Royal College of Physicians | JAG Joint Advisory Group on GI Endoscopy

JAG accreditation programme
Guide to meeting the quality and safety standards

For UK services

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Contents

Introduction 3

Section A: clinical audit requirements 4

- Oesophago-gastro-duodenoscopy (OGD) 5
- Colonoscopy 7
- Flexible sigmoidoscopy 9
- GI bleeding 10
- Endoscopic retrograde cholangiopancreatography (ERCP) 11
- Endoscopic ultrasound (EUS) 12
- Small bowel capsule endoscopy (SBCE) 13

Section B: post colonoscopy colorectal cancer (PCCRC) 14

Section C: adverse event monitoring 18

Acknowledgements 21

Introduction

This guidance has been designed to assist endoscopy services and assessors in their preparation for a JAG accreditation assessment. It defines JAG's expectations for monitoring in the safety and quality domains (CQ2 and CQ4). The full list of accreditation requirements are detailed in *JAG accreditation criteria and evidence requirements*.

The guidance is applicable to acute and non-acute sector facilities, the NHS and the independent sector in the different nations of the UK. JAG aligns its standards to national policies across each of the devolved nations where they exist.

The core part of this guidance must be followed to achieve JAG accreditation. It has been noted where guidance is aspirational but not required for accreditation.

This update is necessary for several reasons:

- To align JAG requirements with new guidance that has been published by other organisations
- To provide greater clarity to JAG assessors and services preparing for accreditation
- To align JAG requirements with the release of post colonoscopy colorectal cancer (PCCRC) datasets
- To reflect the widespread adoption of the National Endoscopy Database (NED)
- To bring guidance in line with the Improving Safety and Reducing Error in Endoscopy (ISREE) strategy.

JAG expects all accredited services in the UK to upload data to NED. This produces standard outputs for key performance indicator (KPI) data so that clinical leads can compare the performance of their individual operators against standards set by the British Society of Gastroenterology (BSG) and benchmark against current UK performance data. NED reduces the burden of audits and allows for a wide range of KPIs to be assessed. In future iterations of NED other KPIs will be included and incorporated as part of JAG requirements.

This document supersedes the following JAG documents - 'JAG Summary guide to Quality & safety Indicators' (2016) and 'A guide to auditing quality and safety items of the Endoscopy Global Rating Scale' (2009).

Section A: clinical audit requirements

Wherever possible, the data for these will be obtained from the NED outputs by utilising the 'JAG audit' button on the NED website. **The current exceptions are upper GI bleeding, ERCP and EUS where services will need to perform separate audits (see below for specific details)**. For services that are not uploading to NED or have not yet gathered at least 12 month's data at the time of an accreditation assessment, then there is a mandatory template that JAG expects to be completed and analysed by the service and signed off by the clinical lead. Data will usually be downloaded from the local ERS.

Doing a large number of procedures does not guarantee competency and so it is important to look at the KPIs of all operators; this should include locums and endoscopists coming to work at the service via 'insourcing'. If the numbers of procedures are lower than the recommended threshold then these operators should first include all their practice (ie including all NHS and independent sector practice). This can be facilitated by NED, which provides an individual with their whole-of-practice performance (provided the unit is uploading to NED). Lower numbers than the minimums described in this document may be acceptable if the main KPIs eg colonoscopy completion rates / comfort scores or intubation rates at gastroscopy are satisfactory. It is also expected that some operators may have lower outcomes than the recognised standards but with good reasons eg those doing advanced therapeutic procedures who may not intend to reach the caecum at colonoscopy or the duodenum at OGD. The clinical lead is best placed to interpret their local dataset.

JAG expects to see:

- The last 12 months of KPI audit data for each procedure performed in the service. All KPIs should be assessed concurrently for every procedure eg colonoscopy. The '*Clinical lead review and action required*' column must be filled in for each operator as stated.
- A timetable setting out the annual schedule for the audit of these KPIs (at the intervals described in this document) aligned to a responsible individual.
- The minutes from recent meetings (over the last 12 months) eg endoscopy users group (EUG) or governance to show that the audits have been carried out as per the timetable and also reviewed. This should include detailed action planning.
- Evidence eg emails that individual operators (including trainees) have been informed of their results with specific action plans drawn up where necessary after each period eg colonoscopy every 6 months. The action plans should be in line with the service's policy for supporting the practice of endoscopists and will range from peer review of practice, attending an external course through to the cessation of practice where there is significant and/or persistent concerns (please see the JAG guidance *managing underperformance in endoscopists*). In almost every audit it is expected that some operators will not reach the required standards.

Oesophago-gastro-duodenoscopy (OGD)

To be audited every 6 months, available from NED (apart from gastric ulcer audit; see below)

A greater number of the standards from *Quality Standards in Upper Gastrointestinal Endoscopy : a Position Statement of the British Society of Gastroenterology (BSG) and Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS)* (2017) will be incorporated in the future into JAG accreditation requirements once they are easily accessible via future iterations of NED. Until then, it is not expected that these additional standards are routinely audited but services are encouraged to do so where they can. At present the JAG auditable outcomes for OGD are:

Quality indicator (per operator)	Minimal standard (where exists)
For individual operators	
Number of procedures (including those directly supervising a trainee within the room)	100
Success of intubation	95%
D2 intubation	95%
J manoeuvre rate	95%
Comfort rate % moderate or severe discomfort (for information)	
Median dose (Age <70) Midazolam*	≤5mg
Median dose (Age <70) Pethidine	≤50mg
Median dose (Age <70) Fentanyl	≤100mcg
Median dose (Age >70) Midazolam	≤2mg
Median dose (Age >70) Pethidine	≤25mg
Median dose (Age >70) Fentanyl	≤50mcg
Greater than recommended dose of sedation	0
Unsedated procedures in % (for interpretation of other results only)	
For the whole service (will need a specific audit as cannot be obtained from current version of NED)	
Gastric ulcers re-scoped within 12 weeks**	100% (where clinically appropriate – see footnote)

Footnotes

- These sedation levels have been extracted from the BSG colonoscopy guidance (see below) and seem appropriate for OGD
- **Gastric ulcers are defined as breaks in the mucosa >5mm in size. It is recognised that in some cases eg those with significant co-morbidity, repeat OGD may not be indicated. This should be recorded on the endoscopy report and assessed with the audit. **JAG acknowledges this audit cannot currently be undertaken from NED (but is likely to be in the future), however believes it is a good indicator of how services function when needing to arrange follow up procedures and therefore should be audited.**
- Photographic evidence of relevant anatomical landmarks (upper oesophagus, gastro-oesophageal junction, gastric body, antrum, duodenal bulb, distal duodenum, incisura (retroflexion) and fundus (retroflexion)) as well as any detected abnormalities should be recorded for all patients; this cannot currently be assessed by NED but JAG encourages services to periodically audit to ensure all endoscopists are compliant.

- JAG does not require a specific audit for PEGs or therapeutic OGD procedures eg dilation, stent insertion, haemostasis. None of this data can currently be acquired from NED but complications and clinical incidents relating to these procedures should be routinely assessed eg via Datix and discussion at endoscopy users / governance meetings. Services are encouraged to do their own audits of all these therapeutic procedures (including an assessment of appropriateness and aftercare) but particularly where concerns exist after analysis of any complications that are detected. It is likely these procedures will be auditable in the future with updates to NED.
- Transnasal upper GI endoscopy (performed in outpatient clinics in some services) should be included in this audit data if under the governance of GI services. JAG does not need to see audit data if this is managed through ENT.

Colonoscopy

To be audited every 6 months, available from NED

These are taken from *UK Performance Indicators & Quality Assurance Standards for Colonoscopy* (2016).

Quality indicator	Minimal standard (where exists)	Aspirational target (where applicable)
For individual operators		
Number of procedures per year (including those directly supervising a trainee within the room)	100	150
Digital rectal examination	100%	
Unadjusted caecal intubation rate*	90%	95%
Terminal ileal intubation rate in % (for information only)		
Polyp detection rate**	15%	20%
Polyp retrieval rate	90%	
Withdrawal time	6 minutes	10 minutes
Rectal retroversion rate	90%	
Comfort score***	<10% moderate or severe discomfort	
Median dose (Age <70) Midazolam	≤5mg	
Median dose (Age <70) Pethidine	≤50mg	
Median dose (Age <70) Fentanyl	≤100mcg	
Median dose (Age >70) Midazolam	≤2mg	
Median dose (Age >70) Pethidine	≤25mg	
Median dose (Age >70) Fentanyl	≤50mcg	
Greater than recommended dose of sedation	0	
Unsedated procedures in % (for interpretation of other results only)		
For the whole service		
Bowel preparation adequate or above for each different regime ****	90%	95%

Footnotes

- *Photographic evidence of the appendiceal orifice, ileocaecal valve, terminal ileum or anastomosis (if applicable) should be recorded for all patients. At present this cannot be audited via NED and so JAG expects that every service has a policy of everyone in the room (operator and assistants) agreeing that one of these landmarks has been reached to record a complete procedure in addition to the photo-documentation of these 'landmarks'. If there are any concerns raised by KPI audit data, then a separate audit can be carried out to ensure these are being recorded correctly for specific operators.
- ** Polyp detection rate - JAG recognises that it is challenging to obtain adenoma detection rates as endoscopy reporting systems are generally not linked to pathology ones to enable

audits to be completed easily. As a result, polyp detection rate or polypectomy rate may be used and will be expected to be in excess of the minimum standard.

- *** Comfort score – this should be agreed by everyone in the room (including the patient where possible)
- **** The NED audit output includes this for each operator which can be interpreted alongside other KPI results.
- All services should have policies for the management of large and large sessile polyps. There should also be a standard policy for where tattoos are placed in the relation to lesions 2cm or more and/or have an appearance suspicious for cancer. This practice is not possible from the current version of NED and so has been removed as a mandatory audit.
- NED cannot currently audit the rate of diagnostic biopsies taken for diarrhoea and so this has also been removed as a core audit requirement for JAG.

Flexible sigmoidoscopy

To be audited every 6 months, available from NED.

Although there are no specific standards for flexible sigmoidoscopy published by the BSG, some of these have been taken from the colonoscopy guidance as JAG feels they are equally applicable.

Quality indicator	Minimal standard (where exists)
For individual operators	
Number of procedures performed (for information only)	
Digital rectal examination	100%
Extent of procedure – splenic flexure in % (for information only)	
Extent of procedure – descending colon in % (for information only)	
Polyp detection rate*	
Polyp retrieval rate	
Rectal retroversion rate	90%
Comfort score	<10% moderate or severe discomfort
Median dose (Age <70) Midazolam	≤5mg
Median dose (Age <70) Pethidine	≤50mg
Median dose (Age <70) Fentanyl	≤100mcg
Median dose (Age >70) Midazolam	≤2mg
Median dose (Age >70) Pethidine	≤25mg
Median dose (Age >70) Fentanyl	≤50mcg
Greater than recommended dose of sedation	0
Unsedated procedures in % (for interpretation of other results only)	
Diagnostic rectal biopsies for diarrhoea	100%
Tattooing all lesions ≥20mm and/or suspicious of cancer outside of rectum and caecum**	100%
For the whole service	
Bowel preparation adequate or above for each different regime ***	90%

Footnote

- JAG recognises that it is challenging to obtain adenoma detection rates as endoscopy reporting systems are generally not linked to pathology ones to enable audits to be completed easily. As a result polyp detection rate or polypectomy rate may be used.
- ** All services should have policies for the management of large and large sessile polyps. There should also be a standard policy for where tattoos are placed in the relation to lesions 2cm or more and/or have an appearance suspicious for cancer.
- *** The NED audit output includes this for each operator which can be interpreted alongside other KPI results.

GI bleeding

To be assessed and audited annually, not available from NED.

JAG expect services to achieve at least 50% of the *NICE Quality Statements for Acute Upper GI Bleeding in Adults* (2013). It is acknowledged that some of these are outside of the direct control of the endoscopy service eg scoring with risk stratification tools at presentation.

No	Standard	Standard met (Y/N)	If no – action plan
1	People with acute upper GI bleeding receive a risk assessment using a validated risk score soon after presentation.		
2	People with severe acute upper GI bleeding who are haemodynamically unstable are given an endoscopy within 2 hours of optimal resuscitation.		
3	People admitted to hospital with acute upper GI bleeding who are haemodynamically stable are given an endoscopy within 24 hours of admission.		
4	People with non-variceal acute upper GI bleeding and stigmata of recent haemorrhage are offered endoscopic treatments (combination or a mechanical method).		
5	People with non-variceal acute upper GI bleeding who continue to bleed or re-bleed after endoscopic treatment and who are haemodynamically unstable are given interventional radiology treatment.		
6	People with suspected or confirmed variceal acute upper GI bleeding are given antibiotic therapy at presentation.		
7	People with acute upper GI bleeding from oesophageal varices are given band ligation.		
8	People with acute upper GI bleeding from gastric varices are given an endoscopic injection of N-butyl-2-cyanoacrylate (this will need early liaison with the local liver unit / tertiary centre if not available onsite).		
9	People with uncontrolled acute upper GI bleeding from varices are given transjugular intrahepatic portosystemic shunts (TIPS) (this will need early liaison with the local liver unit / tertiary centre if not available onsite).		
10	People with acute upper GI bleeding who take aspirin for secondary prevention of vascular events and in whom haemostasis has been achieved are advised to continue on low-dose aspirin.		
In addition, it is expected that all services will collect audit data of the number of patients with acute upper GI bleeds who are haemodynamically stable have an upper GI endoscopy within 24hours		Target ≥75%	

For non-acute services, a standard operating policy is required to show how major complications such as GI bleeds are dealt with including stabilisation and transfer.

Endoscopic retrograde cholangiopancreatography (ERCP)

To be audited every 12 months, not available from NED.

Currently NED can only produce data to show the number of patients who have had an ERCP per operator. JAG believes that it is important that this relatively higher risk procedure is audited. A limited number of key indices have been chosen to be audited against. These will be readily accessible from future iterations of NED (the wording in the table below is aligned to what will be available) and are predominantly taken from *ERCP: The Way Forward. A Standards Framework* (2015). These should be audited where ERCP occurs in the unit or 'off unit' eg in radiology if undertaken by endoscopy staff.

Quality indicator	Minimal standard (where exists)	Aspirational target (where applicable)
For individual operators		
Number of procedures (including those directly supervising a trainee within the room)	75	100
Successful cannulation of clinically relevant duct at 1st ever ERCP (exclude those with previous Bilroth 2 / Roux-en-Y)	≥85%	≥90%
CBD Stone clearance 1st ever ERCP (exclude those with previous Bilroth 2 / Roux-en-Y)	≥75%	≥80%
Extra-hepatic stricture cytology/histology and stent placement at first ever ERCP (exclude those with previous Bilroth 2 / Roux-en-Y)	≥80%	≥85%
Median dose (Age <70) Midazolam*	≤5mg	
Median dose (Age <70) Pethidine	≤50mg	
Median dose (Age <70) Fentanyl	≤100mcg	
Median dose (Age >70) Midazolam	≤2mg	
Median dose (Age >70) Pethidine	≤25mg	
Median dose (Age >70) Fentanyl	≤50mcg	
Greater than recommended dose of sedation	0	
Unsedated procedures in % (for interpretation of other results only)		
% of procedures performed with propofol		
Comfort rate % moderate or severe discomfort		
For the whole service		
Number of cases per year	150	200

Footnote

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

Endoscopic ultrasound (EUS)

To be audited every 12 months, not available from NED.

These indicators are taken from *Performance measures for ERCP and EUS : A ESGE Quality Improvement initiative* (2018).

Quality indicator	Minimal standard (where exists)	Aspirational target (where applicable)
Prophylactic antibiotics before EUS guided puncture of cystic lesions	90%	95%
Frequency of obtaining a diagnostic tissue sample in EUS FNA or FNB (fine needle biopsy) of solid lesions	85%	90%
Median dose (Age <70) Midazolam*	≤5mg	
Median dose (Age <70) Pethidine	≤50mg	
Median dose (Age <70) Fentanyl	≤100mcg	
Median dose (Age >70) Midazolam	≤2mg	
Median dose (Age >70) Pethidine	≤25mg	
Median dose (Age >70) Fentanyl	≤50mcg	
Greater than recommended dose of sedation	0	
Unsedated procedures in % (for interpretation of other results only)		
% of procedures performed with propofol		
Comfort rate % moderate or severe discomfort		
Number of cases per year		

Footnote

- *The sedation dosages are extrapolated from the colonoscopy and OGD guidance. As per ERCP (see footnote above), JAG feels this is a safe starting point in the absence of any specific guidance for EUS.

Small bowel capsule endoscopy (SBCE)

To be audited every 12 months, not available from NED.

These indicators are taken from *Performance measures for small bowel endoscopy: A European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative* (2019).

Quality indicator	Minimal standard (where exists)	Aspirational target (where applicable)
Indication for SBCE	>95%	>95%
Caecal Visualization/Complete small Bowel examination	>80%	>95%
Capsule retention rate	<2%	
Number of cases per year		

There is no current standard for the number of cases that a SBCE endoscopy service should deliver but this should still be recorded as it allows understanding of the numerators for the other standards.

Section B: post colonoscopy colorectal cancer (PCCRC)

PCCRCs are defined as a diagnosis of colorectal cancer (adenocarcinoma) after a colonoscopy has been performed where no cancer was diagnosed.

The *key performance indicators and quality assurance standards for colonoscopy* (2016) states that PCCRCs should be viewed as an adverse event. When determining the most plausible explanation, the World Endoscopy Organisation uses a limit of 5 years after colonoscopy (those more than 5 years are considered to be most likely de-novo cancers). The rate is often calculated for pragmatic reasons, however, for 3 years post colonoscopy. National datasets based on coding may in the future become available annually with the details of every patient diagnosed with a colorectal cancer that has been found after 6 months and within 3 years after a 'negative' colonoscopy (ie no cancer detected) in their service. This will be achieved by linking data from the cancer registry with HES data (or alternatives in the devolved nations). Currently similar data forms part of Getting it Right First Time (GIRFT) data packs for trusts in England. In other countries, until national data is available, a system should be developed locally to capture data (or perform an annual retrospective review of all colorectal cancers diagnosed locally) and review each PCCRC as an adverse event with a similar root cause analysis. In the future it is very likely that JAG will also require a similar assessment of all Post-OGD Upper Gastrointestinal Cancers (POUGICs).

A small number of PCCRCs may grow from rapidly progressing lesions particularly in high risk patient cohorts eg genetic abnormalities, IBD (especially with PSC etc.) who should have regular surveillance procedures. In average risk cohorts there is evidence that it takes over 10 years to progress from normal mucosa to cancer (see WEO publication, hyperlink below). It is therefore proposed that most PCCRCs are due to other factors, for example missed cancers or missed / incompletely resected adenomas. These can be as a result of inadequate bowel preparation, factors relating to the endoscopist (eg not reaching the caecum), rapid withdrawal times, inadequate inspection of the colon or incomplete resection of adenomas. In some cases it may arise because the lack of processes/robust IT recall systems or long waiting times etc.

JAG expects to see that an investigation of contributory factors undertaken for each case which should identify the most plausible cause in order to provide important feedback for the practice of the unit or individuals. This analysis can be labelled as an RCA (root cause analysis), or contributory factor analysis to reduce confusion with other processes related to serious incidents. It should be undertaken by the endoscopy clinical (or governance) lead and any key learning points discussed at an endoscopy or governance meeting. This investigation is considered in conjunction with other KPIs for the endoscopist. It should not in itself define accountability to the endoscopist (see footnote of table below).

From the contents of table 3 in *World Endoscopy Organisation Consensus Statements on Post-Colonoscopy and Post-Imaging Gastroenterology* (2018), a proforma has been drawn up for services to undertake an investigation of contributory factors of every case to determine the most plausible cause. This is because it is challenging to be sure of the exact aetiology given the potential variabilities in cancer biology. The table below has been adapted from this original publication to support services in understanding factors involved in each case, to provide a record of each occurrence and facilitate lesson learning to reduce incidence in future.

PCCRC investigation of contributory factors proforma	
Patient demographics	
Age (y)	
Gender (M/F)	
High risk cohort? (IBD, hereditary forms of CRC) (Y/N)	
Details of procedure that led to cancer diagnosis	
Procedure date	
Procedure type	
Procedure indication (screening/site-check/surveillance/symptom-driven [state symptom]/therapeutic/other abnormal investigation/other/unknown)	
Cancer Details	
Location	
Macroscopic appearance (eg pedunculated, exophytic, ulcerated or diffusely infiltrating)	
Tumour size (horizontal or width in mm)	
Histologic type	
Tumour grade (low/high)	
Treatment planned	
Treatment intent (curative/palliative/unknown)	
TNM stage	
Dukes stage	
Details of preceding procedure	
Procedure date	
Procedure type	
Procedure indication (screening/site-check/surveillance/symptom-driven [state symptom]/therapeutic/other abnormal investigation/other/unknown)	
Unit ID/Name/Location	
Endoscopist ID	
Endoscopist mean withdrawal time (mins) for year of procedure	
Endoscopist Polyp Detection Rate (%) for preceding year	
Make/type of endoscope	
Quality of bowel preparation (use validated scale where possible; or good/adequate/inadequate/not recorded)	
Extent of procedure	
If incomplete, what was the reason (eg looping, luminal stricture etc.)	
Photo of caecum if reached	
Retroflexion performed	
Withdrawal time	
Colonoscopy result (cancer/polyps/other abnormality/normal/unknown)	
If polyp(s) found:	
Number of polyps identified	

List the following for each polyp (continue over if required): 1. Size of polyp(s) (mm) 2. Site of polyp(s) 3. Polyp morphology (Paris) 4. Histological type of polyp (adenoma, serrated etc.) 5. Dysplasia grade (high, low, none) 6. Method of polyp removal (cold snare, cold biopsy, hot biopsy, hot snare, piecemeal EMR, en bloc EMR, ESD, not removed) 7. Completeness of lesion excision (not assessed, incompletely resected, completely resected, not removed)	
Polyp 1	
Polyp 2	
Polyp 3	
Polyp 4	
Polyp 5	
Follow-up plan from preceding procedure	
Follow-up plan (screening/surveillance/site-check endoscopy/refer for therapy/conservative/no recommendation given/unknown)	
What follow-up interval was recommended?	
Was the follow-up plan (if applicable) adhered to?	
If not, provide reason for deviation:	
Final PCCRC categorization (refer to WEO PCCRC categorization)	
What is the most plausible PCCRC aetiology? (see 'most plausible aetiology' table)	
Any 'lessons to be learnt' from	

Most plausible* PCCRC aetiology

Category	All parameters required to meet the category
Possible* missed lesion, prior examination adequate	• No advanced adenomas (>1cm and/or villous, and/or high-grade dysplasia in the same bowel segment • Evidence caecal intubation • Adequate bowel preparation indicated
Possible* missed lesion, prior examination inadequate	• No advanced adenomas (as above) in the same bowel segment • But where either - • Caecal intubation not achieved or documented • Bowel prep was inadequate
Detected lesion, not resected	• Advanced adenoma (see above) detected in the same bowel segment but not removed
Likely* incomplete resection of previously identified lesion	• Advanced adenoma resected from the same bowel segment but no endoscopic / histological evidence of complete resection
Deviation from the planned management pathway**	• Clear deviation from the intended pathway eg a polyp was intended to be removed at a later date but for some reason this did not happen.

Footnote

- *The guidance states the disclaimer that ‘Categorization of PCCRCs according to their most plausible explanations should be used to facilitate quality assurance work or research. This categorization should not be used to define accountability at individual level or as a measure to define or support medico-legal decision making’. JAG recognises, however, that this is a very important aspect of the quality assurance of an endoscopy service and requires dedicated time from its clinical lead to ensure this analysis is done effectively.
- The ‘most plausible aetiology’ in this guidance is used on the basis of a 4 year cut off after the initial colonoscopy. A cut off of 3 years has been supported in the same document to define PCCRCs for the purpose of quality assurance to ensure a good sample size and the assessment of contemporaneous practice.
- **This is a modifying statement – ie you can add it to any of the others, but it is not a separate category per se.

Section C: adverse event monitoring

Endoscopy is an interventional practice with known adverse events that JAG anticipates will occur in all services. Endoscopy adverse events are multifactorial and can arise as a result of the procedure, from the sedation that is administered or poor decontamination of endoscopic equipment as examples. Adverse events may become apparent before, at the time or shortly after a procedure (ie can largely be documented on the appointment day as 'patient safety incidents'). They may also arise some days later and be much harder to capture by the endoscopy service and so will need additional systems to be in place to identify them.

JAG expects to see that:

- A system is in place to capture all suspected patient safety incidents close to the time where patients may have come to harm (including 'near misses'). This must be via an electronic system eg Datix.
- There are also additional practices to capture as comprehensively as possible all morbidity and mortality associated with endoscopy and to disseminate learning to endoscopy users (nurses, gastroenterologists and surgeons). Services need to have ongoing processes in place to identify any patient who is unexpectedly admitted to a hospital within 8 days of an endoscopy or who have died within 30 days of a procedure. This can be done via coding but must be sent to the endoscopy department monthly to be assessed – the majority of admissions and deaths after endoscopy will not have any direct relationship with the procedures but may provide useful learning on decision making and the futility of procedures in high risk patients. JAG recognises that this is challenging and there is no single mechanism to do this in the UK as the various healthcare providers have different IT systems that may not readily interact. Patients may present with later complications at a different service to where they had their endoscopy but a process should be in place to capture this where feasible eg patients taking a copy of their report with them when they attend another hospital and them informing the service where the procedure was undertaken.
- This clinical incident reporting and assessment of morbidity and mortality need to feed into EUG (or similar meetings where endoscopy staff are present) and not just into more distant corporate meetings. Adverse event monitoring and safety issues (ISREE) should be a standard agenda item at each meeting.
- All patient safety incidents should be recorded, for example on Datix. The endoscopy clinical lead should select those that need a root cause analysis (based on their nature, severity and frequency) and who should undertake this. The analysis should determine any 'lessons learnt' which are then minuted at meetings with action plans.
- The outcomes may need to be conveyed to relevant management to facilitate action eg staffing. There is also a duty of candour to the patient to inform them in a timely manner that a patient safety incident has been recorded and that an assessment has taken place.
- Each service should have a nominated safety lead. This can be the clinical or governance lead but should have an identified role to promote safe and share learning from both local and national safety lessons. They should work both within the endoscopy service and report to the local governance and safety team within the host organisation.

These processes must also be done within the independent sector. Morbidity and mortality can be more challenging as the patients will not be admitted to the same site and so specific steps will need to be taken to obtain this information, for example those with NHS contracts asking them to provide

details of patients, or putting requests on post-procedural discharge leaflets for patients / referrers to make contact if problems arrive post discharge.

JAG does not ask for an annual audit of morbidity and mortality. JAG recognises that has a high burden for services with a limited amount of benefit. Instead JAG requests evidence in the minutes of meetings that adverse events are a standing agenda items with ongoing analysis to determine 'lessons learnt'.

Suggested categories for patient safety incidents (PSI) in endoscopy are detailed below and aligned to ISREE:

- Drug errors
- Sedation, IV access or and monitoring
- Technical skills
- Equipment
- Endoscopy non-technical skills (ENTS)
- Training
- Documentation or reporting
- Consent
- Histology or sampling

The table below provides some of the quoted morbidity and mortality rates associated with endoscopy (JAG does not expect specific audits against these but procedures should be in place to prospectively capture cases. If any concerns arise then a full audit of practice should be undertaken). They are taken from the following documents which also provide extra information and guidance:

- *UK Performance Indicators & Quality Assurance Standards for Colonoscopy* (2016)
- *Complications of GI Endoscopy BSG* (2006)
- *The provision of a percutaneously placed enteral tube feeding service* (2010)

Outcome	Standard	Aspirational target (where applicable)
Perforation after endoscopic procedure	**OGD** Diagnostic <1in 3,000 Dilation - Benign Stricture <1 in 100 Malignant Stricture <1 in 20 Achalasia <1 in 20 Gastric outlet obstruction <1in 20 **Colonoscopy** Overall rate <1 in 1000 Diagnostic rate <1 in 2000 After polypectomy <1in 500 After dilatation <1 in 33 After stenting <1 in 10 **Flexible sigmoidoscopy** <1 in 5000	 <1 in 3000 <1 in 4000 <1 in 1500 <1 in 100 <1 in 20 <1 in 10000

	ERCP <1in 50	
Post polypectomy bleed rate (intermediate or greater severity) *	Polypectomy bleed – <1 in 200	<1 in 1000
PEG insertion	Major complications (that result in further endoscopic or surgical intervention / threat to life / hospitalisation or prolonged stay) eg perforation / peritonitis / bleeding <1 in 33	
ERCP specific complication rate	Sphincterotomy requiring transfusion <1 in 50 Clinically symptomatic pancreatitis <1 in 20	
EUS major complications	Perforation, acute pancreatitis, infection, bleeding <1in 100	
Mortality Rates (please note there is a wide variation in quoted mortality rates which will depend on case mix / co-morbidity)	Diagnostic OGD – 1 in 25000 Diagnostic colonoscopy 1 in 15000 Direct procedural related to PEG <1in 100 (30 day rates vary as per case selection, no set standard) ERCP < 1 in 100	

Footnote

- *Severity classification (taken from Quality assurance Guidelines for Colonoscopy, NHS BCSP NHS England – Chilton & Rutter 2011)

Rectal bleeding within 30 days of procedure resulting in any of the following:

Severity	Criteria
Minor	• Procedure aborted • Unplanned post procedure medical consultation • Unplanned hospital admission or prolongation of hospital stay for ≤3days
Intermediate	• Haemoglobin drop of ≥20g/L • Transfusion • Unplanned admission or prolongation for 4 to 10 nights • ITU admission for 1 night • Interventional procedure (endoscopic or radiological)
Major	• Surgery • Unplanned admission or prolongation for >10 nights • ITU admission >1night
Fatal	• Death

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