



Endoscopy Standards for Individual Colonoscopists Performing Bowel Cancer Screening in New Zealand

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Introduction

The Endoscopy Guidance Group for New Zealand (EGGNZ) was established by a number of colleges, specialist societies and other stakeholders with an interest in endoscopy to provide strategic oversight for the Endoscopy Services in New Zealand from a Clinical, Operational and Patient-centred perspective. EGGNZ is hosted by the Northern Cancer Network.

The New Zealand Bowel Cancer Screening Programme (BSP) commenced in 2013 as a pilot programme. The role of EGGNZ in the BCP is to:

- Provide strategic support to National Endoscopy Quality Improvement Programme (NEQIP) and the implementation of the New Zealand Global Rating Scale (NZGRS).
- Advise on colonoscopy competence standards to perform Bowel Cancer Screening (BCS).
- Advise on endoscopy unit standards to provide BCS

EGGNZ has taken International Guidelines along with the experience of the BCS Pilot programme at Waitemata to shape these recommendations.

The whole area of Training, certification, re-certification and accreditation of individuals and endoscopy units is in a state of flux both here in New Zealand and in our close neighbours, the Australian Federation. Therefore some recommendations remain, at present, aspirational.

It is anticipated that these Standards will be reviewed by EGGNZ every 2 years.

This work was compiled by the Individual Standards Working group of EGGNZ, with representatives from Royal Australasian College of Surgeons (RACS), Royal Australasian College of Physicians (RACP), New Zealand Society of Gastroenterologists (NZSG), NZ Paediatric Gastroenterologists, NEQIP, New Zealand Nurses Organisation (NZNO) and NZ Society of Anaesthetists together with input from the Clinical Lead of the BCS Pilot, and has been ratified by the larger steering group of EGGNZ.

Basic principles

EGGNZ believe that Screening and Symptomatic (diagnostic) services should achieve the same minimum levels of quality.

The standards are qualified into **Quality Standards**, that have measurable and recognised Key Performance Indicators (KPIs), **Auditable Outcomes** which are measurable items for which there are no defined KPIs and **Practice Guidelines** which are items that are not suitable for measurement but contribute to uniformity of good practice.

Standards are further categorised into: **Essential**, when they are a requirement for BSP to commence. **Achievable**, when they should be considered to be in place within 12 months of commencing screening or **Aspirational**, which are standards recognised to be more difficult to achieve, but should be possible within 2 years.

EGGNZ Individual Standard 1 (Quality Standard): Experience of Colonoscopist

1.1 Qualifications

Essential

There are basic prerequisite qualifications to perform a colonoscopy in any endoscopy unit. These include:

- 1.1.1 A valid Annual Practising Certificate with the New Zealand Medical Council.
- 1.1.2 Local credentialing to work in the capacity as colonoscopist.

1.2 Previous Experience & Level of Performance

Essential

- 1.2.1 Provide verifiable evidence of achievement of the following Key Performance Indicators (KPIs) taken on at least the last consecutive 100 colonoscopies.
 - a. Caecal Intubation Rate ¹(unadjusted) >90%,
 - b. Adenoma Detection Rate (ADR) of at least 25% in symptomatic patients aged > 50 years, with intact colons

OR, if ADR has not been recorded

 - c. Withdrawal time (in non-interventional cases only) >6min for 90% of colonoscopies.

Achievable

- d. Evidence of Post polypectomy bleeding rate, perforation rate and post-polypectomy perforation rate (which are likely to be necessary to be collated over a longer period) is encouraged.²

Aspirational

- 1.2.2 In future, completion of certification or re-certification in colonoscopy will be mandatory. Comparable standards and processes will be established in New Zealand and in Australia.

1.3 Skills

Essential

- 1.3.1 Level 3 competency of polypectomy (up to 2cm flat lesions) is required. Assessment of this skill can be done by Directly Observed Procedural Skills (DOPS) assessment, which may take some time to perform, but endoscopy leads must ensure that all colonoscopists can deal with this level of polypectomy.

Other key skills include:

- 1.3.2 Competence in biopsy
- 1.3.3 Snare polypectomy (with and without cautery)
- 1.3.4 Submucosal injection
- 1.3.5 Polyp retrieval
- 1.3.6 Tattooing
- 1.3.7 Endoscopic haemostasis of post-polypectomy haemorrhage.
- 1.3.8 Culturally appropriate behaviours

Aspirational

- 1.3.9 Level 4 (EMR) polypectomy should probably be undertaken by designated experts only

¹ Caecal Intubation is defined as 'Visualisation of appendiceal orifice, triradiate caecal fold or retroflexed view of the ileocaecal valve.'

² Quality Assurance Guidelines for Colonoscopy: NHS BCSP 2011, Publication No 6.

EGGNZ Individual Standard 2 (Practice Guideline): Process of Consent

Consent to undergo a BCS is, like any other consent to treatment, a process and does not occur at one point in time.

Essential

The Colonoscopist is responsible for ensuring that:

- 2.1 The patient understands the procedure
- 2.2 The patient understands the associated risks
- 2.3 Correct documentation is completed
- 2.4 The patient is given an opportunity to ask the endoscopist any questions
- 2.5 The consent document should have an indication that, at a minimum, the following aspects have been discussed:
 - a. Sedation risk
 - b. Perforation (suggest quoting a rate of 1 in 1000)
 - c. Bleeding rate (suggest post polypectomy rate of 1 in 100)
 - d. Missed clinically important lesion rate (published rates are wide, so no particular rate is given, consensus that it is probably 1-10%)
- 2.6 Permission to dispose of or return tissue is indicated
- 2.7 Endoscopic Time Out is completed before sedation given or procedure commenced. The presence of a signature on a consent form is also part of the completion of this Time Out.

Achievable

- 2.8 The consent form must be completed outside the procedure room.

EGGNZ Individual Standard 3 (Practice Guideline): Intra-Procedural Techniques

To help ensure uniformity of quality EGGNZ propose the following techniques be used in all BCS colonoscopies. Indeed they represent current good practice in colonoscopy in the 21st century.

Essential

- 3.1 Retroflexion in rectum should be attempted.
- 3.2 Retroflexion in right colon should be attempted where comfortable for the patient.
- 3.3 Biopsies of the terminal ileum to document a complete colonoscopy are discouraged.
- 3.4 Lesions of > 1cm or other suspicious areas should be tattooed with carbon suspension on at least 2 opposing sides of the bowel, usually on the distal side of the lesion. With the exception of:
 - a. Caecum
 - b. Distal 4cm of rectum (i.e. palpable by rectal digital examination)
- 3.5 The following Minimum picture set should be taken;
- 3.6 Minimum picture set:
 - a. To record evidence of completion of procedure:
 - i. Appendiceal orifice
 - ii. And either caecum with IC valve or terminal Ileum
 - b. To ensure common blind spots reviewed:
 - i. Rectum (retroflexed)
 - c. To aid in audit of complications and recurrence:
 - i. Site of interventions – before, during and after.

Achievable

- 3.7 Carbon dioxide insufflation is strongly recommended (as opposed to air) for colonic endoscopic procedures.

EGGNZ recommends that techniques of polypectomy should follow ESGE Polypectomy and EMR guidelines³

³ Colorectal Polypectomy and endoscopic mucosal resection (EMR): European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline.

EGGNZ Individual Standard 4 (Auditable Outcome): Electronic Report Content

It is recognised that, as yet, not all Endoscopy Units planning to perform BCS will have the same reporting system, and so the reporting nodes may not be identical.

Essential

Irrespective of the format used, the following are the minimum data set required.

- 4.1 Indication for procedure
- 4.2 Family history of Bowel Cancer
- 4.3 Type of procedure
 - a. Colonoscopy,
 - b. Post-surgical colonoscopy,
 - c. Flexible sigmoidoscopy etc.
- 4.4 Interval from last endoscopic procedure and type of procedure
- 4.5 Comorbidities
- 4.6 Preparation / Bowel cleansing regimen
- 4.7 Bowel Prep Quality
- 4.8 Boston Score
 - a. taken on withdrawal,
 - b. individual segments and
 - c. total
- 4.9 Insufflation method(s)
 - a. Air / CO₂
 - b. water
- 4.10 Endoscope (s) used
- 4.11 Sedation medication and dose
- 4.12 Assessment of the degree of difficulty of the procedure
- 4.13 Maximum extent on Intubation
- 4.14 Reason if not complete
- 4.15 Patient comfort - Gloucester Comfort Scale (reported, and preferably entered into the report by nurse)
- 4.16 Withdrawal time
- 4.17 Abnormalities detected, and for each:
 - a. Site
 - b. Distance from Ano-rectal junction)
 - c. Sector nomination (caecum, ascending, transverse, descending colon, sigmoid, rectum)
 - d. Size / Morphology
 - i. Maximum diameter in millimetres
 - ii. Polypoid / Non-polypoid / sessile. (⁴Aspirational reporting by Paris classification: Ip Ls, IIb, IIc)
- 4.18 For endoscopic therapy:
 - a. Technique
 - b. Complications
 - c. Completeness (of resections)
- 4.19 Minimum picture set:
 - a. To record evidence of completion of procedure:
 - i. Appendiceal orifice
 - ii. And either caecum with IC valve or terminal Ileum
 - b. To ensure common blind spots reviewed:
 - i. Rectum (retroflexed)

⁴ This data is to be recorded, but may not appear on the patient or GP report

- c. To aid in audit of complications and recurrence:
 - i. Site of interventions – before, during and after.
- 4.20 Recommendations for follow up once histology results are available.

EGGNZ Individual Standard 5 (Auditable Outcome): Delivery of Report to Patient

- 5.1 Before leaving the endoscopy unit, patients should be given a verbal explanation of the results of their procedure. It is preferred that this is usually to be undertaken by the proceduralist, or at least a senior nurse involved in the BCS programme.
- 5.2 Patients should also be given written information to support the verbal explanation.
- 5.3 Written information should include:
 - a. Findings
 - b. Symptoms to watch out for
 - c. When to resume or take relevant medications including anticoagulants
 - d. When it is appropriate to drive or operate heavy machinery
 - e. Contact numbers

EGGNZ Individual Standard 6 (Quality Standard): Performance & Audit

*** Note: these KPIs apply only to outcomes of Colonoscopies performed as a result of the FIT for Bowel Cancer Screening.**

6.1 Individual Performance

Fundamental to ensuring Quality of the diagnostic Intervention of the BSP is on-going and reactive audit.

It is recognised internationally that numbers statistically equate with outcomes, but we also recognise the desire of the NZ BCP to be undertaken in every DHB.

Essential

In order to maintain as high a standard as possible we believe that those colonoscopists performing BCS should undertake a minimum of:

6.1.1 One endoscopy list per week (not necessarily of all BCP cases)

Key Performance Indicators (KPIs) should be subject to routine, repeated audit and reported back to the BCS colonoscopists by the Lead Colonoscopist every 6 months. Interpretation of KPIs for less than 100 cases should be applied with caution.

6.1.2 Withdrawal time minimum of >6 mins in >90% of negative (non-interventional) colonoscopies,

6.1.3 Caecal Intubation Rate (CIR, unadjusted) minimum >95%

6.1.4 Adenoma Detection Rate (ADR) >35% **

6.1.5 Polyp retrieval rate minimum >95% (unadjusted)

**Expected Adenoma Detection Rate for BSP will be calculated from the WDHB Pilot and first round data and this standard will be adjusted accordingly

6.2 Unit performance

Some KPIs are too infrequent to be sensibly reported on an individual level and so for each Endoscopy Unit the KPIs are:

Essential

6.2.1 Overall perforation rate < 1 in 1000

6.2.2 Post polypectomy perforation rate 1 in 500

6.2.3 Post polypectomy bleed 1 in 100

6.2.4 Serious Adverse Events < 5/1000⁵

The following information should be considered essential audit for internal quality purposes (Auditable Outcomes)

6.2.5 Gloucester Comfort Scale

6.2.6 Sedation Drug dose

6.2.7 Use of reversal agents

6.2.8 The percentage of detected cancers and polyps > 1cm given a tattoo, with the exception of those located in:

a. Caecum

b. Distal 4 cm of the rectum (i.e. palpable by rectal digital examination)

6.2.9 Correct completion of consent forms.

6.2.10 Correct completion of Endoscopic Time Out forms.

⁵ Quality Assurance Guidelines for Colonoscopy. NHS BCSP Publication No 6 February 2011

EGGNZ Individual Standard 7 (Auditable Outcome): Continuing Endoscopic Medical Education

As Endoscopy practice is ever changing it is highly recommended that BCS Colonoscopists also take a reflective view of their practice. This should include:

Essential

- 7.1 Participate in continuing colonoscopy medical education and quality improvement programmes including Direct Observation of Procedural Skills (DOPS).
- 7.2 Attend Continuing Endoscopic Medical Education (CME-E) at least every 3 years.
- 7.3 Comply with future re-certification
- 7.4 Attend appropriate Multidisciplinary meetings

Aspirational

- 7.5 Undergoing periodic 360 degree feedback

Appendix

Levels of Colonoscopic Competency:

Level 0: The operator does not remove any lesions, referring on all patients with any detected lesions. The operator will be able to biopsy lesions, and pathological material may inform the decision to refer. Basic level of competency for diagnostic flexible sigmoidoscopy (FS) but not recommended for screening FS.

Level 1: Removing lesions <10 mm in diameter at FS. Rationale: larger lesions will indicate a need for colonoscopy and can be removed when the colonoscopy is performed. Tissue is required from smaller lesions to decide whether colonoscopy is necessary. Thus any person performing FS screening should have this level of competency.

Level 2: Removing polypoid and sessile lesions <25 mm providing there is good access. All colonoscopists should have this level of competency.

Level 3: Removing smaller flat lesions (<20 mm) that are suitable for endoscopic therapy, larger sessile and polypoid lesions, and smaller lesions with more difficult access. Some flat lesions <20 mm with poor access might be unsuitable for this level. Any person doing colonoscopy for positive faecal occult blood test (FIT) in a screening programme should have this level of competency.

Level 4: Removing large flat lesions or other challenging polypoid lesions that might also be treated with surgery. This is the type of lesion that would not be removed at the first colonoscopy because of time constraints, if applicable, or because the surgical option needs to be discussed with the patient. If the patient chooses to have endoscopic therapy, then he/she should be referred to a level 4 competent endoscopist. This level of competency would be expected of only a small number of regionally based colonoscopists.

It is recognised that the methodology does not currently exist to reliably recognise who has achieved the proposed levels of competence⁶. Thus, until a competency-based assessment process is available the clinical lead of the service should be satisfied that:

- The professionals have the necessary competence;
- The unit has the necessary equipment; and
- In the event of a serious adverse event, it will be possible to manage the patient locally or transfer the patient safely to another institution with the expertise and facilities to care for the patient.

N.B. A review of capabilities may identify shortcomings that can be addressed with further training or investment. This training and investment should occur before screening begins.

⁶ European guidelines for quality assurance in colorectal cancer screening and diagnosis; 2010.

Glossary of Terms

Credentialing	The process of review and verification of fitness to practice typically performed by an organisation to grant specific clinical privileges such as performing procedures at that institution.
Certification	The action or process of providing someone with an official document attesting to a status or level of achievement. For EGGNZ this would attest to a level of competence in an endoscopic procedure.
Accreditation	The process of officially recognizing a person or body as being qualified to perform a particular activity. In the context of Endoscopy, this would be recognizing a Unit as being up to a particular standard to perform Endoscopy.
Withdrawal Time	This is taken from the time the colonoscopist starts viewing the colon, i.e. after having inspected the terminal ileum
Caecal Intubation	Defined as passage of the colonoscope proximal to the ileo-caecal valve with visualisation of the appendiceal orifice, triradiate caecal fold or retroflexed view of ileocaecal valve. Verification is preferably by photograph of these, with the addition of the terminal ileum if intubation is achieved.
Caecal Intubation Rate (unadjusted)	This means that <u>all</u> colonoscopies are included in the KPI, even if they are not completed due to difficult anatomy, poor bowel prep or non-traversable stenotic lesions.
Serious Adverse Events	Any event resulting in hospitalisation or death. As defined in Quality Assurance in Colonoscopy. UK BCSP 2011.

Abbreviations

BCS	Bowel Cancer Screening
BSP	New Zealand Bowel Screening Programme
CME-E	Continuing Endoscopic Medical Education
DOPS	Direct Observation Procedural Skills
EGGNZ	Endoscopy Guidance Group for New Zealand
FOBT	Faecal Occult Blood Test
FS	Flexible Sigmoidoscopy
GESA	Gastroenterological Society of Australia
KPI	Key Performance Indicators
NCN	Northern Cancer Network
NEQIP	National Endoscopy Quality Improvement Programme
NZGRS	New Zealand Global Rating Scale
NZNO	New Zealand Nurses Organisation
NZSG	New Zealand Society of Gastroenterology
RACP	Royal Australasian College of Physicians
RACS	Royal Australasian College of Surgeons

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