients, this should be by a ward visit by a member of the ERCP team.

Timeliness, list booking and waiting list management

Booking of ERCP lists often involves a combination of procedures from both inpatient and outpatient sources, sometimes with transfers from other units and a variety of urgency ranging from planned elective procedures to very urgent (<24 hours) acute inpatients. Added to this, procedure complexity can vary substantially and an increasing number are referred for deep sedation or general anaesthetic (DS/GA) lists. Booking an ERCP list and managing the waiting list is, therefore, more complex than for many other endoscopy procedures.

The GIRFT report identified that there was a significant variation in the percentage of day-case ERCP procedures performed per unit, with some centres having very low rates.[3] Owing to the extended time to recover and monitor patients after the procedure, some units may struggle to offer same-day discharge to outpatients booked beyond a certain time in the day. Where this is the case, units should prioritise booking outpatients earlier in the day to ensure that the patient can be recovered and discharged the same day and there should be a written policy for this in the SOP.

While the time taken to complete an ERCP can vary considerably, a standard approach to time allocation per procedure should be adopted by units to allow optimum use of list capacity without frequently overrunning. However, where it can be anticipated that a procedure will take significantly longer (eg, a large bile duct stone requiring advanced therapeutics) this

should be identified at the time of vetting for appropriateness to allow the correct time allocation at booking.

NICE 2015 Quality Standard 104 states that 'adults with CBD stones who need emergency ERCP should have it within 24 hours'. Currently, very few units or networks are able to provide 7 days per week access to ERCP. Nonetheless, a solution to this Standard should be an objective in the planning of networks in the near future.

The Standard also states that 'adults with CBD stones causing jaundice should have ERCP within 72 hours of diagnosis'.[5] The majority of units (85%) are compliant with this most of the time (>50%) but only 35% report being compliant almost all of the time (>90%). Furthermore, only 42% of units audit their compliance with this Standard. Given the significance in relation to patient outcomes, it is essential that units find ways to achieve this. In smaller units, this may be through the use of networks to improve timeliness. All units should audit their compliance with this and examine the components of the pathway if there are delays (eg, from diagnosis to referral and from referral to procedure).

There are a number of circumstances where stents may be left in situ for a defined period of time before removal or replacement. Delaying such procedures can lead to significant and potentially lethal clinical consequences due to sepsis from blocked stents or buried irretrievable stents. The GIRFT report identified that there is variation in effective surveillance for patients with biliary stents and only 62% of Trusts were running a database system to track patients with removable biliary stents.[3] In the organisational survey, 23% of units have written policies on requesting removal of temporary stents and a variety of processes are followed. Tracking to ensure stents are removed or replaced when necessary is essential to reduce the risk of biliary sepsis. Thus, departments must have a reliable means to track the booking of these procedures. Where planned procedures are delayed beyond their expected booking date this should be identified and escalated.

Lack of anaesthetic provision may also lead to delays in these procedures potentially with significant consequences. Units offering anaesthetist-supported procedures should monitor and declare the waiting times specifically for these procedures.

Statements

6. Outpatients should be booked sufficiently early in the day to facilitate same-day discharge.
7. All patients with CBD stones and jaundice should be treated within 72 hours of diagnosis and units should audit their compliance with this.
8. Units should identify the specific waiting times for patients requiring anaesthetic procedures and there should be a process for tracking planned stent removal/exchange procedures with an escalation policy if there are delays.
9. Booking policies should be stated in the unit SOP.

Consent

From the organisational survey and the stakeholder interviews, it is evident that consent processes vary substantially among units, with examples where the required standards as laid out in the latest BSG and ESGE guidance and stipulated clearly in the recent Coroner's inquest are not met.[16 18 23 24]

19% of units report that the consent form for ERCP may be completed by a nurse. While this is commonplace for simpler procedures, the latest BSG guideline update recommends that 'The person completing the consent form …. will depend on the specific procedure but for high-risk procedures will require either considerable personal experience in the procedure or dedicated training that should be formally approved through local governance procedures'.[16]

For outpatients, preprocedure information is provided in a clinic by 57%, whereas postal information is provided in 81% and online resources in 9%, with some units combining approaches. The form is signed in clinic in only 5% whereas the majority complete the form in the endoscopy unit on the day. The BSG Consent guideline update states that 'The location in which consent is confirmed on the day of the procedure should be confidential, in a different location to the endoscopy treatment room and offer sufficient privacy and dignity to allow the patient to consider their decision'.[16] By contrast, the survey demonstrated that for outpatients the form is signed in a shared space by 26% of patients. For inpatients, a preprocedure visit to offer information with a doctor, nurse or fellow is provided in 54% whereas the remainder relies on information provided to the patient on the ward by the referring team. The consent form is signed on the ward in 40% whereas 29% use a shared space in the endoscopy unit to complete the consent discussion with either an ERCP doctor or specialist nurse.

In our stakeholder groups, patients reported disappointment with the level of communication and lack of opportunity to ask questions about ERCP and its associated risks prior to their procedure. Patients reported that a combination of a face-to-face consultation and leaflet to take away was felt to be ideal as this gave people information to reflect on. Patients who underwent emergency ERCPs often felt that there was minimal explanation of risk and complications. However, these patients also noted that the urgency of their condition meant that it was not possible to take time for decision-making and consider risks. Also, being in considerable pain, or on strong painkillers, meant that they felt they could not have taken in, and reflected on, detailed information at that time.

It is evident that, despite clear guidance from BSG, ESGE, legal precedent and clear preferences from patients, many units struggle to meet the demands

of informed consent for this particularly high-risk procedure.

All outpatients having ERCP should, at a minimum, have access to discuss the procedure face to face or over the phone with an ERCP endoscopist or an individual from the ERCP team who has received dedicated training in individualised ERCP consent in advance of attending for the procedure, supplemented by written or online material. This gives the opportunity to discuss the procedure with the patient and review the indication, which may lead to altered treatment plans. The choice of face to face or over the phone will depend on patient preferences and practicality based on distance from the hospital and urgency of the procedure. Ideally, the patient would sign the consent form before attending the unit for the procedure. However, where this is not practical, this should occur in a private space in the unit, as outlined in the BSG guidelines.

All inpatients should receive a visit from a similarly trained individual from the ERCP team prior to attending the unit. This will also allow adequate preassessment and consideration of fitness for the procedure. While the emergency nature of ERCP may make it difficult to meet these standards in some patients, this should be the exception and not the rule. Many inpatients attendingfor ERCP will do so on a trolley and often await the procedure in busy recovery units. If this is the case it is essential that the patient has the opportunity to read and sign the consent form before attending the unit, with the exception of rare emergencies.

Units receiving patients transferred from other hospitals should ensure the principles of informed consent are adhered to and that the patient receives appropriate information and discussion from the host team, supplemented by remote consultation as required.

At present, there is no clearly defined curriculum or framework to describe training in ERCP consent for non-ERCP endoscopists. This should be a priority going forward but, in the meantime, consent discussions with clinicians who are not ERCP endoscopists should be confirmed and countersigned by an independent consultant ERCP endoscopist prior to the patient entering the procedure room.

Statements

10. All outpatients having ERCP should have access to discuss the procedure face to face or over the phone with a member of the ERCP team in advance of attending for the procedure. This should be supplemented by written or online material. All inpatients should receive a visit from a member of the ERCP team prior to attending the unit.
11. Despite the often urgent nature of ERCP, units should take steps to adhere to the requirements of unrushed and private consent conversations as outlined in the BSG guidelines on consent.
12. ERCP-trained nurses and other members of the ERCP team can contribute to patient information, assessment and the consent process throughout the patient journey but the final confirmation of consent should be by an ERCP endoscopist.

Procedure

Case preparation

Patients attendingfor ERCP frequently have significant comorbidities and may be sick from jaundice or cholangitis. It is essential that the patient is as well as possible in order to tolerate the demands of the procedure along with sedation or anaesthesia. In selected cases at risk of decompensation, or those in critical care units, preprocedure anaesthetic review should be available. Careful attention to the patient's medication is required to ensure that they fulfil the requirements of the BSG guidelines on antiplatelet and anticoagulant medication.[25] Patients isolated for infection control issues should be identified so that the necessary arrangements can be made in the department.

Frequently patients will be at risk of dehydration from prolonged fasting prior to the procedure so measures to ensure that patients receive intravenous fluids before attending the unit will minimise this risk and is strongly encouraged. Up-to-date blood test results should be made available and checked including where relevant, coagulation screen, renal and liver function. Pacemaker and cardiac devices should be identified in advance and the necessary checks made before the patient attends the unit.

Relevant scanning should be available and reviewed as required by the endoscopist supported, if necessary, by a specialist radiologist. In the individual survey, 16% of ERCP endoscopists felt that they were not adequately supported by specialist gastro-intestinal (GI) radiologist. It is important that there is access to specialist radiology when considering interventions such as biliary stenting and where this is not available measures must be put in place to rectify this, perhaps looking at a networked solution. When a patient is transferred from another unit it is essential that the imaging is made available to the receiving unit. In circumstances of specialist (eg, paediatric) procedures the required on-site support from allied specialties should be alerted that the case is going ahead.

Statement

13. Careful attention to preprocedure preparation should include reviewing radiology, checking blood results, medication, cardiac devices, ensuring the patient is hydrated with intravenous fluids and that the necessary support specialties are notified in advance of the procedure. Specialist radiological support should be available to review imaging where required.

Safer surgical checklists

Following the implementation of the WHO Safe Surgical Checklist in 2009, National Safety Standards for Invasive Procedures (NatSSIPs) were introduced across the NHS 2015 and updated in 2023 (NatSSIPs2).[26] These latest standards document 8 steps that should be taken for invasive procedures, though steps can be amended and procedures that are performed in a dedicated area are suited to a specialty-specific checklist that is proportionate to the risks and processes in that area. The standards state that, based on the risk within that specialty, the type of anaesthesia and procedure (major vs minor procedure), particular checks may be more or less applicable. Nonetheless, certain steps such as team brief, sign-in, time-out, implant checks and sign-out must always occur though in some cases sign-in and time-out can occur together and debrief may not always be required.

In the UK survey, a team brief involving all members of the team always occurred in 74% of units but only sometimes or never in 22% and 4%, respectively. Regarding the sign-in/time-out, most units combine this but 59% use a standard endoscopy checklist that may miss elements that are specifically relevant to ERCP such as pregnancy and blood test checks. 38% use an adapted preprocedure list while 3% either only sometimes or never perform a preprocedure checklist.

In the ESGE position statement on performance measures for the team-centred approach to advanced endoscopic procedures, it is recommended that a WHO abbreviated/adapted checklist should be documented prior to the procedure.[27] They argue that most generic endoscopy checklists would not adequately address the idiosyncrasies of advanced procedures, and checklists need to be nuanced or individualised to the clinical circumstance, for example, to check anticoagulation, requirement for antibiotic prophylaxis or antiplatelet medication and advanced equipment checks.

ERCP is a service in which implants (stents) are frequently used. The correct choice (length, covered, uncovered) and ensuring it is in date is paramount and errors occur where this is not checked.

Furthermore, ERCP is an environment in which complications occur, which, as well as being harmful for patients, can be stressful for staff. Postprocedural debriefs should be encouraged, particularly in the event of a significant adverse event but can have positive impacts on team morale if used after successful procedures too.[27] A summary of key components of safer surgical checklists relevant to ERCP is included in table 3.

Table 3 Safer surgical checklist components relevant to an ERCP list

Prelist briefing	Patient details, comorbidities, ASA Review of relevant blood results Procedure information and key steps Equipment required
Sign-in/time-out	Identity confirmation Consent documentation confirmed Procedure planned Pregnancy disclaimer Implants that may affect diathermy Dental issues Review of blood results Review of anticoagulant medication Comorbidities Requirement for antibiotic prophylaxis
Implant time-out	Stent description Stent length and diameter Expiry date
Postlist debrief	Controlled drugs signed Equipment issues Samples labelled and sent Good practice Adverse events

ASA, American Society of Anaesthesiologists; ERCP, Endoscopic Retrograde Cholangiopancreatography.

Statements

14. Before any ERCP list, a full team briefing should occur. This should involve all members of the team (endoscopist(s), nursing team, radiographer and anaesthetist) in which cases are reviewed, potential difficulties highlighted and potential equipment (including endoscope) requirements reviewed.
15. Before each ERCP procedure, a minimum of a sign-in and time-out should occur that should include all of the basic endoscopy requirements (eg, identification, consent) but also components specific to ERCP (eg, clotting, pregnancy checks).
16. Whenever a stent is to be used, there should be a further time-out in which it is checked that the correct stent is being used and is in date.
17. Debriefs should occur at the end of lists and should focus on good practice and discussion about adverse events.

Staff well-being and teamwork

In the individual survey, 97% of ERCP endoscopists reported that they felt confident performing ERCP most of the time and 95% enjoyed their lists most of the time, with only a small number reporting dissatisfaction or lack of confidence. However, ERCP can be a tiring and stressful environment to work in. In the stakeholder group interviews, nurses described the environment as 'challenging', 'complex', 'intense' and 'difficult' and the culture of the room was often described as not being either inclusive, calm or supportive.

Fatigue is a significant element of ERCP practice given the need to concentrate for extended periods of time, standing upright and wearing lead gowns. Lists should be booked taking into consideration skill mix and complexity such that late finishes should be the exception, not the rule. Late finishes should be monitored and if they are frequent, the reasons behind this

should be investigated and rectified. Steps must be taken to minimise fatigue, including the provision of lightweight lead gowns. Breaks should be taken, particularly after a lengthy case. There should be easy access by an accessible phone to support staff if a procedure is proving lengthy or difficult. Drinks to maintain hydration should be available. Staff changes should be minimised during a list but should be encouraged between morning and afternoon sessions. Where staff changes do occur during a list, a repeat briefing may be necessary.

Communication and teamwork, situation awareness and leadership are all key elements of endoscopic non-technical skills (ENTS) that will lead to better outcomes from procedures.[28] There is an acknowledged shortfall of nurses who are keen to enter the ERCP environment. Attempts to enhance this environment should be encouraged to ensure that ERCP lists can be staffed by well-trained and enthusiastic nursing staff. A focus on teamwork in ERCP is particularly relevant and should be encouraged through training processes that include all members of the ERCP service team.[29] An acceptance of the risks of ERCP enshrined in a learning culture accompanied by well-constructed team briefs and debriefs will also benefit the well-being of the team and procedure outcomes.[27]

Statement

18. A focus on teamwork to foster a welcoming, just and learning culture in the ERCP room should be developed in all ERCP teams. Lists should be booked to avoid fatigue, with the provision of breaks and access to support staff.

Avoidance and management of complications

Pancreatitis is the most common complication of ERCP. Risk factors for pancreatitis and other complications have been identified in many studies and should be evaluated for all patients.[7] Such risk factors should be taken into consideration in the process of case selection and the consent discussion, as identified in the recent Coroner's inquest.[18]

Measures to reduce pancreatitis include use of rectal NSAIDs, placement of pancreatic ductal stents and aggressive intravenous fluid regimes. In the Individual survey, 25% of endoscopists always and 51% usually follow standard ESGE guidance on placement of pancreatic stents in the circumstance of inadvertent guidewire insertion into the pancreatic duct and only 3% of units have a written policy in this respect.[7] 44% of units have a written policy regarding rectal NSAID use whereas the remainder rely on individual practice. Adherence to international guidelines in relation to reducing the risk of pancreatitis should be mandatory and enshrined in written unit standard policies.

Early recognition and management of complications such as perforation or haemorrhage will lead to better outcomes. Endoscopists should be observant for the features of perforation during a procedure including worsening patient discomfort and be alert to free air on the X-ray image. While the absence of free gas does not exclude a perforation, its presence confirms it. While the acquisition of ERCP images varies significantly between practitioners, endoscopists should always scrutinise the final image to ensure that there is no evidence of a complication.

Pathways for managing suspected adverse events should be clearly identified and documented, including measures to access on-call teams, support for the deteriorating patient and emergency CT scans or IR.[27] A culture of early recognition and escalation of complications to the endoscopist from recovery nurses should be encouraged and a process of notification of complications established so they can be reviewed in morbidity and mortality (M&M) meetings. Duty of Candour policies should be followed in relation to ERCP complications and enshrined in the written unit SOP.

Statement

19. Unit policies for prevention and recognition of complications from ERCP should be enshrined in the written unit SOP. A culture of early recognition of complications during and after the procedure should be encouraged and enhanced through team-based training.

Postprocedure

Recovery

The purpose of the immediate postprocedure period is to ensure safe and timely recovery from administered sedation or anaesthetic, early detection and management of adverse events should they occur and the provision of information after the procedure before discharge.

Recovery from sedation or anaesthesia is the same for ERCP as any endoscopic procedure, though patients are often more comorbid and may have had a longer procedure requiring higher doses of sedation so require careful monitoring in recovery.

In 44% of units, ERCPs are performed in radiology. In circumstances where procedures are being performed away from the main endoscopy unit patients should have access to the same minimum standard recovery facilities and monitoring as all patients who have had an ERCP before discharge or return to the ward. It is also important that patient recovery should occur outside of the endoscopy room to allow satisfactory patient flow during the list.

ERCP recovery should be sufficiently staffed by nurses trained and experienced in monitoring and managing patients for cardiovascular complications following sedation and they should have access to appropriate medical support if adverse events occur.

Units should adopt a policy of monitoring patients carefully in the post-ERCP period with nurses trained

in recognising the symptoms of pancreatitis or other ERCP-related adverse events such as perforation. Development of pain that does not settle with simple analgesia should prompt urgent review by a clinician experienced in managing patients post-ERCP and usually admission into hospital. Although ESGE suggests testing serum amylase and/or lipase as a means of triaging safe discharge, in practice this is difficult to implement and is, therefore, not encouraged.[7] Patients should have access to blood tests or urgent imaging with CT scanning where there is a suspicion of perforation.

There is no universally accepted time duration for monitoring patients before discharge. Extended monitoring will result in inappropriate delays to discharge and a reduction in the proportion of cases being performed as day cases, whereas short monitoring periods will result in delayed diagnosis for patients discharged before the symptoms of an adverse event have developed. Most patients with pancreatitis will develop symptoms within a few hours so patients should be monitored for a minimum of 4 hours after the procedure. It may be clinically appropriate in selected low-risk patients to be discharged sooner, but not less than 2 hours after a procedure. Such patients should receive adequate safety netting advice and be reviewed by an ERCP endoscopist before discharge. Circumstances in which this is expected to occur should be noted in the unit SOP. However, units should monitor and audit all readmissions after ERCP.

Statement

20. Patients should be recovered in a suitable environment, equipped and staffed by nurses trained in recognising adverse events related to ERCP. Four hours is the minimum recommended recovery period, although in some selected cases 2 hours may be sufficient.

Discharge

In our stakeholder interviews, some patients reported that their conversation with the doctor was too soon while they were still feeling the effects of sedation. Some patients also reported that the content of this postprocedure discussion was inadequate and that they did not find out all relevant information until much later. Patients suggested that a postprocedure conversation between the endoscopist, patient and, if wished, a relative or caregiver, would be beneficial. To encourage better communication with the patient postprocedure these discussions should be undertaken in dedicated quiet rooms and not while the patient is on a bed in the recovery area. In addition to this, the presence of a friend, relative or caregiver during these discussions should be encouraged according to the patient's wishes.

Prior to discharge, it is important that patients receive adequate information about their procedure, the next steps and safety netting advice.[27] The GIRFT report stresses this in relation to the risks of biliary sepsis but this is relevant for late presentation of other adverse events such as pancreatitis and patients should be encouraged to seek advice and help in the circumstances of ongoing symptoms after the procedure. This is standard advice for all endoscopies but is particularly important for high-risk procedures such as ERCP. Units should develop post-ERCP leaflets and/or weblinks that advise patients on what to do and who to contact in the event of an adverse event.

Statement

21. Patients should receive information about their procedure and next steps in a private room once they have recovered from sedation. Written discharge information should be provided that gives advice about ERCP-specific adverse events and how to contact the hospital in the circumstance of developing such symptoms.

Follow-up after ERCP: repeat procedures and stent tracking

Temporary stents are commonly placed during ERCP procedures. Biliary stents used due to incomplete clearance of stones can become blocked resulting in biliary sepsis and metal stents used to treat benign strictures can become embedded if left for too long, which at worst can result in major biliary complications.

Plastic pancreatic stents inserted as prophylaxis may pass spontaneously but this should be checked with an abdominal X-ray and arrangements for removal made if it is still present. While the advent of biodegradable stents may alter practice, where a stent has been inserted as a temporary measure, this should be made clear in the ERCP report along with the plan for removal.

After a temporary stent is inserted, only 61% of hospitals have an administrative system for monitoring and recalling patients within the planned interval. Where such a system exists, it is administered by clerical staff in 53%, nurses in 22% and others in 25%. The GIRFT report similarly found variation in effective surveillance for patients with biliary stents with only 62% of Trusts running a database system to track patients with removable biliary stents.[3] This tracking is needed to ensure repeat procedures and stent removals are carried out on time and with fewer complications for patients as a result.

Statement

22. Trusts need to ensure that there is a reliable system in place for tracking patients with stents that require removal or exchange and ensuring that this is performed on time.

The ERCP team

Nursing

Successful therapeutic endoscopy is a consequence of teamwork.[27] This is nowhere more relevant than

in ERCP due to the wide range of equipment that is in use, sometimes lengthy procedures and the risk of complications. In the stakeholder interviews, ERCP nursing was seen as a complex skill to learn with a high level of knowledge required. Some reported the ERCP environment as challenging with a room culture governed by the endoscopist whereas valuing the skill of the ERCP nursing workforce garners a more positive working environment favouring better outcomes and encouraging nurses to advance their skills and undertake additional training to support ERCP.

For the procedure, the ERCP team includes the endoscopist, radiographer and nursing assistants who support with patient care and equipment preparation. However, the role of nursing in ERCP is far broader than this. In the room, an experienced ERCP nurse may anticipate next steps and assist with guidewire manipulation, stent delivery and can offer advice and support for the endoscopist and remainder of the team during the procedure.

ERCP nursing and leading an ERCP room requires a specific skillset that should be recognised as an integral part of the procedure and supported by the wider team. In the organisational survey, 47% of units required a formal assessment of ERCP-specific competency before they could lead a room whereas in 33% of units, ERCP competencies are not defined and there is no specific sign-off process. In view of the complexity of the procedures and the opportunity for error, competencies should be defined and demonstrated before a nurse can lead a room.

In addition, it is important that specialist ERCP nurses should demonstrate and, where necessary, receive training in leadership skills and ENTS as well as in indications for ERCP, pancreaticobiliary anatomy and physiology, equipment and ERCP complications.[28] Nurses should be encouraged and empowered to offer opinions and advice and be part of shared decision-making in all aspects of the procedure including prominent roles in preprocedure and postprocedure briefings and procedure checklists.

Care of the ERCP patient is not limited to the procedure room and there are several key roles outside of the ERCP room that are vital to support positive outcomes. Senior nurses and supporting staff assist with stock management and list preparation to ensure essential equipment is available and patients are prioritised and listed appropriately. Preassessment is essential to ensure that patients are adequately prepared and informed prior to their procedure. Currently, this occurs in only 64% of units whereas this should be universal. Senior ERCP nurses and unit managers should ensure that there is appropriate training in postprocedural care, including early recognition of complications and deteriorating patients. Finally, senior ERCP nurses should have key roles in investigating adverse events and in clinical safety and governance, contribute to MDT discussions (both at a local and network level) as well as supporting training for other nurses within the unit and the wider network.

There is an increased role for advanced clinical practitioners (ACP) who can assist with patient assessment on the ward and counselling before and after the procedure. The latest BSG guidance on consent states 'For high-risk urgent procedures patients should have access to an appropriately trained individual who can discuss the risks and alternatives to the patient on an individualised basis before they attend the endoscopy department for the procedure.'[16] This role can be successfully fulfilled by an appropriately trained ACP with a specialist interest in gastroenterology or hepatology. Currently, a specialist nurse routinely reviews patients on the ward prior to the procedure in only 16% of units and expansion of this role should be encouraged.

As noted above, there is currently no recognised curriculum or framework for training in ERCP consent. Nonetheless, consent for ERCP should involve a collaborative approach such that all ERCP and endoscopy nursing staff should be encouraged to participate in providing information and contribute to the consent process to the level of their ability and training.

The organisational survey demonstrated that the vast majority of units use three (76%) or more nurses to support an ERCP list, but that 6% of units use only two nurses. However, stakeholder interviews reported that there was a shortage of trained ERCP nurses and sometimes lists were understaffed. While the number of nurses required to support an ERCP list will vary, in the absence of anaesthetic support, the minimum should include one for patient care (head end) and two for equipment preparation and endoscopist assistance. If the list is performed on a remote site the number may be greater whereas if the procedure is supported by an anaesthetist and operating department practitioner (ODP) the number may be reduced.

While it is the case that an ERCP list should have appropriately trained and qualified nursing presence, it is recognised that the technical and non-technical skills required to support an ERCP list can be acquired by other allied health practitioners, for example, ODPs, healthcare assistants, assistant practitioners and nursing assistants and such individuals can support or lead ERCP lists where they have acquired and demonstrated the appropriate competencies in line with local governance protocols.

The number of nurses that a unit needs to train will vary. A balance has to be accepted between ensuring that there are sufficient trained staff to support regular lists allowing for absences, breaks and avoiding all-day lists on the one hand, while on the other, ensuring that trained nurses spend sufficient time in ERCP rooms to maintain their skills. In doing so, lead nurses, units and networks should ensure that nurses adopting a specialist ERCP role are adequately trained and signed off in defined competencies. Cross-departmental

training and experience across an ERCP network is encouraged to support high-level practice even in lower volume units and facilitate movement of staff between units if required. Training ERCP nurses in these specialist techniques requires that staff should be supported to attend training courses both in terms of time and finance and the creation of more specialist courses that support nurse training in ERCP should be a priority.

Statements

23. Each unit should have a list of nurses who have received training and are competent to lead an ERCP list. Nurses who lead ERCP lists should receive specialist training in hepatobiliary anatomy, ERCP indications, complications and equipment.
24. ERCP units should identify the competencies, training and credentialing needs (supported by the network) of ERCP nurses and ensure that nurses leading an ERCP room have received appropriate training and been signed off as competent.
25. ERCP nurses should have access to audit and CPD sessions both online and at face-to-face meetings, supported by an appropriate budget.
26. Nurses who lead ERCP rooms should have regular updates on the use of equipment at a minimum every 6 months. A network approach to this should be developed and nurses supported to be released to attend local specialist centres in order to achieve this.
27. ERCP lists should be supported by a minimum of three staff. Two must be registered healthcare staff and one must be a registered nurse. One member of staff should be trained in leading ERCP lists.
28. Each ERCP unit should have a named lead ERCP nurse that is responsible for supporting the training and mentoring of other ERCP nurses, troubleshooting equipment problems, ensuring appropriate stock levels and supporting governance processes within the unit.
29. Units should develop and support the expanding role of specialist nursing in ERCP to support patient preassessment and postprocedure care, especially for inpatients.
30. ERCP units should implement nurse preassessment for outpatient ERCP.
31. ERCP networks should identify a lead ERCP nurse to support training and movement of nurses between ERCP units within the network.

Management

Running an ERCP service is complex. Patients come from diverse sources, many are very acute and follow-up requirements are important. Services require support from other departments such as radiology and anaesthetics. Processes to ensure follow-up procedures and stent removals occur on time are essential but variable in the UK.[3] Given the acuity of ERCP procedures,[6] waiting times should be monitored and actioned and there should be notice when staffing levels mean list numbers fall below an accepted level, for example, due to annual leave, for which there should be a defined action plan. In this circumstance, options for movement of patients within a network to maximise capacity may need to be considered. The governance processes for ERCP are time-consuming but essential. Likewise, the acknowledged need for MDTs requires support at a managerial and clerical level. For these reasons, it is recommended that an ERCP service is supported by a triumvirate of lead endoscopist, nurse and manager who have dedicated time to enhance the service.

Statements

32. An ERCP service should be supported by a triumvirate of lead ERCP endoscopist, lead ERCP nurse and a member of the management team who is identified in assuring the quality of the ERCP service.
33. The lead ERCP manager should have roles in waiting list management (and publication), list booking, staffing levels, equipment management and supporting governance and CPD.
34. List numbers and capacity should be monitored and there should be an action plan in the ERCP SOP if numbers fall below a defined level.

The patient

ERCP may be a daunting prospect for many patients. They are frequently unwell and may be on opioid or other medication that impairs cognition, which must be considered as part of the capacity assessment for consent. Ideally, as a result, family members or friends should be involved in these discussions.

A patient attending for ERCP may not be at their best due to illness, fear and cognitive overload. ERCP is often required urgently but time should still be made for detailed discussions and information provision. In the UK, most ERCP continues to be performed under conscious sedation, yet there are critical steps in an ERCP that require completion for a safe outcome. This could potentially lead to a prolonged procedure during which the effect of sedation diminishes. These factors may result in an uncomfortable, agitated or at worst a non-compliant patient. Such circumstances should prompt early abandonment of the procedure, as soon as it is safe to do so, with early access to DS/GA to support comfortable and safe completion of the procedure objectives. In order to meet the needs of such patients, networks will need to look to expand the availability of DS/GA lists.

Units and all members of the wider ERCP team must recognise and accommodate these patient factors. A fully informed and reassured patient will likely be more compliant with the procedure resulting in a better experience for both the patient and team alike and in all probability a better clinical outcome. In the context of the procedure, this will be achieved by considering the patient as part of the team.

Further benefits will be achieved through involving patients to review information platforms, which

should consider and explain all steps of the procedure, particularly, the process and use of conscious sedation if it is to be used. Patient feedback should be sought for all elements of the service and this should be evaluated in departmental governance meetings. While there are validated Patient Reported Experience Measures for endoscopy generally, these should be developed and validated for ERCP specifically to facilitate this process.[30]

Statement

35. Feedback from patients who have had ERCP should be sought and fed back to unit and network governance meetings.

Supporting specialties

As a purely therapeutic procedure, high-quality ERCP is predicated on timely imaging and close collaboration with interested radiologists. A radiologist will be a key member of the ERCP MDT and radiology expertise should be readily available to review images and discuss cases within the MDT setting and on an ad hoc basis. The majority (87%) of respondents in the individual survey felt adequately supported by specialist GI radiologists. However, lack of trained specialist radiologists, access to image review and reporting and radiologists having job planned time to be available to support ERCP were among the top five most commonly suggested improvements to specialist radiology support. The most common suggested improvements were holding regular meetings with specialist radiology (16%) and the facility to perform combined procedures with IR (15%).

A significant proportion of patients undergoing ERCP are on surgical pathways leading to cholecystectomy or pancreaticobiliary surgery though alternative surgical management strategies such as laparoscopic CBD exploration may be appropriate for some patients under consideration of ERCP who have an in situ gallbladder. Optimum management of complex cases occurs at an intersection between surgical, interventional radiological and endoscopic techniques, which are under continuous development and refinement. The best patient management requires close collaboration between diagnostic radiology, endoscopy, surgery and IR to ensure a personalised approach with the selection of the best management strategy for that individual. Thus, radiological and surgical input into the ERCP MDT is required.

Adverse events due to ERCP may uncommonly require surgery or IR and urgent or failed procedures may require percutaneous biliary drainage (PTBD). A clear pathway to access 7-day PTBD either on-site or within the network is an essential attribute of an ERCP service. In the survey 55% of units had 7-day access to PTBD either in their own hospital or via a formal network arrangement, 12% relied on informal arrangements and 33% of units reported not having access to PTBD 7 days a week. Therefore, a close and collaborative relationship between the ERCP, surgical and radiological teams is crucial to the delivery of a high-quality safe ERCP service. Onsite access to acute surgical or IR expertise in the event of adverse events is preferable but where this is not consistently available, it should be noted in the departmental SOP and a clearly defined pathway to acute surgical and radiological expertise within the network should be described.

Anaesthetic engagement and support are important for the development and delivery of elective DS/GA lists and also in emergency or clinically unstable cases. While not every unit will have access to GA/DS there should still be access to anaesthetic support for acute or unstable cases. The latter may often be carried out in theatre as patients will usually be very unwell and unstable. Although rare events, all units should have clear and agreed pathways for these circumstances.

Statements

36. Specialist radiological support should be available to review imaging prior to ERCP for all units.
37. Where MDT input is required, radiological and surgical input should be available.
38. Urgent access to acute surgical and IR expertise should be available for all units, either locally or via network pathways, defined in the unit SOP.
39. Anaesthetic support for emergency or clinically unstable cases should be available in all units.

CPD, clinical governance, safety and KPIs

Continuous professional development

CPD is central to providing high-quality, safe patient care. The GMC's updated guidance on Good Medical Practice states that: '*You must take steps to monitor, maintain, develop, and improve your performance and the quality of your work, including taking part in systems of quality assurance and quality improvement to promote patient safety across the whole scope of your practice*' 'and, regarding CPD (Domain 1, point 13c), this includes '*regularly taking part in training and/or continuing professional development.*'[31]

From the BSG survey, it is clear that some clinicians struggle to achieve regular or adequate CPD specifically related to ERCP: 38% last undertook online CPD related to ERCP more than 12 months previously while over half of respondents (58%) had not attended any face-to-face ERCP CPD activities in the last 12 months. Half of respondents (53%) had no job-planned time for ERCP-related CPD and a similar percentage felt they had inadequate time allocated to this activity in their job plan. 79% of endoscopists surveyed felt they would like 1–2 hours per week of ERCP-related CPD and many suggestions for improving access to CPD were put forward, including dedicated CPD time which was supported by managers (suggested by 28%), more online training courses (22%) and more in-person training courses (20%). Other possibilities

included peer-to-peer support, visits to tertiary centres and specific ERCP-related conferences or courses.

One-third of respondents suggested formalised governance and audit review would be helpful and, in the related stakeholder interviews, this was also highlighted as central to practitioner development, particularly for more junior endoscopists, as it provided opportunities to reflect, learn and improve.

Statement

40. All endoscopists performing ERCP should have adequate time for specific ERCP-related CPD agreed in their job plans, which should include a minimum of 4 hours a month. The content and reflective learning from CPD should be available at annual appraisal.

Clinical governance and patient safety

Clinical governance in the NHS can be described as 'system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'. The GMC 'Good Medical Practice Guide 2024' also mandates that all registered medical practitioners participate in quality improvement to promote patient safety.[31]

ERCP is a high-risk endoscopic procedure. It is, therefore, crucial that individual clinicians, departments and the wider organisation ensure that appropriate clinical governance arrangements are in place to oversee and monitor safety, quality and patient experience. Individuals and teams should be confident that their ERCP practice is safe and of high quality and compares well when benchmarked against other practitioners, other units and published KPI or auditable outcomes for ERCP. The 2014 BSG document 'The Way Forward' outlined a number of clinical KPIs relevant to individual practitioners and units that are relevant today and should remain the minimum standard of clinical practice.[2]

The organisational survey showed that in many units good clinical governance arrangements are in place. 90% of units, for example, reported collation of routine quality assurance information. However, this means that 10% of units do not collate this information. It also showed that only 60% of units carry out planned patient record reviews to assess M&M. The main barriers to learning from clinical practice were identified as digital records not supporting easy audit reporting, lack of administrative support, lack of clinician time to carry out or oversee the work and lack of formal governance processes. Audit was particularly difficult for referral centres, where subsequent admissions happen in other units. 20% of units do not carry out any M&M reviews for patients referred from other units.

In stakeholder interviews, ERCP MDT meetings taking place prior to the procedure were seen as a useful tool for governance and discussion of complex cases, as well as best practice in patient selection. Provision for an ERCP MDT is, however, often lacking. Barriers to this were cited as lack of scheduled time in job plans and isolation of endoscopists performing ERCP from other ERCP colleagues locally or in wider networks.

In order to implement these changes and ensure compliance with KPIs and clinical governance standards, units should have a nominated clinical lead for their ERCP service, with adequate job planned time to facilitate this work. In most cases, it is likely this will be an ERCP endoscopist, though in smaller units this could be the endoscopy lead or another appropriate clinician who takes overall responsibility for the ERCP service.

All units should contribute data to the National Endoscopy Database (NED), which in turn will provide some clinical audit data. However, NED is unable to provide outcomes, complications or mortality data, which currently need to be collated manually. Linkage to Hospital Episode Statistics (HES) is desirable but not routinely available. Currently, such data are collated by clinicians or fellows. The ability to routinely collate such outcomes data for audit and governance should be developed and job planned within units, ideally with administrative team support. Networks and units should describe how and who collects these data within their SOP.

Further consideration for the safety and governance arrangements should be given to units in private or independent hospitals where different challenges may be met. The survey identified 8 (5%) private hospitals providing ERCP. For endoscopists working in private hospitals, whole practice data can be considered if they also work in the NHS, but there may be significant difficulties in terms of ensuring adequate patient numbers, obtaining/maintaining nursing skills and providing similar access to benign/malignant MDTs. It is essential in this respect that the entire ERCP team have regular access to procedures and that any shortfalls in procedure numbers, training and MDT access are addressed by the hospital with compelling evidence available that this has been achieved.[32]

Key performance indicators

Those KPIs adopted from the 2014 Standards Framework document that have not been repeated elsewhere in this document are listed in tables 4 and 5. Units and networks should have a process for monitoring individual KPIs as listed in the tables. The priority is high-quality safe practice evidenced by clinical outcomes. If individual performance levels are not achieved, or if performance or safety concerns are raised in other ways, there should be an agreed process for managing this in accordance with national guidance.[33 34]

Table 4 Clinical key performance indicators (KPIs) relevant to individual practitioners and services, adapted Wilkinson *et al*[2]

Input (objective)	Output (minimum)	Output (achievable)	Evidence
Able to undertake common procedures to high standard	Competence in level 1 and 2 procedures plus extraction of stones >10 mm in diameter	Endoscopists who deliver regional services also competent in levels 3 and 4 procedures.	Audit/rate card
Able to achieve success rates that meet 'family and friends test'	Successful cannulation (of clinically relevant duct) in 85% of 1st ever ERCPs* CBD Stone clearance at 1st ERCP in ≥75%* 80% patients with extrahepatic stricture have stent sited and cytology or histology taken at 1st ERCP where appropriate*	Successful cannulation in ≥90% of 1st ever ERCPs CBD Stone clearance at 1st ERCP in ≥80% >85% patients with extrahepatic stricture have stent sited histopathology/cytopathology taken at first ERCP	
Able to perform procedure with acceptable level of risk to patient	Complication rate for level 1 and 2 procedures <6%*		
Delivers ERCP as part of individualised package of care that draws on MDT	Full participation in core clinical services, including regular MDT meeting	Shares data and service developments across regional network	MDT meeting register, appraisal, network meetings
Has lead in educating others on role of ERCP	Trains year 1–3 trainees in indications, consent process and identification of complications	Able to deliver safe and effective hands on tuition Can undertake formative and summative assessments of ERCP trainees Able to mentor newly appointed consultants	Appraisal. Trainee feedback Evidence of participation in postgraduate and/or basic skills courses (including 'train the trainer course')

*On completion of mentorship (see training). Figures based on intention to treat, after exclusion of patients with Billroth II/Roux-en-Y anatomy. For patients with suspected CBD stone successful clearance defined as empty CBD with no stent in situ at end of procedure. Siting of stent requires proximal end of prosthesis to traverse stricture and (for plastic stents) distal end to traverse papilla.
CBD, common bile duct; ERCP, Endoscopic Retrograde Cholangiopancreatography; MDT, multidisciplinary team.

10 years have elapsed since the standards framework was published. It is now expected that, with respect to caseload numbers, individuals and units should meet the 'achievable' levels of 100 and 200 cases per annum, respectively, and that these should now be the auditable standard. While there is a lack of a clear-cut evidence base to support these precise thresholds, higher individual and unit procedure numbers have been associated with better patient-related outcomes both in malignant and benign disease, reduced adverse events and greater adherence to clinical guidelines.[35–40] The priority in stressing these numbers is in promoting equal access for all patients to high standards of care.

Mandating higher numbers encourages the allocation of a sufficient number of lists and job planned time for ERCP and may encourage individuals into subspecialisation with a greater focus on ERCP-specific governance and commitment to CPD. Further, helping individuals and units to achieve higher numbers through shared network working will avoid isolated practice, enhance training and improve the working

Table 5 Clinical key performance indicators relevant to individual practitioners and services, adapted from Wilkinson *et al*[2]

Input (objective)	Output (minimum)	Output (achievable)	Evidence
A service delivered by competent ERCP Practitioners	Endoscopists meet the minimum KPIs referenced in table 4	Endoscopists meet or exceed the achievable KPIs referenced in table 4	Sources of evidence referenced in table 4
A service that has sufficient capacity to deliver high-quality ERCP at a time determined by patient need	Non-urgent ERCP available on-site 52 weeks of year Emergency ERCP can be arranged Monday to Friday	Non-urgent ERCP list available every weekday Emergency ERCP can be arranged at weekends	Audit/GRS
A service with facilities for alternative and out of hours biliary drainage (on-site or as part of a clinical network)	Percutaneous transhepatic biliary drainage (PTBD) available 7 days a week, and within 24 hours of failed ERCP with duct opacification	The most appropriate form of biliary drainage (ERCP or PTBD) can be arranged 7 days a week	Review of cases/audit
A service with safe and appropriate sedation practice	Adheres to safe sedation practice [28] and can access anaesthetic support for patients who need it (onsite or as part of network)	Service can provide regular lists with dedicated sedationist/ anaesthetist.	Peer visit/GRS/Audit

ERCP, Endoscopic Retrograde Cholangiopancreatography; GRS, Global Rating Scale.

environment for clinicians. These factors will inevitably benefit patient outcomes.

Although it is recognised that for some individuals these higher numbers may represent a challenge to achieve, the priority remains the clinical outcome for the patient and not the wishes of the clinician. Currently, audit tools are too insensitive to allow detailed analysis of a clinician's performance so annual numbers remain an essential, though not the only, factor to consider.

Where an individual's annual number of 100 cases is not being met, and a clinician wishes to continue to provide ERCP this should be recognised and discussed with clinical managers and/or network leads. The discussion should take into consideration other factors including a clinician's auditable clinical outcomes, transferable skills from other therapeutic work, lifetime experience and the overarching needs of the service. The output from the discussion should describe in writing a process, with achievable timelines, to support that clinician to meet the standards and (rarely) any exemptions that may be appropriate. This should include, where required, additional training, mentoring and facilitating additional lists either in the clinician's own unit or within the wider network. The priority is a demonstrably safe clinical practice underpinned by adequate procedure numbers.

In stressing higher procedure numbers for units and individuals, there is a strong need to avoid the unintended consequences of driving experienced clinicians away or closing small units serving the needs of remote geographical areas. Networks will need to examine the needs of their population and consider solutions including movement of staff and/or patients between centres. Where exceptions occur, they should be recognised and noted within the network documentation with plans to mitigate the consequences of reduced numbers clearly described.

It should also be stressed that higher annual numbers should not occur at the cost of unnecessary procedures. A high-quality service will have low (and reducing) numbers of repeat procedures and very low numbers of negative cases where anticipated pathology (eg, CBD stones) is not present at the time of the procedure. These two elements of a service should be carefully audited and reported to the network clinical governance meeting.

It is anticipated that as time passes, with improved data acquisition, workforce contraction and the training of pancreaticobiliary-focused specialists the problem related to procedure numbers will diminish, but nonetheless, network and unit leads should not wait for this to occur and need to address these issues as a priority.

Statements

41. All units providing ERCP must have in place governance arrangements that specifically focus on ERCP practice. This must include a designated medical governance lead with adequate job planned time. This must also include regular and documented review meetings with relevant members of the MDT. The clinical governance arrangements must include as a minimum a retrospective review of:
a. 30-day complication and mortality rates.
b. Incidents.
c. Complaints and compliments.
d. Risk management.
e. Patient experience.

42. Referral centres should put in place systems that enable M&M reviews of patients who might have experienced readmissions to other units.

43. All units providing ERCP must carry out regular quality and safety audits of the ERCP service that cover the key quality and safety standards outlined in this document.

44. All units providing ERCP must have a designated medical clinical lead for ERCP who is responsible for ERCP service delivery and governance. This role should be supported by adequate job planned time.

45. All units performing ERCP should have an agreed process for determining and addressing endoscopist underperformance or safety concerns.

46. Individual ERCP endoscopists should perform a minimum of 100 procedures per annum and ERCP units should perform a minimum of 200 procedures per annum. Where a unit or individual does not meet the required numbers this should be reviewed by clinical or network leads and written plans developed to correct this.

Equipment and services

The ERCP unit and procedure room

The responses to the ERCP survey demonstrated that the facilities for ERCP delivery have areas needing improvement, with 50% of individual responders finding them mostly adequate with minor areas of improvement and 14% somewhat inadequate with some key limitations or problems. In addition to this, lack of space in the ERCP room was seen as a barrier to increasing the number of anaesthetist-supported lists for 34% of responders, and lack of space in the recovery room was seen as a barrier to providing facilities for safe recovery and discharge of the patient for 27% of responders.

This was reflected in the stakeholder interviews where there was felt to be a trade-off between the location of the room and the equipment depending on the room being in a dedicated endoscopy unit where patient flow is managed by the endoscopy team as opposed to the radiology department or theatres which have alternative systems of patient management.

Rooms in which ERCP procedures are performed need to be dedicated for use with ionising radiation including the doors and windows with warning lights for when radiation is in use. They also require additional dedicated equipment, storage

facilities and dedicated staff for stock management. While this is possible in endoscopy units with a dedicated fluoroscopy room, ERCP is provided in the radiology department in 44% of units and in the operating theatre in 3%. This presents greater challenges as it results in equipment needing to be taken to and from the fluoroscopy rooms in other departments, potentially leading to equipment being unavailable and/or disruptions in patient flow. Furthermore, units built in other departments may not have the appropriate room layout and ergonomics for endoscopic procedures, leading to risks to staff and patients. It should be noted that it is JAG policy that ERCP occurring outside of the endoscopy department should be subject to the same training and governance standards as if it had occurred within the endoscopy department and reports should be recorded on the Endoscopy Reporting Software.[33]

Recovering patients postprocedure should occur in an area with adequate access to trained staff who can carry out the regular postprocedural checks and are aware of postprocedural complications that may occur after ERCP or associated with sedation.[31] There may be a need for more intense monitoring of post-high-risk or anaesthetic procedures, and patients may need one-to-one nursing, which needs to be factored into workforce planning. In addition, a private room should be available for discussions between patients, supported by a friend, relative or caregiver if desired, and a member of the ERCP team to advise on the outcome of the procedure and provide safety netting advice.

Statements

47. ERCP should be performed in dedicated fluoroscopy rooms with sufficient space to accommodate the endoscopy, radiology and, where required, anaesthetic teams and their equipment.
48. The ERCP room should be located in a space where there is prompt access to all of the equipment that may be needed during the procedure and which promotes efficient patient flow.

Ergonomics

The use of lead gowns was highlighted as a concern in the stakeholder interviews, with staff reporting musculoskeletal pain associated with prolonged wear. The weight of the lead aprons was seen as a barrier for nurses training to assist in ERCP procedures.

Musculoskeletal injuries are common among ERCP endoscopists.[41] Lead aprons used in ERCP can weigh up to 9.1 kg and confer a high static load on the neck, shoulders and back whereas a two-piece apron has a load distribution advantage between the spine and pelvis.[42] Lead aprons and neck coverings suitable for the user's size should be available. They should be lightweight and ideally should be a separate skirt and top. If this is not available, supportive belts to be worn with the aprons should be made available. Removal of lead aprons between procedures should be encouraged, and simple interventions such as a convenient area to hang them should be made available.

Prolonged awkward postures are a risk factor for work-related strain injury, and neutral posture allows optimisation of energy expenditure while reducing force production.[42] Thus, the position of the monitor, fluoroscopy screen and procedure table height should be flexible and allow optimisation to the needs of individual endoscopists and nursing staff. The screens should also allow adequate views by the ERCP nurses and radiographers. Nurses should be provided with height adjustable stools with sufficient space to allow them to focus on the patient as well as be able to access monitoring equipment and their paperwork. In addition to this, there needs to be space in the room for trolleys, equipment preparation and to allow easy access to commonly used equipment and intraprocedural medication such as sedation, reversal agents and antispasmodics. Consideration of ergonomic principles may have a benefit in reducing the risk of work-related strain and radiation exposure.[43] Furthermore, trip hazards including trailing cables should be well covered and marked out.

Statements

49. Appropriately sized lightweight leads should be available for all staff participating in ERCP.
50. Room design should allow sufficient space for equipment storage and preparation and should be optimised to minimise musculoskeletal strain on staff participating in ERCP.

Fluoroscopy equipment and radiation protection

The provision of fluoroscopy among organisations was equally divided between units that use a mobile C-arm and a static fluoroscopy unit. The fluoroscopy units were rated as mostly adequate with minor areas for improvement by 42% of respondents and as somewhat inadequate with some key limitations or problems by 19%. The stakeholders interviewed felt that mobile C-arms were more likely to be encountered in the endoscopy department screening rooms rather than static fluoroscopy units (fixed C-arms), which were more commonly seen in the radiology department. Concerns were raised about potentially poorer imaging quality with mobile C-arms.

Mobile C-arms give out less energy and are designed to be used in rooms that may not necessarily be lead-lined and thus have lower imaging quality. Wherever possible, ERCP should be carried out in a dedicated fluoroscopy room with a fixed C-arm. This is especially important in centres that perform Schutz grades 3 and 4, which will likely require a higher imaging definition to allow for the adequate assessment and management of more complex pancreaticobiliary

pathology. Complex (grades 3 and 4) ERCP should be avoided where imaging quality is inadequate with a mobile C-arm.

Radiation doses were not recorded for individual procedures in 26% of organisations, and 17% did not monitor radiation exposure to ERCP endoscopists and nursing staff. Dosimeters are a mandatory legal requirement for all staff, including temporary staff within the department and their use should be implemented and monitored.

Almost half of organisations do not provide a radiation safety course. These are not in line with Ionising Radiation Medical Exposure Regulations (IRMER) regulations, where the onus of monitoring radiation exposure to staff falls on organisations with a recommendation to provide a regulation safety course to all staff who work with ionising radiation. IRMER courses are available for non-radiologists and are a mandatory safety requirement for staff working with ionising radiation.[44 45] Educating staff on ionising radiation not only improves their adherence to safety measures but also increases their understanding of how they can minimise radiation exposure in the room by simple measures such as where they stand in relation to the fluoroscopy unit and reducing fluoroscopy time and should, therefore, be mandatory for all ERCP endoscopists on a regular basis.[46]

PPE (personal protective equipment) for staff working with ionising radiation shielding measures include lead aprons, thyroid shields and eye protection with lead glasses.[42 47] Ocular exposure is similar to thyroid exposure during ERCP and can lead to cataracts and other ocular diseases such as macular degeneration. However, lead glasses are often not available in ERCP rooms or advocated as part of routine radiation shielding.[48] In addition, units should be able to provide acrylic and protective lead shields to reduce exposure to scattered radiation.[46 49] The PPE provided should meet the requirements of the user, and if required, personal assessments should be carried out to ensure that the legal requirements for protection against radiation-related illness are met.

There is a gender discrepancy in the ERCP workforce, with only 4% of ERCP endoscopists in the UK being female. Additional concerns were raised in the stakeholder interviews, specifically in relation to female staff. These include adequate cover of breast tissue and continued working with radiation while pregnant. Axillary covers should be considered to decrease radiation exposure in breast tissue.[50] Consideration should be made for more frequent dosimeter checks for pregnant women. Pregnant staff should have risk assessments performed if they will be participating in ERCP, with reassurance that the actual dose of radiation to the pregnant woman and fetus would be well below the recommended limits.[51]

Statements

51. Fluoroscopy equipment used for ERCP should be of sufficient standard that allows real-time analysis of images and visualisation of ductal anatomy to the level required for the procedure.
52. Radiation doses should be recorded for individual procedures, and radiation exposure to staff should be monitored using dosimeters. These should comply with local standards for radiation dosing and protection.
53. All units should provide a radiation safety or equivalent course with attendance mandated for all those working with ionising radiation.
54. Adequate PPE should be provided including eye protection glasses for all procedures.

X-ray acquisitions

There is no guidance covering standard image acquisition for ERCP, which is reflected in the variation in responses within the survey. In regard to X-ray acquisitions in cases for stone extraction, control films (with no contrast injected) were taken by 55% of respondents, an underfilled contrast cholangiogram by 71% and a cholangiogram with full opacification of the CBD/common hepatic duct/intrahepatic ducts in 49%. After stone extraction, 92% of respondents performed an X-ray acquisition with the extraction balloon inflated at the papilla with contrast above, 27% following the removal of all accessories with duodenoscope in situ and 45% following the removal of the duodenoscope.

The fluoroscopy images captured during ERCP should narrate the events that occurred during the ERCP with the ability to allow a detailed retrospective review of each case. This is essential to facilitate further clinical decision-making, especially if there is a complication from the procedure or it is incomplete. Furthermore, in the event of a medicolegal claim, stored images provide an essential reference point for reviewing the procedure.

Thus, standard images in every ERCP should include, at a minimum, a control image (no contrast or accessories), a cholangiogram and a final full abdominal exposure at the completion of the procedure. Further images should be taken that demonstrate any pathology that is encountered and significant steps taken during the procedure (including inadvertent events such as pancreatic duct cannulation). In the case of stone disease, a high-quality cholangiogram should be taken at the end of the procedure demonstrating, as far as possible, duct clearance where it has occurred. In addition, if the fluoroscopy machine is capable of capturing screening cine loops, then these should also be saved as they minimise the need for additional radiation.

Statements

55. Standard images at each ERCP should include a control image, a cholangiogram and a final full abdominal exposure at the completion of the

procedure. In addition to this, for cases of stone disease, a further cholangiogram should be taken confirming duct clearance where it has occurred.

56. Further images should be taken to demonstrate pathology encountered and significant events during the procedure.

Duodenoscopes and accessories

Two-thirds of the duodenoscopes being used by organisations are less than 5 years old. The endoscopists rated the duodenoscopes as mostly adequate with minor areas for improvement at 54% and somewhat inadequate with some key limitations at 7%. Perceived advantages of newer endoscopes include disposable caps which can potentially reduce duodenoscope-associated infections.[52] Despite these advances, reducing human error in reprocessing remains a key factor in reducing contamination.[53] Newer duodenoscopes with disposable caps or single-use duodenoscopes may be associated with additional device-associated adverse events.[54] The role of single use duodenoscopes is yet to be clearly defined in clinical practice and needs to take into consideration the handling characteristics, costs and environmental impact.[55 56]

There is a complexity involved in the standard equipment used in any ERCP. It is important to ensure that stock levels are sufficient to meet the demands of frequent lists and that there are systems to facilitate prompt replacement of equipment to ensure that key items are always available on demand. Dedicated systems for stock management are thus required. A standard ERCP uses a minimum of a guidewire, cannulation device and contrast and the number of additional equipment consumables increases with procedure complexity. Focusing on biliary strictures the length, diameter and type of stents can be vastly different between cases with a similar underlying disease process. In addition to this a full armament of equipment is required to allow management of unexpected findings or intraprocedural complications.

There needs to be an understanding of how to set up and operate the equipment and the ability to troubleshoot when needed by the endoscopists and nursing staff. Although some equipment is used more frequently, others such as baskets or lithotripters may be used less frequently so there is an onus for continued training and refreshing the skills of the nursing workforce.

Statements

57. There should be a sufficient number of duodenoscopes with adequate processing facilities to reduce the risk of duodenoscope-associated infections and to support a full (4 cases) ERCP list without delays due to reprocessing.

58. Staff should be trained to use the available equipment in the unit, especially those items that are used less frequently.

59. Dedicated systems should be available for stock management to ensure continuous availability of all equipment based on the complexity of ERCP being performed in individual units.

Deep sedation and general anaesthesia

The surveys indicated a desire for more DS/GA availability with 84% of responders feeling that their unit required more access to DS/GA lists and 62% having a preference to perform all ERCP under DS/GA. The main barrier to increasing DS/GA availability was a lack of anaesthetist availability for 86%. Other barriers included cost, monitoring and unavailability of ODPs to support anaesthetists.

Across organisations, there exists a provision of a DS/GA endoscopy service with 26% having regular lists each week, and 58% having access on an ad hoc basis. 16% of organisations have access to two or more regular DS/GA lists per week; of these, 34% are exclusively for hepato–pancreatico–biliary (HPB) endoscopy. Criteria for patient allocation to a DS/GA list include previous patient intolerance (93%), anticipated sedation risk to the patient (57%) and anticipated complexity of the procedure (53%).

The BSG sedation guidelines state that the sedation dose should be tailored to the procedural complexity, patient factors, procedure type and duration. Specifically regarding ERCP, the use of DS/GA is suggested for complex ERCP (Schutz grades 3 and 4) and combined EUS and ERCP procedures.[57]

Younger patients may have reduced tolerance to ERCP under conscious sedation, resulting in more unsuccessful or incomplete procedures, so consideration may need to be given to increasing access to DS/GA for these patients.[58 59] Patients who are critically ill and need emergency ERCP should have an anaesthetic review and be performed on an anaesthetic-supported list.

Some patients who underwent ERCP under conscious sedation who were interviewed as part of the stakeholder groups found the experience of ERCP traumatic even when they had a positive outcome from the procedure and most would have preferred to have received a GA. This is clearly an area where more work is needed to improve the patient experience.

Although DS/GA can reduce list capacity, a quality service would meet the minimum standards laid out in the BSG sedation guidelines through increased local or network access to DS/GA lists. It is recognised that lack of availability of DS/GA can result in failed procedures. The joint position statement from the BSG, JAG and Royal College of Anaesthetists in 2019 indicated that the availability of anaesthetist-led DS/GA needed to be expanded in the UK, a situation that has not improved significantly since then.[15] This unmet demand will continue to increase as procedure complexity, interventional EUS and combined EUS and ERCP procedures become more common. Work is required by unit

and network leaders to improve access to anaesthetist-supported lists in all hospitals to meet this demand, supported by collation of audit data. This should be augmented by national bodies (including the BSG) and patient groups to campaign for greater anaesthetic input to ERCP services.

Statements

60. Access to adequate numbers of DS/GA lists should be improved and made available regularly across organisations or networks.
61. Patients should be prioritised for DS/GA based on patient tolerance, the complexity of the procedure and patient factors, including the need for emergency ERCP or in unwell patients. If DS or GA are required but not available in the local hospital, facilities should be available to transfer the patient to an organisation that can provide this.

Network provision and MDT

A key recommendation made by the BSG ERCP working party in 2014 was the development of regional networks working on a hub and spoke model.[2] The fostering of informal regional ERCP interest groups as a step on the path to formalised networks was a focus of the first wave of the BSG ERCP quality improvement programme between 2017 and 2019.

The GIRFT gastroenterology report in 2021 recommended the consolidation of services, the use of ERCP MDT and the creation of regional ERCP networks.[3] NHSE in 2020 identified the development of endoscopy networks as a key priority with an initial focus on developing ERCP networks highlighted in 2023.[60] THE NHSE ERCP draft network and service recommendations build on the BSG 2014 standards framework document, and the recommendations are pertinent to ERCP services in other UK nations. The benefits of network ERCP provision have been widely articulated and are detailed on the NHSE website and elsewhere in this document.[61] They include resource optimisation, quality improvement, equitable access to tertiary expertise and a platform for high-quality training and collaborative research. Quality networks comprise human connections that enhance the working environment as well as standards and pathway development.

In the survey, 62% of units reported working within some form of a regional network, 10% had a formal network arrangement and 25% had no network arrangements. Questions where at least 30% of units had poor compliance included having a dedicated ERCP/benign MDT, working in a regional network and having written guideline/policies for ERCP clinical pathways.

As a wholly therapeutic intervention, ERCP does not exist in isolation and the development of regional networks must occur in a multidisciplinary way with key stakeholders as well as endoscopy (eg,surgery and radiology) involved at the outset. The determination of network area and the configuration of hub and spokes will be made locally and in most cases is likely to align with existing HPB cancer network hub and spoke arrangements (figure 1). There will be regional variation as to what works locally but it is important to avoid overlap of the clinical workload between the cancer and non-cancer networks.

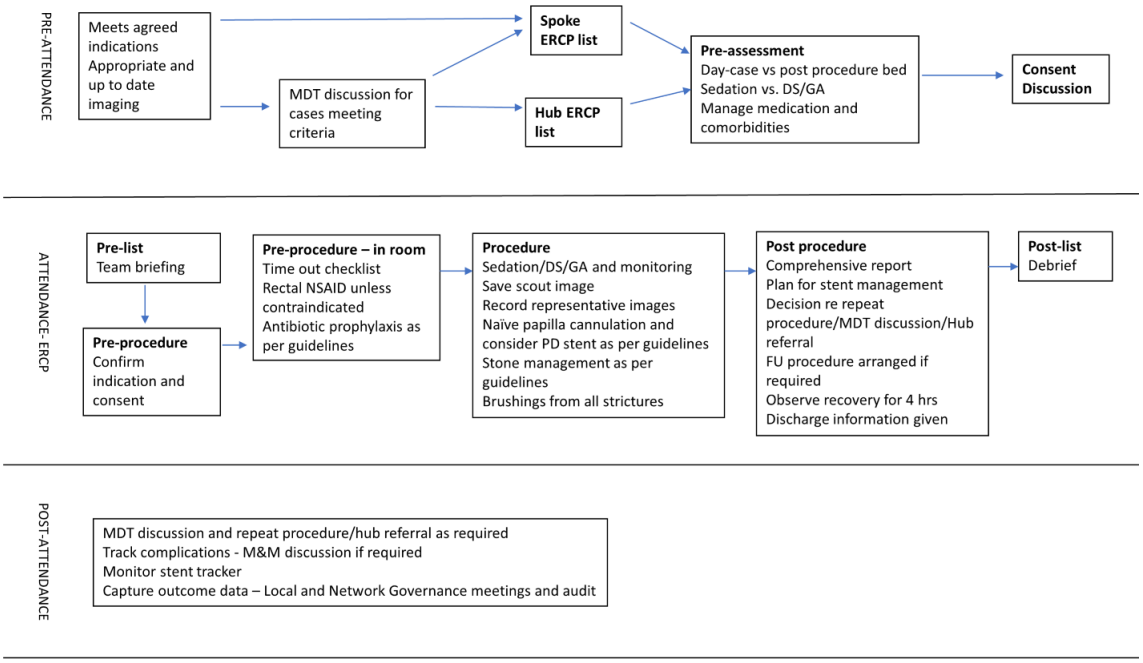

Figure 1 Role of network in ERCP service provision. DS/GA, deep sedation or general anaesthetic; ERCP, Endoscopic Retrograde Cholangiopancreatography; MDT, multidisciplinary team; M&M, morbidity and mortality; NSAID, non-steroidal anti-inflammatory drug.

It is expected that networks will develop and formalise protocols and pathways for endoscopic management of common conditions such as bile duct stones and sampling and palliation of biliary strictures. These pathways will reflect regional endoscopic and surgical expertise in accordance with the latest guidelines and will define which patients should be treated in referral centres.[4 6 8]

For example, there will be agreed protocols for:

1. Which patients with their gallbladder in situ undergo ERCP followed by cholecystectomy and which are considered for cholecystectomy and CBD exploration.
2. Agreed criteria for referral for per oral cholangioscopy and electrohydraulic lithotripsy or laser lithotripsy.
3. Appropriate maximum number of repeat procedures before onward referral to network Hub.
4. Ensuring timely ERCP or alternative drainage for patients with biliary sepsis.
5. Patients requiring referral for combined EUS and ERCP for biliary strictures.

Regular unit ERCP MDTs should occur to discuss complex cases not meeting the threshold for onward referral and to review results of endoscopist and unit KPIs. This MDT may occur as part of a regular upper GI/HPB MDT and existing endoscopy unit review of KPIs or as an independent meeting, depending on local needs. Regular network MDT with radiological, nursing and surgical representation will be held with the expectation of regular attendance by all ERCP endoscopists with this recognised in job plans.

The remit of the MDT will include, at a minimum, discussion of complex cases that are not clearly catered for by the agreed pathway. However, MDTs must not delay urgent procedures where these are required. In addition, there should be a regular network meeting with standing agenda items covering unit and individual KPIs, M&M data, network workforce and CPD. Network meetings for CPD/audit should be on an annual basis but individual units can carry out M&M more regularly, as appropriate for the unit. Audit and M&M meetings should include all members of the ERCP team, of which nurses are an integral part. However, provision should be made for emergency procedures where large members of the team and/or wider network are involved in such meetings.

The development of regional networks is envisioned as being complimentary to and in collaboration with pre-existing cancer and benign networks and pathways.

Statements

62. ERCP services should work collaboratively within a region, health board or integrated care board in a hub-and-spoke model with clear and formalised leadership and terms of reference.
63. Each network should develop and agree a pathway of care encompassing preprocedure, procedure and postprocedure care and data collection.
64. Each network should have a regular MDT to discuss complex or challenging cases, to which all units from the network should have access.
65. Each unit should participate in a network CPD/audit day at least annually. In addition, every unit performing ERCP should have regular M&M/audit meetings that include all members of the ERCP team.
66. Each network should agree formal protocols and pathways for the management of common pancreaticobiliary conditions.
67. Each network should develop and agree cover/backfill arrangements to maximise use of capacity to minimise patient waiting times and travel distance.
68. Each network should develop and agree measures to enable cross unit working of medical and nursing staff to enhance training.
69. Each network should develop and agree in collaboration with regional HPB service criteria a pathway for biliary drainage within 24 hours in urgent cases.
70. Each network should ensure that practitioner and unit annual volume are audited and the minimum numbers of 100 and 200 cases, respectively, is achieved as soon as feasible.

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