

A guide to auditing quality and safety items of the Endoscopy Global Rating Scale

The quality and safety items have led to some misunderstanding and services have found providing audits of quality and safety for JAG Visits challenging, particularly if they do not have a modern IT system for collecting data.

There have been concerns about the volume of audit required and whether once standards have been achieved it is necessary to continue to audit. This guide deals with these issues.

THE FUNCTION OF THE 'CLINICAL QUALITY' DOMAIN OF THE GRS

The Clinical Quality domain of the GRS is designed to assess the quality and safety of a service without being excessively burdensome. Major functions of this domain are to:

- respond to the challenges raised by the 2004 NCEPOD report – 'Scoping our Practice'. This report highlighted major issues with quality, safety and appropriateness of procedures
- reassure the uninformed patient that they will be cared for in a safe and high quality environment.

Inevitably there is a limit to what information it is reasonable to capture because a point of diminishing returns is reached:

At the point of diminishing returns, the gain achieved by the process is outweighed by the effort invested in it

There will inevitably be different opinions on when this point is reached. This guide describes a compromise position for the items 'safety' and 'quality of the procedure'.

The audit processes for quality and safety have much in common but there are a few fundamental differences (for example some safety issues cannot be predicted).

Quality and safety outcomes are evident:

- immediately - before the patient leaves the department
- late - after leaving the department

Some outcomes such as perforation and bleeding after polypectomy may be **first** evident immediately, or late.

It is recommended that different processes are used to monitor immediate and late outcomes.

Some endoscopic outcomes are causally associated with the procedure and/or the decision to investigate. Others are dependent on factors beyond endoscopy. For gastrointestinal bleeding use of intravenous PPIs, resuscitation facilities, nursing care and surgical care may all affect outcome.

It is recommended for the GRS that Units only acquire and review information directly relevant to the procedure. For example duct decompression following ERCP is an important late quality outcome directly related to the procedure (keep in the GRS) whereas death from GI bleeding has many contributory factors (leave out of the GRS).

IMMEDIATE OUTCOMES

Immediate outcomes are relatively easy to capture but more challenging to record in a reliable way. Endoscopy reporting systems (ERS) are generally good at capturing the key quality outcomes

but not so reliable at capturing key safety outcomes, particularly if they are identified **after** the report is completed

It is recommended that, as a minimum, an endoscopy service should have processes in place (preferably IT based) to capture all immediate quality and safety outcomes (as defined above). Some safety items will be missed by an ERS and a separate process will be required for capturing these. Some quality outcomes such as failed endoscopy may not be captured on a reporting system. If immediate outcomes are captured on a continuous basis then it should be possible for them to be reviewed at least twice a year.

All quality and some safety outcomes are predictable, but some safety outcomes are unpredictable.

It is recommended there be a separate process for capturing unpredictable safety outcomes (see ACIs below). This could be linked to the process of capturing known adverse events identified after the endoscopy report is completed using a 'session proforma' (see example in appendix).

WHEN SHOULD ADVERSE EVENTS BE RECORDED AS ADVERSE CLINICAL INCIDENTS?

The method of adverse clinical incidents (ACIs) reporting is based on the process the airline industry uses to avoid major catastrophes. The idea is that ACIs identify system weaknesses before they lead to avoidable death or mutilation. Processing ACIs is a laborious practice that may be inappropriate for **known** adverse events in endoscopy. The key is that adverse events are recorded and acted upon if a reversible weakness in the system, or the performance of an individual, is identified.

It is recommended that if there is a process in place for recording and acting upon expected adverse events, it is not necessary to record these as ACIs. Anything unexpected is recorded as an ACI. Final decision on this matter should rest with individual Trust Clinical Governance departments.

LATE OUTCOMES

Late outcomes are less frequent but, in the absence of an electronic patient record, more difficult to capture than immediate outcomes. There are basically three types of processes for capturing late outcomes:

- prospective audit of known outcomes,
- prospective register of known outcomes and
- retrospective review of untoward events.

Prospective audit

Prospective audit is a standard technique that usually provides a snapshot of performance. It is not suitable for capturing uncommon or unexpected outcomes or events, unless the sample size is very large. The key components of prospective audit are

- it is truly prospective
- outcomes are determined at the outset
- consecutive patients are captured and none are missed
- the sample size is large enough to determine whether performance is outside an acceptable range
- audits are carried out at a frequency that can detect problems in a timely manner

Example: bile duct decompression is an important late quality outcome following ERCP. There is no standard but it is a recommended quality outcome for all attempts at biliary decompression. An occasional prospective audit would be sufficient for this outcome.

Prospective register of adverse events

This method differs from prospective audit because it is a continuous process rather than a snapshot of outcomes. It is suitable for uncommon events that do not usually lead to death or operation such as ERCP pancreatitis. It is preferable to prospective audit, but more difficult to undertake.

Example: post ERCP pancreatitis is too infrequent to be captured by a prospective audit unless the sample size is very large. ERCP pancreatitis would not always be captured in a review of 30 day mortality, or 8 day unplanned surgery. The only reliable way to capture this complication would be to have a process that recorded this outcome for every patient undergoing ERCP. It is appreciated that in the absence of an electronic patient record this is very difficult to do.

Retrospective review of untoward events

This method requires identification of untoward events and linking them in time with an endoscopic procedure. An example of this technique is a review of the case files of every patient who dies within 30 days, or has an unplanned operation within 8 days, of an endoscopy. The aim is to determine whether the procedure contributed to the death or whether it was inappropriate. It is not perfect because some patients will die at home, others may be admitted elsewhere and in some it may be difficult to attribute cause.

Example 1: 30 day mortality and 8 day non-elective surgery rates will capture many of the delayed safety outcomes. It is recommended that the file of every patient falling into these groups is reviewed to determine the extent the endoscopy contributed to the unplanned operation or death, and to assess appropriateness of the procedure.

Example 2: raised amylase might be used as a 'case-finding' method for post-ERCP pancreatitis.

It is recommended that the method used for identifying late safety and quality outcomes be tailored to the outcome. Prospective audit is laborious and it is recommended that the minimum frequency of this technique should be once/year. Prospective registers, 30-day mortality and 8-day unplanned surgery should be monitored continuously and reviewed at least 2x/year

Once standards have been achieved is it necessary to continue to audit?

The simple answer is yes.

Quality and safety

The patient experience and quality and safety have, quite rightly, become key policy areas. The need to continually demonstrate we are providing high quality and safe care has increased not lessened. The GRS and the JAG accreditation process have provided the endoscopy service with a method of demonstrating it provides high quality and safe care.

Costs and benefits

Providing continuous audit data and reviewing it requires resource and valuable clinical time. However, better clinical outcomes, fewer complaints and less litigation reduce costs and save clinical time.

The burden

Once audit becomes engrained in the culture of a service it will be, and seem, less onerous. Services will find smarter ways of collecting and displaying data, creating automated systems that

will reduce the burden. Once standards improve, the knock on effects of identifying poor performance (the difficult and most time consuming part) will decline.

The staff

Health professionals who know and can demonstrate they provide a high quality and safe service have greater job satisfaction. More satisfied staff provide better care and aspire to higher standards.

The case for continuous audit is a very powerful one.

APPENDIX ONE

Summary table of quality and safety indicators (adapted from BSG quality and safety indicators)

Mandatory levels for GRS are only relevant to quality outcomes. The frequency for audits for quality is a maximum of twice/year to coincide with the GRS census dates. Monitoring of safety outcomes is a more continuous and, in some regards, less complicated process so the minimum frequency remains 2x/year.

Glossary

Q and S	Quality and Safety outcome
AO	Auditable Outcome
I an L	Immediate and Late outcome
ERS	Endoscopy Reporting System
SP	Session Proforma
PA	Prospective audit
30/8	30/7 and 8/7 reviews

Procedure	Outcome	Type Q/S	Standard QS/AO	Timing: I/L	Possible monitoring methods		Mandatory for GRS level	Frequency of review per year
All	Number of procedures performed by each operator	Q	AO	I	Continuous monitoring	ERS	C	2
	Unplanned admissions	S	AO	I/L	Continuous monitoring 30/7 and 8/7 review Prospective register	SP		2
	Unplanned operations within 8 days	S	AO	L	30/7 and 8/7 review	30/8		2
	30 day mortality	S	AO	L	30/7 and 8/7 review	30/8		2
	Use of flumazenil	S	AO	I	Continuous monitoring	ERS /SP		2
	Use of naloxone	S	AO	I	Continuous monitoring	ERS /SP		2
	Need for ventilation	S	AO	I	Continuous monitoring	SP		2
	Perforation	S	AO	I/L	Continuous monitoring 30/7 and 8/7 review Prospective register	SP 30/8		2
	Bleeding	S	A0	I/L	Continuous monitoring 30/7 and 8/7 review Prospective register	SP 30/8		2
	Sustained drop in O2 saturation <90%	S	A0	I	Continuous monitoring	SP		2

Procedure	Outcome	Type Q/S	Standard QS/AO	Timing: I/L	Possible monitoring methods		Mandatory for GRS level	Frequency of review per year
OGD	Success of intubation	Q	AO	I	Continuous monitoring	ERS	C	2
	Completeness of procedure	Q	AO	I	Continuous monitoring	ERS	C	2
	Repeat endoscopy for gastric ulcers within 12 weeks. (100%).	Q	QS: 100%	I	Continuous monitoring	ERS	B	2
OGD – GI bleed	Haemostasis after endoscopic therapy (exact definition to be determined locally)	Q	AO	I	Continuous monitoring	ERS	A	2
OGD -dilatation	Perforation for benign stricture	S	QS: <1:100	I/L	Continuous monitoring Prospective audit 30/7 and 8/7 review	SP 30/8		2
	Perforation for malignant stricture	S	QS: <1:20	I/L	Continuous monitoring Prospective audit 30/7 and 8/7 review	SP 30/8		2
	Perforation for achalasia	S	QS: <1:20	I/L	Continuous monitoring Prospective audit 30/7 and 8/7 review	SP 30/8		2
	Perforation for pyloric stenosis	S	QS: <1:20	I/L	Continuous monitoring Prospective audit 30/7 and 8/7 review	SP 30/8		2
	Satisfactory position of metallic stent	Q	AO	I	Continuous monitoring	ERS	A	1
Colonoscopy and FS	Colonoscopy completion rate	Q	QS: 90%	I	Continuous monitoring	ERS	C	2
	Adenoma detection rate	Q	QS: >10%	I	Continuous monitoring	ERS	C	2
	Polyp recovery	Q	QS: >90%	I	Continuous monitoring	ERS	B	2
	Sedation and analgesia doses	Q	AO	I	Continuous monitoring	ERS	C	2
	Comfort levels	Q	AO	I	Continuous monitoring	ERS	A	2
	Tattoo suspected malignant polyps and small tumours	Q	AO	I	Continuous monitoring	ERS	B	2
	Good quality bowel prep	Q	QS: >90%	I	Continuous monitoring	ERS	C	2
	Diagnostic colo-rectal biopsies for persistent diarrhoea	Q	QS: 100%	I	Continuous monitoring	ERS PA	A	2
	Perforation FS	S	QS: <1:5000	I/L	Continuous monitoring 30/7 and 8/7 review	SP 30/8		2
	Perforation colonoscopy	S	QS: <1:1000	I/L	Continuous monitoring 30/7 and 8/7 review	SP 30/8		2
	Post polypectomy bleed requiring transfusion	S	QS: <1:100	L	Prospective audit 30/7 and 8/7 review	PA		2
Polypectomy perforation	S	QS: <1:500	I/L	Continuous monitoring 30/7 and 8/7 review	SP		2	

Procedure	Outcome	Type Q/S	Standard QS/AO	Timing: I/L	Possible monitoring methods		Mandatory for GRS level	Frequency of review per year
ERCP	Completion of intended therapeutic procedure	Q	QS: 80%	I	Continuous monitoring	ERS	B	2
	Decompression of obstructed system	Q	AO	L	Prospective audit 30/7 and 8/7 review	PA 30/8	B	1
	Sphincterotomy bleed requiring transfusion	S	QS: <2%	L	Prospective audit 30/7 and 8/7 review	PA 30/8		1
	Sphincterotomy perforation	S	QS: <2%	I/L	Prospective audit 30/7 and 8/7 review	PA SP		1
	Clinically symptomatic pancreatitis	S	QS: <5%	L	Prospective audit 30/7 and 8/7 review	PA		1
	Mortality	S	QS: <1%	L	30/7 and 8/7 review	30/8		1
	Antibiotics for incomplete drainage	S	QS: 100%	L	Prospective audit 30/7 and 8/7 review	PA		1
PEG	Satisfactory placement of PEG (satisfactory determined at the end of the procedure)	Q	AO	I	Continuous monitoring	ERS	C	2
	Infection requiring antibiotics	S	AO	L	Prospective audit 30/7 and 8/7 review	PA		1
	Peritonitis	S	AO	L	Prospective audit 30/7 and 8/7 review	PA		1
	Bleeding requiring transfusion	S	AO	L	Prospective audit 30/7 and 8/7 review	PA		1
	30 day mortality	S	AO	L	30/7 and 8/7 review	30/8		2
EUS	Completion of diagnostic procedure	Q	QS: >90%	I	Continuous monitoring	ERS	A	1
	Adequate FNA/biopsy mediastinum/LNs/other	S	QS: >90%	L	Prospective audit	PA	A	1
	Adequate FNA/biopsy pancreas	S	QS: >75%	L	Prospective audit	PA	A	1
	Major complications: Perforation Acute pancreatitis Infection bleeding	S	QS: <1%	L	Prospective audit	SP PA	A	1

Auditable outcomes and quality indicators for quality item

Level C

- Number of procedures performed by each operator
- Success of intubation of OGD
- Completion of OGD
- Colonoscopy completion rate
- Adenoma detection rate
- Sedation and analgesia for colonoscopy
- Quality of bowel prep
- Satisfactory placement of PEG

Level B

- Repeat endoscopy for gastric ulcers within 12 weeks.
- Colonic polyp recovery
- Tattoo of small tumours and suspected malignant polyps
- Completion of intended therapeutic ERCP
- Decompression of obstructed ducts

Level A

- Comfort levels for colonoscopy
- Haemostasis after endoscopic therapy
- Satisfactory position of metallic stent for oesophageal obstruction
- Diagnostic biopsies for diarrhoea
- All quality outcomes for EUS

Workload for typical unit to achieve level A for quality and safety items

- Continuous monitoring of immediate quality and safety outcomes with IT system
- Continuous monitoring of immediate quality and safety outcomes with a method of capturing events after completion of report
- One prospective audit of ERCP
- One prospective audit of PEG
- One prospective audit of EUS
- One prospective audit for therapeutic oesophageal procedures
- A process for continuous review of 30/7 mortality and 8/7 unplanned admission

Two review meetings per year