Appendix D: Guidelines for the Implementation of a National Quality Improvement Programme in GI Endoscopy – Version 5.0

Developed by

The Working Group
GI Endoscopy National QI Programme,
Conjoint Board of RCPI & RCSI

CONJOINT BOARD IN IRELAND
of the
Royal College of Physicians and Royal College of Surgeons
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1. Introduction

Endoscopy is a central element in the diagnosis of gastrointestinal (GI) disease. The provision of a high quality, timely and accurate service with an associated quality patient experience is a key goal for all. Patients have a right to expect that they have appropriate access to the service and that the service provided is of the highest possible standard.

1.1. Background

The Conjoint Board of the Royal College of Physicians of Ireland (RCPI) and the Royal College of Surgeons in Ireland (RCSI) launched the National Quality Assurance Programme in GI Endoscopy in October 2011 in collaboration with the National Cancer Control Programme and the National Cancer Screening Service. As of 2014, this programme has been undertaken with funding support from the HSE Quality Improvement Division (HSE QID). The HSE QID has contracted with the RCPI to develop and project manage this programme as set out in the service level agreement (SLA). The aim of this programme is to establish a quality improvement framework in each endoscopy unit that ensures the provision of a high quality, consistent and accurate service which will translate into a quality patient experience.

The development of a National Quality Assurance Intelligence System (NQAIS) in collaboration with the HSE’s Health intelligence unit, allows users to store, analyse, report, and share QI data and results. It has provided a significant added benefit to participating hospitals on the QI Programmes in Histopathology, Radiology and GI Endoscopy. By comparing the data and statistics available on the NQAIS platform against the Guidelines set out by the Working Group of the GI Endoscopy QI Programme, participant endoscopy departments can drive quality improvement activities in their hospitals.

1.2. Purpose

This document provides guidance to Endoscopy units on the implementation of a QI Programme in GI Endoscopy.

The purpose of this document is to define key areas of quality improvement (QI) in the delivery of endoscopic procedures and to embed them in routine clinical practice. It also aims to facilitate each Endoscopy unit in monitoring its own performance and, where necessary, initiate improvement.

GI endoscopy is fundamental to the management of upper and lower gastrointestinal disease. It has diagnostic, therapeutic and preventative roles. All endoscopy procedures need to strike a balance between benefit and harm. These procedures are invasive with the potential for causing serious and significant adverse events. For example colonoscopy performance was found to be variable in England with poor completion rates and higher than expected perforation rates.

Current international quality standards for endoscopy, including colonoscopy, are based on varying levels of evidence ranging from expert consensus to evidence from randomized controlled trials. The systematic and ongoing collection and scrutiny of endoscopy procedure performance data provide the opportunity to define and quantify specific procedure related risk in diagnostic and therapeutic endoscopy.

The fundamental aim of this QI Programme is to establish a quality improvement framework in each endoscopy unit that ensures the provision of a high quality, consistent and accurate service with an associated quality patient experience.

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1.3. **Time and Resources**

Each endoscopy unit must have an established endoscopy user group, a designated endoscopy clinical lead consultant in post and an Endoscopy Reporting System (ERS). The endoscopy users group should be a multidisciplinary team forum that meets regularly. The use of multidisciplinary team meetings and resources is important to performing quality improvement activities in endoscopy, as clinicians with different backgrounds will add value to these activities.

The Conjoint Board of RCPI and RCSI, supported by HSE Office of the Chief Information Officer (HSE OCIO), has developed an IT system which assists in the recording, collation and reporting of data pertaining to these guidelines in a manner which minimises the impact on service delivery.

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2. **Guidelines on using NQAIS-Endoscopy**

2.1 **Sign off QI data in NQAIS-Endoscopy**

The Clinical Lead may note some issues when reviewing the KQD Report which could be due to local performance issues or data entry issues. For example, the percentage of Repeat endoscopies requested for gastric ulcer detected might be less than expected. This could be due to clinicians not requesting a repeat endoscopy, but more likely it is due to the recording of the request in free text rather than the drop down option. Data collection should be considered when evaluating statistics in NQAIS-Endoscopy.

2.2 **Further review of KQD reports**

Communication and Improving Standards

KQD reports should be reviewed by the Clinical Lead at least quarterly to ensure areas of concern and/or best practice are identified and acted on. To facilitate communication and highlight learning opportunities, KQD reports should be discussed at multidisciplinary Endoscopy User Group meetings.

It is also recommended that the learning from QI activity in the Endoscopy Unit be communicated to the Quality and Safety Committee in each hospital. The standardised, quarterly KQD reports could provide a straightforward method of delivering this information to the Committee. Opportunities for recognising high quality and making improvements should be identified and quality improvement initiatives developed and implemented accordingly.

The ongoing regular review of QI programme data and management of poor performance sits firmly at a local hospital/unit level. Appropriate governance structures and processes should be developed and put in place locally to identify and manage underperformance. These governance structures and processes need to be cognisant of the fact that there may be performance issues that are not identified by the QI programme.

It should be noted that the default central statistic in NQAIS-Endoscopy is based upon cases performed as Endoscopist 1. Cases performed as Endoscopist 2 can be viewed by ticking various options when creating NQAIS-Endoscopy reports.

Endoscopist 1 Definition: The clinician who performs the majority of the procedure.
Endoscopist 2 Definition: A clinician present in the procedure room during the course of the procedure and who also provides some support to the primary endoscopist (verbal or physical).

3. Quality Indicators and Activities

The National Guidelines for Implementation of a QI programme in GI Endoscopy set out a number of outcomes and specific recommendations for endoscopy units. The following terminology is used to describe the data which is to be recorded, the standards (where available) against which to measure performance and the key recommendations to be made:

- **Key Quality Data**: refers to the information that is to be captured for the QI programme. This data will be captured to facilitate future audit and review.
- **Quality Indicator**: refers to an outcome for which there is a sufficient evidence base to recommend a standard e.g. caecal intubation rate
- **Key Quality Target**: refers to the target associated with Quality Indicators
- **Key Recommendation**: refers to recommendations that should be implemented in each endoscopy unit to fully support quality improvement activities. Where quality indicators are absent, due to lack of sufficient evidence with which to base a standard upon, a key recommendation will usually be made. These recommendations are wholly endorsed by the Steering Committee of the Specialty QI Programmes.

4. Numbers of Procedures

There is evidence that endoscopic proficiency increases with the number of procedures performed ². Low numbers of procedures are associated with a greater risk of complications. The lowest complication rate in a population based study of outpatient colonoscopy, for example, was associated with the highest number of procedures (i.e., >300 per endoscopist per year ³, ⁴. However performing a large number of endoscopy procedures alone is not sufficient proof of competency. It is important to note that:

- Low numbers are likely to be (but not always) associated with poor performance.
- Low numbers mean the sample size for key performance indicators (KPIs) is low and the confidence intervals around the observed performance will be wide.

Large numbers are required to provide accurate estimates of performance particularly if events are infrequent. The 95% confidence interval for a completion rate of 90% for 150 colonoscopy procedures per year is 85%-95%. The 95% confidence interval for a completion rate of 90% for 300 colonoscopy procedures per year is 87%-93% ⁵.

Technically excellent endoscopists will find it easier to maintain adequate skills with low numbers. An average or poor performer will not be able to maintain adequate performance with low numbers. Low numbers are less of an issue for less demanding procedures. Conversely the more demanding the procedure, e.g. ERCP, the more important volume becomes.

It is recommended that the annual number of procedures performed by each endoscopist is documented to ensure that the sample size for other quality indicators (Section 4 and Section 5) is sufficient. In the event that other quality targets are not met, the endoscopist and his/her Clinical should consider the volume of procedures done.

**Key Quality Data:**

- Number of OGD procedures performed by each Endoscopist
Key Recommendation:

- Endoscopists should endeavour to keep their number of procedures high in order to keep their skills at proficient levels.
- The annual number of procedures performed by each endoscopist should be reviewed collectively in the endoscopy unit with the designated clinical lead for the service.

BowelScreen Standard:

To support the maintenance of colonoscopists’ clinical competence, a minimum number of screening colonoscopies should be undertaken each year. In addition one hour should be set aside for each screening colonoscopy.

<table>
<thead>
<tr>
<th>Quality measure</th>
<th>Minimum number of colonoscopies undertaken annually by each screening colonoscopist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Minimise harm and maximise benefit to screening population</td>
</tr>
<tr>
<td>Standard</td>
<td>&gt;300 colonoscopies (symptomatic and screening) per annum</td>
</tr>
<tr>
<td>Accountability</td>
<td>• Colonoscopist</td>
</tr>
<tr>
<td></td>
<td>• Self-reported by colonoscopist to screening colonoscopy units</td>
</tr>
</tbody>
</table>

5. Upper GI Endoscopy

5.1. Sedation and analgesic doses

Many patients tolerate upper endoscopy with only topical anesthesia of the oropharynx, however some patients may need sedation. Sedation improves patient tolerance of the procedure but can contribute to cardio-respiratory complications following endoscopy in high-risk patients, particularly the elderly. See also Section 5.1.

In cases in which a patient has multiple endoscopy procedures in one patient visit, the following recording practices should be utilised:

1. Procedure A’s record should have what sedation was given at the time of the Procedure A.
2. Procedure B’s record should have the sedation given for the Procedure A AND what was given for Procedure B. This is important in the case that this record is part of an internal audit.
Key Quality Data:
- Sedative type and quantity used for patients under 70 years of age expressed as a median figure per Endoscopist
- Sedative type and quantity used for patients 70 years of age and older expressed as a median figure per Endoscopist
- Number of times each reversal agent is used expressed as a percentage of all OGD procedures performed per endoscopist.

Key Recommendations:
- Sedative should be used to achieve moderate sedation; where the patient displays purposeful response to verbal stimulation.
- The median level of sedation for older patients (≥ 70 years of age) should be approximately half that of patients under that age.
- The use of reversal agents should be minimised. Its use should require that case be reviewed.

Key Quality Targets:
- Median quantity of Midazolam:
  - ≤5mg for patients below 70 years of age
  - ≤3mg for patients 70 years of age and above
- Median quantity of Fentanyl ≤100 mcg
- Median quantity of Pethidine ≤50mg

5.2. Success of intubation
An oesophago-gastro-duodenoscopy (OGD) necessitates successful intubation into the oesophagus.

Key Quality Data:
- Number of successful intubations expressed as a % of all ‘intend to’ OGD cases per endoscopist

Key Quality Target:
- Successful Intubation in ≥95% of all OGD cases

5.3. Retroflexion (J manoeuvre)
Retroflexion, also known as the J manoeuvre, allows for a full view and inspection of the cardia and fundus of the stomach. It is an important quality measure of the completeness of the procedure. Ulcers in the body of the stomach and fundus tend to arouse more clinical suspicion 6.

Key Quality Data:
- Number of cases in which retroflexion was performed expressed as a % of all OGD cases per endoscopist

Key Recommendation:
- Retroflexion (J manoeuvre) in stomach to visualise fundus in > 95% of cases

5.4. Duodenal Second part intubation
The endoscope should be passed through the pylorus to examine the first and second parts of the duodenum. It is an important quality measure of the completeness of the procedure.

Key Quality Data:
5.5. Repeat endoscopy

Gastric cancer can present with the endoscopic appearances of a benign gastric ulcer. It has been recommended practice that patients found to have a gastric ulcer at endoscopy should have multiple biopsies taken from the ulcer margin or base. Traditional practice has been that all gastric ulcers should be followed with repeated endoscopy to ensure ulcer healing on treatment. Opinion remains divided on the need for endoscopic follow up for gastric ulcer with no endoscopic or histological features of malignancy at the index oesophago-gastro-duodenoscopy (OGD) with some reports questioning and others advocating the approach. However, international guidelines still recommend repeat endoscopy in the follow up of all cases of gastric ulcer.

There are many reasons why endoscopists may elect not to follow up gastric ulcers endoscopically. For example, the lesion may appear obviously benign, or there may be associated non-steroidal anti-inflammatory drug (NSAID) use. Also, a Helicobacter infection, or the patient’s age or medical condition may dissuade the endoscopist from performing further invasive procedures.

Key Recommendations:

- If repeat endoscopy is not indicated due to a specific reason, this should be recorded on the patient’s record.

Key Quality Data:

- Number of repeat endoscopies requested to be performed within 12 weeks due to the presence of gastric ulcer expressed as a % of total OGD cases with gastric ulcer detected per endoscopist

Quality Indicator:

- Repeat endoscopy for gastric ulcers is requested to be performed within 12 weeks of original procedure

Key Quality Target:

- 80% of cases in which a gastric ulcer is found should have a repeat endoscopy requested within 12 weeks.

6. Colonoscopy

6.1. Sedation and Analgesic Doses

Colonoscopy can be an uncomfortable experience but this discomfort can be reduced by careful patient preparation and sedation. Sedation improves patient tolerance of colonoscopy, however, excessive sedation is considered to be an important contributor to cardio-respiratory deaths following endoscopy in high risk patients. This is particularly relevant for older patients (≥ 70 years of age) where the median level of sedation should be approximately half that of patients under that age.

A 2004 report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), Scoping our Practice found that there were 1,818 deaths after therapeutic GI endoscopic procedures. NCEPOD advisors judged that the sedation given was inappropriate in 14 per cent of cases, usually because an overdose of
The use of flumazenil, a benzodiazepine antagonist, or naloxone usually indicates that the patient has been given a relative overdose of benzodiazepine.

It has been reported that most of the risk of colonoscopy is related to sedation. Cardio-respiratory complications are infrequent for patients without known heart or lung disease, but monitoring of oxygenation and blood pressure should be performed for all sedated patients. While hypoventilation, cardio-pulmonary events and vasovagal reactions may be related to pain and distension caused by the endoscopic procedure, in most cases they are more closely associated with the use of sedatives and opioids. Reduction in risk for these reactions has been observed when sedation is given only as required. Sedative should be used to achieve moderate sedation, where the patient displays purposeful response to verbal stimulation.

Sedatives and anxiolytics such as benzodiazepines have no analgesic properties when conventional doses are given systemically and attempts to use them to control pain will result in significant overdose. Pain control requires the administration of specific analgesic agents. The most popular of these agents are fentanyl and pethidine and should whenever possible be given before the benzodiazepine, and their effect observed before the administration of the benzodiazepine.

In cases in which a patient has multiple endoscopy procedures in one patient visit, the following recording practices should be utilised:

1. Procedure A’s record should have what sedation +/- analgesia was given at the time of the Procedure A.
2. Procedure B’s record should have the sedation +/- analgesia n given for the Procedure A AND what was given for Procedure B.

Key Quality Data:

- Sedative type and quantity used for patients under 70 years of age expressed as a median figure per Endoscopist
- Sedative type and quantity used for patients 70 years of age and older expressed as a median figure per Endoscopist
- Number of times each reversal agent is used expressed as a percentage of all Colonoscopy procedures performed per endoscopist.

Key Recommendations:

- Sedative should be used to achieve moderate sedation; where the patient displays purposeful response to verbal stimulation.
- If deeper levels of sedation are required, for example with the use of propofol, it is necessary that an anaesthetist be present.
- Propofol’s use should be limited to exceptional cases and the reason for its use should be documented.
- Opioids should, whenever possible, be given before benzodiazepines and their effect observed before proceeding.
- The median level of sedation for older patients (≥ 70 years of age) should be approximately half that of patients under that age.

Key Quality Targets:

- Median quantity of Midazolam:
  - ≤5mg for patients below 70 years of age
  - ≤3mg for patients 70 years of age and above
- Median quantity of Fentanyl ≤100 mcg
• Median quantity of Pethidine ≤50mg
• Reversal Agent Usage should be in <1% of all cases

6.2. **Comfort levels**
While the principle indicator for assessing competence in colonoscopy is caecal intubation rate, patient comfort during endoscopy is also considered to be another measure of endoscopy performance quality. Comfort is a key recommendation and central to any patient-centred QI programme in GI Endoscopy. It is therefore proposed to measure a comfort score for each procedure using the modified Gloucester Scale below.

**Gloucester Scale**
- 1 - No: No discomfort – resting comfortably throughout
- 2 - Minimal: One or two episodes of mild discomfort, well tolerated
- 3 - Mild: More than two episodes of discomfort, adequately tolerated
- 4 - Moderate: Significant discomfort, experienced several times during the procedure
- 5 - Severe: Extreme discomfort, experienced frequently during the procedure

**Key Quality Data:**
- Median comfort level score per endoscopist

**Key Recommendation:**
- Use the modified Gloucester scale above
- Comfort scores should be assessed by a 3rd party who will usually be an endoscopy nurse and agreed with the endoscopist before recording

**Key Quality Target:**
- 80% of colonoscopy cases should have a comfort score of a 1 or 2.

6.3. **Tattooing**
Tattooing is an important technique for lesion location at surgery, identification of colonic lesions (suspected malignancy) or resection sites at future colonoscopy (repeat therapeutic colonoscopy or incomplete/suspected incomplete removal of lesions). Tattooing of sites or lesions with sub-mucosal injection that may require later surgical or endoscopic localisation is recommended.

It has been advised to tattoo the area with an indelible compound e.g. India ink, SPOT. While concerns have been raised about the safety of indelible markers, published studies to date report a low complication rate for both of these products.

**Key Quality Data:**
- Number of colonoscopies with tattooing of suspected malignant tumours expressed as a % of all colonoscopies with suspected malignant tumours detected per endoscopist

**Key Recommendation:**
- Endoscopy units should have an agreed and documented endoscopy users group policy on tattooing
- 60% of colonoscopies with suspected malignant tumours should be tattooed.
6.4. **Caecal Intubation**

Caecal intubation rates (CIR) is one of the key quality indicators of colonoscopy. Caecal intubation rates are affected by a number of factors including age, sex, low BMI, bowel cleansing, sedation, diverticular disease and general health status.\(^\text{20,21,22}\)

Adjusted completion rates (for factors such as bowel prep or obstruction) are open to diverse interpretation and it is recommended to use unadjusted rates for the standard.

It is recommended that the CIR standard should be an unadjusted (intention to scope) figure of 90%. It is also strongly recommended that photographic evidence of caecal intubation is obtained. This is consistent with the performance standards adopted by the US Multi-Society Task Force on Colorectal Cancer\(^\text{23}\) and Cancer Care Ontario Colonoscopy standards.\(^\text{24}\)

**Key Quality Data:**
- Number of colonoscopies where the terminal ileum / caecum / anastomosis has been reached expressed as a % of total colonoscopies per endoscopist

**Key Quality Target:**
- Minimum Target: 90% of colonoscopy cases should reach the terminal ileum/caecum or anastomosis (adjusted only for obstructing lesions)
- Achievable Target: 95% of colonoscopy cases should reach the terminal ileum/caecum or anastomosis (adjusted only for obstructing lesions)
- Clear photographic evidence of the terminal ileum/caecum/anastomosis must be obtained

6.4.1 **Caecal Intubation Photographic Evidence Audit**

Each hospital group clinical lead should establish standards for each unit in conducting caecal intubation photographic evidence audit. The outcomes of the audit should be reported to the QI Programme annually.

The goal of this is to ensure that the entire colon is visualised and that the quality of photographs obtained is sufficiently high to ensure that evidence of this is present in all cases.

**Key Quality Data:**
- Number of colonoscopies completed with clear photographic evidence expressed as a percentage of all colonoscopies completed per endoscopist

6.5. **Polyp Detection Rates**

There is good evidence of varying rates of detection of high-risk lesions and of missed lesions in back to back colonoscopy studies.\(^\text{25}\) Internationally accepted guidelines on performance indicators of colonoscopy recommend monitoring direct or proxy markers of detection of suspicious lesions including polyps, adenomas or withdrawal times.\(^\text{26,27}\)

**Key Quality Data:**
- Colonoscopies with polyps detected expressed as a % of total colonoscopies per endoscopist

**Key Quality Target:**
- 20% of all colonoscopies have a polyp(s) detected
6.6. **Polyp Recovery**

Incomplete excision of a high risk lesion is associated with an increased risk of development of cancer \(^{28,29}\). Incomplete removal of tissue may also lead to misclassification of pathology. There are currently no validated methods of determining completeness of excision but it is possible to measure retrieval rates for pathological material. The recommended standard requires retrieval of 90% of all excised polyps.

**Key Quality Data:**

- Number of polyps with histology requested expressed as a % of all polyps excised per endoscopist

**Key Recommendation:**

- Polyp histology requested > 90% of all excised polyps
6.7. Polypectomy and endoscopic mucosal resection (EMR)

The QI Programme recognises that considerable therapeutic expertise exists within the wider endoscopy community. However, some endoscopists may not wish to provide conventional screening but may provide an enhanced therapeutic endoscopic service (tertiary referral). EMRs should only be carried out by expert and experienced endoscopists with access to appropriate surgical backup with locally agreed protocols in place if a transfer becomes necessary.

6.8. Bowel Preparation

Effective bowel preparation is critical to ensure a detailed visual examination of the bowel. To date no single bowel preparation for colonoscopy has emerged as consistently superior over another. Good bowel preparation supports improved polyp detection and caecal intubation. Poor bowel preparation is associated with failure to reach the caecum and hinders the detection of lesions.

Validated scoring systems exist such as the Ottawa and Aronchick scales. The following scale is recommended for use:

- **Excellent**
  - no or minimal solid stool and only clear fluid requiring suction
- **Adequate**
  - collections of semi-solid debris that are cleared with washing/suction
- **Complete despite poor prep**
  - solid or semi-solid debris that cannot be cleared effectively but which still permits intubation to caecum
- **Failed due to poor prep**
  - solid debris that cannot be cleared effectively and prevents intubation to caecum.

**Key Quality Data:**
- Record the bowel preparation for each colonoscopy. Express the total number of colonoscopies with Adequate and Excellent scores as a % of all colonoscopies.

**Key Recommendation:**
- Use the above scale to record the quality of bowel preparation for each procedure.
- It is recommended that there should be colonic cleansing protocols in place and the effectiveness of these should be monitored continuously by the endoscopy user group.

**Key Quality Target:**
- Minimum Target: Bowel preparation described as excellent or adequate in > 90%
- Achievable Target: Bowel preparation described as excellent or adequate in > 95%

6.9. Diagnostic colo-rectal biopsies for persistent diarrhoea

Mucosal biopsies should be obtained in all patients presenting with diarrhoea. Samples should be obtained from normal looking colon. Ileal intubation and biopsy is strongly recommended in this group.

**Key Quality Data:**
- Number of colonoscopies with mucosal biopsies taken expressed as a % of cases which presented with persistent diarrhoea per endoscopist.

**Key Recommendation:**
- Ileal intubation and biopsy is strongly recommended in this group.

**Key Quality Target:**
• Diagnostic mucosal biopsies for persistent diarrhoea in 95% of cases

6.10. Colonic Perforation

Perforation is defined as evidence of air, luminal contents or instrumentation outside the GI tract. It may result from direct mechanical trauma to the bowel wall during insertion, over-insufflation of the colon (barotrauma) or from therapeutic procedures (hot biopsy, polypectomy, dilatation). Widely varying perforation rates have been reported from the literature.

• Results from a study in the 1970s revealed a perforation rate of 0.2% for diagnostic colonoscopy and 0.32% for polypectomy.\(^{34}\)
• A study published in 2008 revealed a perforation rate of 0.6%\(^{3}\).
• In a series of 1172 patients with 1555 polypectomies there was one perforation\(^{35}\).
• A population based study of Medicare patients aged 65 years or older the overall perforation risk was 1:500; the incidence of perforation in the screening group was 1:1000. Risk factors identified for perforation were increasing age and diverticulosis\(^{36}\).
• In the BSG colonoscopy audit the perforation rate was 1:769\(^{1}\).

Key Quality Data:

• Number of incidents of colonic perforation expressed as a % of all colonoscopies
• Number of incidents of post polypectomy perforation expressed as a % of colonoscopies where polypectomy is performed

Key Recommendations:

• All incidence of perforation should be recorded in the adverse events log and reviewed by the lead clinician using local protocol

Key Quality Target:

• The following outcomes are put forward as guidelines on expected incidence of colonic perforation although current hospital systems may not allow for capture of all necessary data to reflect these targets:
  - Colonoscopy perforation rates <1:1000 per 1000 colonoscopies performed
  - Post polypectomy perforation rate <2 per 1000 colonoscopies performed

6.11. Post-polypectomy bleeding (PPB)

Bleeding is the most frequent adverse event following polypectomy. A variety of studies have reported bleeding rates 0.3–6.1% of polypectomies.\(^{37,38}\) The risk of bleeding increases with the size of polyp and location with some series reporting up to 10% bleeding rates for polyps larger than 2 cm located in the right colon. Around 90% of PPB should be amenable to conservative management without the need for surgical intervention.

Key Quality Data:

• Number of incidents of post polypectomy bleeding requiring transfusion expressed as a % of colonoscopies where polypectomy is performed

Key Recommendations:

• All incidence of post polypectomy bleeding requiring transfusion should be recorded in the adverse events log and actioned by the lead clinician.
• The following outcome is put forward as a guideline on expected incidence of post polypectomy bleeding requiring transfusion although current hospital systems may not allow for capture of all necessary data to reflect this target:
  - Post polypectomy bleeding requiring transfusion <1:100 (for >1cm polyps)

Key Quality Target:
• <1% of colonoscopies where polypectomy is performed per endoscopist

6.12. Post Colonoscopy Colorectal Cancer (PCCRC)

A Post Colonoscopy Colorectal Cancer (PCCRC) is the diagnosis of a CRC within three years of negative screening colonoscopy. CRC diagnosed at the next screening colonoscopy is likewise considered a PCCRC if it occurs within three years of most recent colonoscopy.

PCCRCs may occur because of an aggressive rapidly growing tumour, following an incomplete removal of a polypoid lesion or may have been missed at the initial colonoscopy.

PCCRC rate is a key quality measure of colonoscopy. Within the context of the QI Programme and BowelScreen Programme, it will be a number of years before the PCCRC can be calculated. Evidence from a retrospective study in the UK, involving both screening and non-screening colonoscopies, reports PCCRC rates varying from 2.5 per cent to 8.6 per cent. Within the BowelScreen programme, it would be expected that the PCCRC would be closer to the lower range. The proposed PCCRC rate uses the appearance of cancer over three years following a complete colonoscopy as the gold standard: the true positives plus the false negatives. The PCCRC rate is defined as the number of false-negative colonoscopies divided by the gold standard.

7. Key Recommendations

The following activities are key recommendations as defined by the Conjoint Board of RCPI and RCSI, to ensure that key quality data is being recorded but also to fully support quality improvement activities.

7.1. Adverse Events

Adverse events can occur immediately or several days after an endoscopy procedure. An immediate adverse event is defined by an adverse event occurring before the patient leaves the endoscopy department.

- All immediate adverse events should be recorded in the adverse events log that is maintained in the department
- This log should be reviewed by the designated Endoscopy Clinical Lead on a quarterly basis

An adverse event occurring after this is a late outcome. Endoscopic services need to have processes in place to identify and record adverse outcomes occurring after the patient leaves the endoscopy department.

7.2. Audit and Review

- The outcomes in this document are reviewed at least quarterly in each Endoscopy unit by the designated Endoscopy Clinical Lead

7.3. Multidisciplinary Team Involvement

- Each Endoscopy unit should involve their multidisciplinary team in the process of recording data, the review and discussion of data and in quality improvement activities in daily activities and at regular endoscopy users group meetings
7.4. **Surveillance intervals**
- Each Endoscopy unit should refer to the guidance on endoscopic surveillance intervals as found in Appendix I – III, and VI, of this document

7.5. **Guidelines for Antibiotic Prophylaxis in Endoscopy**
- Each Endoscopy unit should refer to the guidance document on Antibiotic Prophylaxis as found in Appendix IV of this document

7.6. **Guidelines relating to Anticoagulant and Antiplatelet Therapy**
- Each Endoscopy unit should refer to the guidance document on Anticoagulant and Antiplatelet Therapy as found in Appendix V of this document
# 8. Summary Targets and Recommendations Table

<table>
<thead>
<tr>
<th>Key Quality Data</th>
<th>Target/Recommendation</th>
<th>Reason/Evidence for Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Volume of OGD procedures, Flexible Sigmoidoscopy and Colonoscopy procedures performed by each Endoscopist</td>
<td><strong>RECOMMENDATION:</strong> Performing more procedures is a possible means to increase proficiency in meeting KQD targets</td>
<td>International Standards</td>
</tr>
<tr>
<td><strong>Upper GI Endoscopy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Percentage of successful intubations per endoscopist</td>
<td>≥95%</td>
<td>Working Group Opinion</td>
</tr>
<tr>
<td>3./4. Median sedative dosage, per endoscopist, based upon sedative type and patient cohort (e.g. patients under 70 years of age, and patients 70 years of age and older)</td>
<td>Median quantity of:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Midazolam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≤5mg for below 70yrs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≤3mg for above 70yrs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fentanyl</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤100mcg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pethidine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤50mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reversal Agent – &lt;1% of all cases</td>
<td>International Standards and Working Group Opinion</td>
</tr>
<tr>
<td></td>
<td><strong>General Anaesthetic</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e.g. Propofol - record use, irrespective of dose</td>
<td></td>
</tr>
<tr>
<td>6. Percentage of cases in which Duodenal 2nd part intubation was achieved per endoscopist</td>
<td>≥95%</td>
<td>International Standards</td>
</tr>
<tr>
<td>7. Percentage of repeat endoscopies requests in cases where gastric ulcer(s) is present. Repeat endoscopy to be completed within 12 weeks.</td>
<td><strong>RECOMMENDATION:</strong> ≥80%</td>
<td>International Standards and Working Group Opinion</td>
</tr>
</tbody>
</table>
## Colonoscopy

### Key Quality Data

<table>
<thead>
<tr>
<th></th>
<th>Target/Recommendation</th>
<th>Reason/Evidence for Target</th>
</tr>
</thead>
</table>
| 8./9. | Median sedative dosage, per endoscopist, based upon sedative type and patient cohort (e.g. patients under 70 years of age, and patients 70 years of age and older) | Median quantity of:  
- **Midazolam**  
  - <=5mg for below 70yrs  
  - <=3mg for above 70yrs  
- **Fentanyl**  
  =<100mcg  
- **Pethidine**  
  =< 50mg  
Reversal Agent – <1% of all cases | International Standards and Working Group Opinion |
| 10. | Number of times each reversal agent is used | General Anaesthetic  
- e.g. Propofol - record use, irrespective of dose | |
| 11. | Percentage of cases where the comfort level score is 1 or 2 per endoscopist | ≥80%  
(of colonoscopies with a score of 1 or 2) | Working Group Opinion and National Data - NQAIS |
| 12. | Caecal Intubation Rate | Minimum Target: ≥90%  
Achievable Target: ≥95% | International Standards |
| 13. | Percentage of colonoscopies where polyps are detected | ≥20% | Working Group Opinion and National Data - NQAIS |
| 14. | Percentage of cases where bowel preparation is classified as excellent or adequate | Minimum Target: ≥90%  
Achievable Target: ≥ 95%  
(of colonoscopies recorded as excellent or adequate) | International Standards |
<p>| 15. | Percentage of cases where mucosal biopsy was taken where persistent diarrhoea was present, per endoscopist | ≥95% | International Standards and Working Group Opinion |</p>
<table>
<thead>
<tr>
<th>Key Quality Data</th>
<th>Recommendations</th>
<th>Reason/Evidence for Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upper GI Endoscopy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Percentage of cases in which retroflexion was performed</td>
<td>≥95%</td>
<td>International Standards</td>
</tr>
<tr>
<td><strong>Colonoscopy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Number of polyps with histology requested expressed as a % of all polyps excised per endoscopist</td>
<td>≥90%</td>
<td>International Standards</td>
</tr>
<tr>
<td>18. Percentage of colonoscopies where tattooing of suspected malignant tumours took place</td>
<td>≥60%</td>
<td>Working Group Opinion</td>
</tr>
<tr>
<td>19. Number of incidents of colonic perforation</td>
<td>&lt;1 per 1,000 colonoscopies performed</td>
<td>International Standards and Working Group Opinion</td>
</tr>
<tr>
<td>20. Number of incidents of post polypectomy perforation</td>
<td>&lt;2 per 1,000 colonoscopies performed</td>
<td>International Standards and Working Group Opinion</td>
</tr>
<tr>
<td>21. Number of incidents of post polypectomy bleeding requiring transfusion</td>
<td>&lt;1% colonoscopies where polypectomy is performed</td>
<td>International Standards and Working Group Opinion</td>
</tr>
</tbody>
</table>
9. References


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29. UK Colorectal Cancer Screening Pilot Group. Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom. BMJ 2004;329:133


10. Appendices

10.1. Appendix I – Surveillance Following Adenoma Removal

Colonscopic surveillance following adenoma removal (EU 2010)

Baseline colonoscopy (CS)³

Low risk
1–2 adenomas and both small (<10 mm)

and tubular and low grade neoplasia²

Intermediate risk
3–4 small adenomas or at least one 10 mm – 19 mm

or villous or high grade neoplasia²

High risk
≥ 5 small adenomas or at least one ≥ 20 mm

A
Routine Screening¹

B
3 years

Notes
¹ Baseline colonoscopy must be complete in order to accurately assess risk.
² Optional additional criteria
³ Other consideration: age, family history, accuracy and completeness of examination
⁴ Clearing colonoscopy to check for missed lesions

Findings at surveillance CS
- One negative exam → 5 yearly
- Two consecutive negative exams → Routine Screening¹
- Low or intermediate risk adenomas → B
- High risk adenomas → C

Findings at surveillance CS
- Negative, low or intermediate risk adenomas → 3 yearly
- Two consecutive negative exams → 5 yearly
- High risk adenomas → C

Fig. 9.1 Recommended surveillance following adenoma removal. (For explanation see Recommendations 9.1 – 9.20 and Sections 9.3 – 9.5)

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10.2. Appendix II – Colitis Surveillance

COLITIS SURVEILLANCE

SCREENING COLONOSCOPY AT 10 YEARS
(preferably in remission, pancolonic dye-spray)

LOWER RISK
Extensive colitis with NO ACTIVE endoscopic/histological inflammation
OR left-sided colitis
OR Crohn’s colitis of <50% colon

3 Years

INTERMEDIATE RISK
Extensive colitis with MILD ACTIVE endoscopic/histological inflammation
OR post-inflammatory polyps
OR family history CRC in FDR aged 50+

5 Years

HIGHER RISK
Extensive colitis with MODERATE/SEVERE ACTIVE endoscopic/histological inflammation
OR stricture in past 5 years
OR dysplasia in past 5 years declining surgery
OR PSC / transplant for PSC
OR family history CRC in FDR aged <50

1 Year

BIOPSY PROTOCOL
Pancolonic dye spraying with targeted biopsy of abnormal areas is recommended, otherwise 2-4 random biopsies from every 10 cm of the colorectum should be taken

OTHER CONSIDERATIONS
Patient preference, multiple post-inflammatory polyps, age & comorbidity, accuracy & completeness of examination

10.3. Appendix III – Surveillance flow charts for Barrett’s oesophagus.

Surveillance flow chart for non-dysplastic Barrett’s oesophagus.

* Interval depends on the degree of clinical confidence about diagnosis (accuracy of endoscopic report and number of biopsies)


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Surveillance flow chart for dysplastic Barrett’s oesophagus.

MDT, multidisciplinary team; OGD, oesophagogastroduodenoscopy

“A pathological finding of indefinite for dysplasia does not exclude the presence of dysplasia, therefore a 6-month follow-up is warranted. Six-monthly surveillance and endoscopic treatment are generally recommended for low-grade and high-grade dysplasia, respectively.”

Recommended flow chart for the management of high-grade dysplasia (HGD) and early oesophageal adenocarcinoma (OAC)

EC, early cancer; HRE, high-resolution endoscopy; OGD, oesophagogastroduodenoscopy; RFA, radiofrequency ablation.

“A diagnosis of HGD and early OAC should be discussed in a multidisciplinary team (MDT) setting, and treatment options should be explained in the clinic to the patient. Endoscopic treatment and surgery are generally recommended for mucosal disease and submucosal cancer, respectively. Good prognosis cancer with involvement of superficial submucosal layers (sm1) can be treated endoscopically in patients at high surgical risk.”


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10.4. Appendix IV - Guidelines for Antibiotic Prophylaxis in Gastrointestinal Endoscopy

<table>
<thead>
<tr>
<th>Scenario for prophylaxis</th>
<th>Antimicrobial prophylaxis</th>
<th>Antibiotics</th>
<th>Dose/route</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients with valvular heart disease, valve replacement, and/or surgically constructed systemic-pulmonary shunt or conduit, or vascular graft.</td>
<td>Prevention of infective endocarditis or conduit/graft infection</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>2. ERCP for the following patient groups:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. ongoing cholangitis or sepsis elsewhere</td>
<td>Prevention of procedure-related bacteremia</td>
<td>Be guided by recent culture results. Patients should already have been established on antibiotics</td>
<td>May need advice from clinical microbiologist</td>
</tr>
<tr>
<td>b. biliary obstruction and/or common bile duct stones and/or straightforward stent change</td>
<td>Prevention of cholangitis</td>
<td>Not indicated unless biliary decompensation not achieved. A full course of antibiotics becomes indicated if adequate biliary decompensation is not achieved during the procedure</td>
<td></td>
</tr>
<tr>
<td>c. ERCP when complete biliary drainage unlikely to be achieved (e.g., sclerosing cholangitis and/or hilar cholangiocarcinoma) (special considerations may apply in case for a repeat ERCP; see Section 7.2.4)</td>
<td>Prevention of cholangitis</td>
<td>Ciprofloxacin</td>
<td>750 mg orally 60–90 min before procedure (but not recommended in children)</td>
</tr>
<tr>
<td>d. communicating pancreatic cyst or pseudocyst</td>
<td>Reducing risk of introducing infection into cavity</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>e. biliary complications following liver transplant</td>
<td>Prevention of cholangitis</td>
<td>As (c) PLUS amoxicillin or Vancomycin</td>
<td>1 g intravenously single dose or 20 mg/kg intravenously infused over at least 1 h</td>
</tr>
<tr>
<td>3. Endoscopic ultrasound intervention for the following patient groups:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. fine needle aspiration solid lesion</td>
<td>Prevention of local infection</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>b. fine needle aspiration of cystic lesions in or near pancreas, or drainage of cystic cavity</td>
<td>Prevention of cyst infection</td>
<td>Ce-aminopenicillin</td>
<td>1.2 g intravenously single dose</td>
</tr>
<tr>
<td>4. Percutaneous endoscopic gastrostomy (PEG)</td>
<td>Prevention of peristomal infection</td>
<td>Ciprofloxacin or Ce-aminopenicillin</td>
<td>750 mg one oral dose or 1.2 g intravenous injection or infusion just before procedure</td>
</tr>
<tr>
<td>Possibly reduced risk of other infections such as aspiration pneumonia</td>
<td></td>
<td>Cefuroxime</td>
<td>750 mg intravenous injection or infusion just before procedure</td>
</tr>
<tr>
<td>5. Variceal bleeding (not strictly prophylaxis)</td>
<td>Prevention of infections such as bacterial peritonitis</td>
<td>Tetracycline can be used if past anaphylaxis or angioedema with penicillin or cephalosporin</td>
<td>400 mg intravenously for adults</td>
</tr>
<tr>
<td>Seek advice of local microbiologist or regional liver</td>
<td>Piperacillin/tazobactam</td>
<td>4.5 g intravenously three times daily</td>
<td></td>
</tr>
<tr>
<td>6. Profound immunocompromise (e.g., neutropenia &lt;0.5 x 10⁹/L or advanced haematological malignancy)</td>
<td>Prevention of procedure-related bacteremia</td>
<td>Only indicated in procedures with high risk of infection (e.g., sclerotherapy, dilatation, ERCP with obstructed system)</td>
<td>Discuss with haematologist and/or clinical microbiologist</td>
</tr>
</tbody>
</table>

ERCP, endoscopic retrograde cholangiopancreatography.

10.5. Appendix V - Guidelines relating to Anticoagulant and Antiplatelet Therapy

Guidelines for the management of patients on warfarin or dopidogrel undergoing endoscopic procedures (EUS: endoscopic ultrasound, ERCP: endoscopic retrograde cholangiopancreatography, EMR: endoscopic mucosal resection, PEG: percutaneous endoscopic gastroenterostomy, FNA: fine needle aspiration, INR: international normalized ratio, AF: atrial fibrillation, VTE: venous thromboembolism, LMWH: low molecular weight heparin)

Veitch AM, Gut 2008;57:1323 doi:10.1136/gut.2007.142497

Aspirin

Aspirin therapy can be continued for all endoscopic procedures.
10.6. Appendix VI - Summary of recommendations for colorectal cancer screening and surveillance in moderate risk family groups

<table>
<thead>
<tr>
<th>Moderate risk family history categories</th>
<th>Life-time risk of CRC death (without surveillance)</th>
<th>Screening procedure</th>
<th>Age at initial screen (if older at presentation instigate forthwith)</th>
<th>Screening procedure and interval</th>
<th>Procedures/yr/300 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal cancer in 3 FDR in first degree kinship*, none &lt;50 yrs</td>
<td>~1 in 6–10</td>
<td>Colonoscopy</td>
<td>50 yrs</td>
<td>5 yly colonoscopy to age 75 yrs</td>
<td>~18</td>
</tr>
<tr>
<td>Colorectal cancer in 2 FDR in first degree kinship*, mean age &lt;60 yrs</td>
<td>~1 in 6–10</td>
<td>Colonoscopy</td>
<td>50 yrs</td>
<td>5 yly colonoscopy to age 75 yrs</td>
<td>~60</td>
</tr>
<tr>
<td>Colorectal cancer in 2 FDR ≥60 yrs</td>
<td>~1 in 12</td>
<td>Colonoscopy</td>
<td>55 yrs</td>
<td>Once-only colonoscopy at age 55 yrs. If normal—no follow-up</td>
<td>12</td>
</tr>
<tr>
<td>Colorectal cancer in 1 FDR &lt;50 yrs</td>
<td>~1 in 12</td>
<td>Colonoscopy</td>
<td>55 yrs</td>
<td>Once-only colonoscopy at age 55 yrs. If normal—no follow-up</td>
<td>10</td>
</tr>
<tr>
<td>All other FH of colorectal cancer</td>
<td>&gt;1 in 12</td>
<td>None</td>
<td>N/A</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>Incident colorectal cancer case (age &lt;50 yrs, or MMR prediction &gt;10%), not fulfilling Lynch syndrome criteria</td>
<td>N/A</td>
<td>Tumour MSI and/or IHC analysis§</td>
<td>N/A</td>
<td>Standard post-op follow-up unless Lynch syndrome (LS) features on tumour analysis or a mutation identified, then LS surveillance applies</td>
<td>20</td>
</tr>
</tbody>
</table>

*Affected relatives who are first-degree relatives of each other AND at least one is a first degree relative of the consultand. No affected relative <50 years old (otherwise high-risk criteria would apply). Combinations of affected relatives in a first-degree kinship include: parent and aunt/uncle and/or grandparent; OR 2 siblings/1 parent; OR 2 siblings/offspring. Combinations of 2 affected relatives in a first-degree kinship include: parent and grandparent, or >2 siblings, or >2 children, or child + sibling. Where both parents are affected, these count as being within the first-degree kinship.
†Clinical Genetics referral recommended.
‡Centres may vary depending capacity and referral agreements. Ideally all such cases should be flagged systematically for future audit on a national scale.
§Refer to Clinical genetics if IHC loss or MSI-H.
©Cancer research UK (http://info.cancerresearchuk.org/cancerstats/) and ISD Scotland (http://www.isdscotland.org/isd/183.html).

BSG Guidelines for colorectal cancer screening and surveillance in moderate and high risk groups, Table 3, Page 683, Gut 2010;59:666e690. doi:10.1136/gut.2009.179804
10.7. Appendix VI1 - Governance

Steering Committee

Members: HSE Quality Improvement Division, HSE OCIO, HSE Acute Hospitals Division, Private Hospitals Association (PHA), Dept of Health, Faculty of Radiologists, Faculty of Pathology, National Endoscopy Clinical Lead, NOCA, RCPI

Observer: HIQA

Conjoint Board of the RCSI and RCPI

Programme Management Education, Quality Dept,

HSE OCIO

Endoscopy Working Group

Reference Panel(s)

Local Hospital Management and Participant Teams *

* Note Data owner is the local dept. & governance of the data is with that dept.’s local, regional and national governance structures
# REVISION HISTORY

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Reason For Changes</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Team (S Boyle / G Farr)</td>
<td>19.09.11</td>
<td>Original Baseline Guidelines</td>
<td>1.0</td>
</tr>
<tr>
<td>Project Team (S Boyle / G Farr)</td>
<td>17.05.12</td>
<td>Updated to reflect the requirements specification for the ICT solution of the programme. Also changes to membership of the Steering Committee</td>
<td>2.0</td>
</tr>
<tr>
<td>Project Team (S Boyle)</td>
<td>25.09.14</td>
<td>Updated to reflect advanced surveillance models for Barrett’s Oesophagus, Adenomas, Ulcerative Colitis and the addition of family risk groups. Introduction amended to reflect current status of programme. “Polyps” removed from KQD 5.3 – Tattooing.</td>
<td>3.0</td>
</tr>
<tr>
<td>Project Team (S Treleaven)</td>
<td>19.06.16</td>
<td>Updated to reflect new number of procedures guidance. Updating WG and SC members Updated QA to QI Update Introduction and Background to include QID involvement and NCCP exiting as funder Sedation Clarification Formatting</td>
<td>4.0</td>
</tr>
<tr>
<td>Project Team (S Treleaven &amp; C Canavan)</td>
<td>28.09.16</td>
<td>Updated Summary Table – formatting and clarification on Key Quality Data</td>
<td>4.0</td>
</tr>
<tr>
<td>Project Team (S Treleaven)</td>
<td>15.07.17</td>
<td>Updated to align these Guidelines with the Quality Assurance Guidelines of BowelScreen</td>
<td>5.0</td>
</tr>
</tbody>
</table>