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The Endoscopy Governance Group for New Zealand

The EGGNZ Individual Standards for Colonoscopy in Bowel Cancer Screening – behind the guidelines

Dr Russell Walmsley

Chair, Endoscopy Governance Group for New Zealand

Endoscopy Governance Group for New Zealand

"To support Quality Endoscopy across the public and private sectors in New Zealand"

- To provide oversight, leadership and advice on quality improvement in Endoscopy Services in New Zealand.
- To provide oversight and direction to the quality improvement framework of the National Endoscopy Quality Improvement Programme (NEQIP).
- To provide a forum for gaining professional consensus and agreement on clinical standards.
- To plan, develop and work with stakeholders to deliver standards documents.
- To advise on Accreditation of Endoscopy services to those standards.
- To work closely with other stakeholders to maximise opportunities for shared learning's and the development of consistent approaches to quality in endoscopy across New Zealand.

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Stake Holders

- Royal Australasian College of Surgeons (RACS)
- NZAGS (General Surgeons) surgical training responsibility
- Royal Australasian College of Physicians (RACP)
- RACP Advanced Training Committee
- New Zealand Society of Gastroenterology (NZSG)
- NZ Nurses Organisation (NZNO)
- NZ Conjoint Committee (NZCC)
- National Endoscopy Quality Improvement Programme (NEQIP)
- Colorectal Surgical society of Australia and New Zealand (CSSANZ)
- Bowel Cancer Screening Programme (BCSP)
- Royal New Zealand College of General Practitioners
- Ministry of Health including Health Workforce NZ
- National Clinical Network for Paediatric Gastroenterology
- Australia & New Zealand Gastric & Oesophageal Surgical Association (NZGOSA)
- Paediatric Surgeons
- New Zealand Society of Anaesthetists (NZSA)
- New Zealand Private Surgical Hospitals Association (NZPSHA)
- Nurse Executives of New Zealand (NENZ)
- Nurse Endoscopists Training Programme Representation

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- 2016 MoH funded Chair and EO for EGGNZ.
- Contract included developing;
  1. Endoscopy Standards for Individual Colonoscopists Performing Bowel Cancer Screening in New Zealand
  2. Endoscopy Unit Standards for Performing Bowel Cancer Screening in New Zealand

1. Completed July 2018

Available for download from http://www.endoscopyquality.co.nz/

Guideline Development

- Literature Review
  - England, Ireland, Scotland, Netherlands, Canada (BC), European Union, ESGE
- Working Stream
  - RACS, RACP, NZSG, CCRNZ, CCNZ Gastro Nurses College, Private
- Steering Group Review
- Repeat
- Consensus agreement
- Formal invitation for comments form Stake Holder societies
- Steering Group review
- Publication, July 2017

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Bowel Cancer Screening Programme for New Zealand

"The National Bowel Screening Programme aims to save lives by detecting bowel cancer at an early stage when it can often be successfully treated"

MOH National Screening Unit https://www.nsu.govt.nz

- ? Reduce CRC incidence
- MoH Strategic Themes; "Closer to home"

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

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- **Basic principles**
- **EGGNZ Individual Standard 1: Experience of Colonoscopist**
- 1.1 Qualifications
- 1.2 Previous Experience & Level of Performance
- 1.3 Skills
- **EGGNZ Individual Standard 2 (Practice Guideline): Process of Consent**
- **EGGNZ Individual Standards 3 (Practice Guideline): Intra-Procedural Techniques**
- **EGGNZ Individual Standards 4 (Auditable Outcome): Electronic Report Content**
- **EGGNZ Individual Standards 5 (Auditable Outcome) : Delivery of Report to Patient**
- **EGGNZ Individual Standards 6 (Quality Standard): Performance & Audit**
- 6.1 Individual Performance
- 6.2 Unit performance (directly related to actions of BCS Colonoscopists).
- **EGGNZ Individual Standard 7 (Auditable Outcome): Continuing Endoscopic Medical Education (CME-E)**

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

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
- **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: Experience of Colonoscopist

Qualifications

- **Essential**
- There are basic prerequisite qualifications to perform a colonoscopy in any endoscopy unit. These include:
  - A valid Annual Practicing Certificate with the New Zealand Medical Council.
  - Local credentialing to work in the capacity as colonoscopist.

EGGNZ Individual Standard 1: Experience of Colonoscopist

Previous level of Experience & Performance

Essential

- Provide verifiable evidence of achievement of the following Key Performance Indicators (KPIs) taken on at least the last consecutive 100 colonoscopies.
  - Caecal Intubation Rate* (unadjusted) >90%,
  - Adenoma Detection Rate (ADR) of at least 25% in symptomatic patients aged > 50 years, with intact colons
- **OR,** if ADR has not been recorded
  - Withdrawal time (in non-interventional cases only) >6min for 90% of colonoscopies.

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

Caecal Intubation Rate

Colorectal cancers from Ontario Cancer registries 2000-2005.
Post Colonoscopy Colorectal Cancer (PCCRC) = if complete colonoscopy in previous 7-13 months.
1260 cancers were PCCRs

- 6.8% of distal CRCs.
- 12.4% of proximal tumours.

Multivariate model for predicting PCCRC

	Proximal Cancers	p value	Distal cancers	p value
% Completeness for endoscopist				
<80%	1.00 (referent)	.002	1.00 (referent)	.03
80%–84%	1.16 (0.86–1.56)		0.90 (0.65–1.25)	
85%–89%	0.69 (0.51–0.93)		0.65 (0.47–0.89)	
90%–94%	0.66 (0.50–0.87)		0.71 (0.54–0.93)	
95%+	0.72 (0.53–0.97)		0.73 (0.54–0.97)	

EGGNZ Quality Standards
Previous Experience ; 1.2.1 a. Caecal Intubation Rate 1 (unadjusted) >90%
Performance & Audit; 6.1.3 Caecal Intubation Rate (CIR, unadjusted) minimum >95%

Adenoma Detection Rate and Risk of Colorectal Cancer and Death NEJM, 2014;370:14:1298

- 314,872 colonoscopies performed by 136 gastroenterologists
- ADR 7.4-52.5%
- 712 interval cancers
- Quintiles of ADR:
  - 7.35-19%, 19-23.85%, 23.86-28.4%,28.4-33.5%, 33.51-52.5%
- Highest vs lowest ADR quintile HR 0.52

- ***For each 1% increase in ADR = 3% decrease in CRC risk***

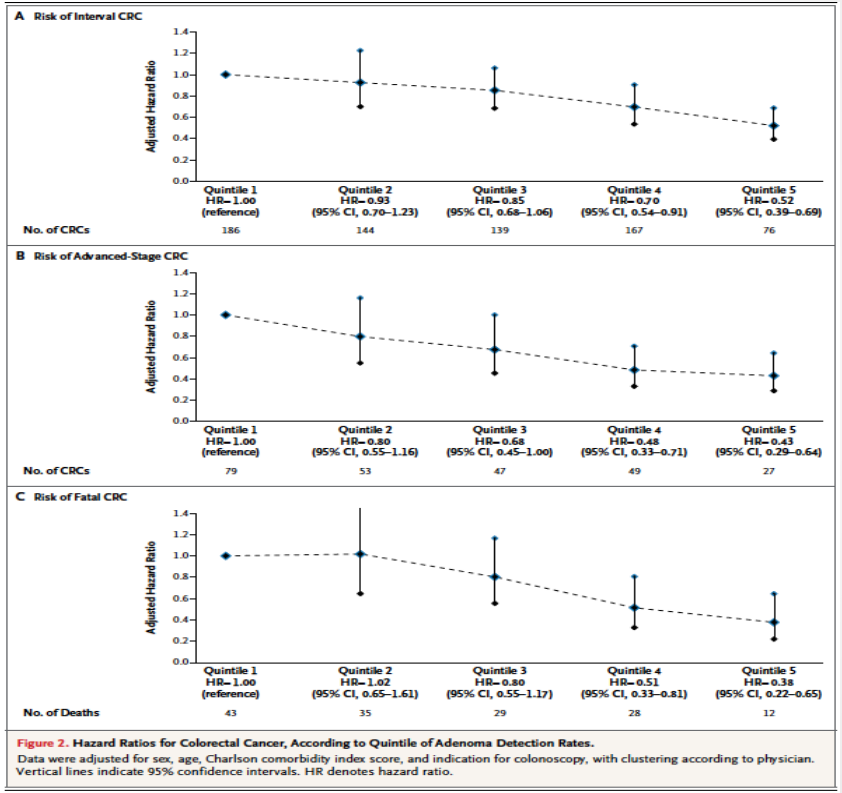
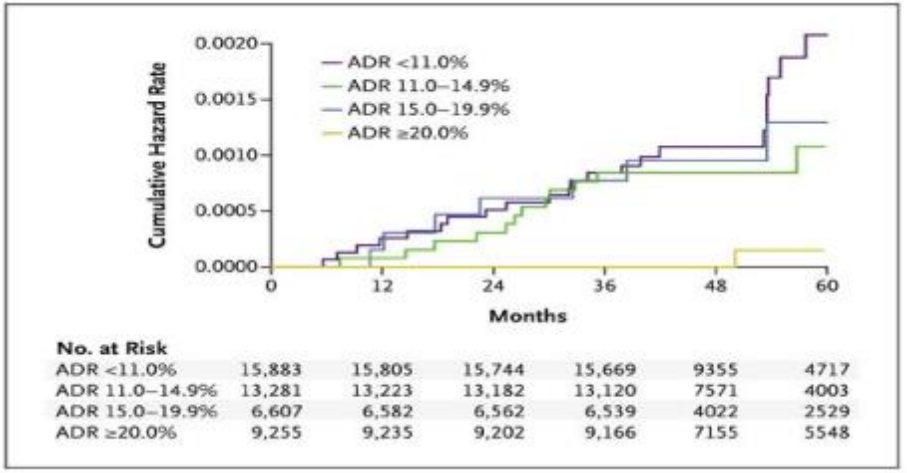


Figure 2. Hazard Ratios for Colorectal Cancer, According to Quintile of Adenoma Detection Rates.
Data were adjusted for sex, age, Charlson comorbidity index score, and indication for colonoscopy, with clustering according to physician. Vertical lines indicate 95% confidence intervals. HR denotes hazard ratio.

Adenoma Detection Rate and Risk of PCCRC

- 45,026 colonscopies in National CRC screening Programme in Poland, 2000-2004.
- 186 endoscopists
- 42 Interval Cancers



- ADR associated with interval CRC (p=0.008) [all groups vs >20%]
- CIR not associated (p=0.5)

Quality Indicators for Colonoscopy and the Risk of Interval Cancer
NEJM 2010;362:1795-803

ADRs from comparative studies with different indication

Author	study type	n colonoscopies	Results
Adler[68]	prospective	1397	carcinoma/polyps: screening 16.0%, bleeding 22.1%, symptoms* 7.7%
Anderson[69]	retrospective	9100	significantly higher ADR in screening-colonoscopy (37%) vs. surveillance-colonoscopies (25%)
Chey[70]	prospective	917	IBS vs. healthy controls: histologically significanlty lower adenoma rate in IBS group
De Bosset[71]	prospective	509	polyp/neoplasia ≥ 1 cm, screening 28.5%, symptomatic 15.4%, FOBT pos. 27.5%, haematochezia 28.8%
Gupta[72]	retrospective	41775	risk for obstipation only indication lower for relevant findings than obstipation with screening or s screening only
Kuoh[73]	retrospective	2633	significantly less risk for neoplasia for abdominal pain indication compared to iron deficiency anaemia and rectal bleeding
Lasson[74]	prospective	767	indication PR bleed (n=405): carcinoma 13.3% (n=54), adenoma >1cm 20.5 % (n=83)
Lieberman[75]	retrospective	6669	polyp/neoplasia ≥ 1 cm: screening 6.5%, non specific symptoms 7.3%, FOBT+ 17.0%
Minoli[76]	prospective	1123	carcinoma: screening 8%, symptoms 6.2%, haematochezia 11.9%
Neugut[77]	retrospective	1172	adenoma >1cm or carcinoma depending on indication: PR bleed 14.5%, abdominal pain 7.1%, Change in bowel habits 7.1%,
Obusez[78]	retrospective	786	constipation only indication: adenoma 2.4% (n=19), ADR for patients < 40 years 2.9%, <50 years 1.7%
Patel[79]	prospective	559	prevalence of IBS in 559 patients with Rome III criteria only 15.4% (n=21) with additional red flag criteria ** 27.7% (n=117)
Pepin[80]	retrospective	563	constipation as only indication: carcinoma 1.7%, adenoma 19.6%, advanced adenoma 5.9%

EGGNZ BSP standard

1.2.1 b. ≥25%, in all patients > 50 years.

6.1.4 >35% ** adjusted from WDHB/1st round data

Withdrawal Times and Adenoma Detection

- 12 Gastroenterologists performed 7882 colonoscopies over 15 months.
- 2053 initial screening colonoscopies.
- Compared neoplastic lesion detection rate in screening colonoscopies of those with 6 minutes withdrawal with those> 6 minutes.
- Non-interventional colonoscopies.

Results:

Neoplasms in 23.5% (9.4-32.7%)

Withdrawal times 3.1-16 minutes

Mean non-interventional WT >6 minutes vs. < 6 minutes:

Neoplasm 28.3% vs 11.8% (p<0.001)

Advanced neoplasms 6.4% vs 2.6% (p 0.005)

Barclay et al NEJM 2006: 355;2533

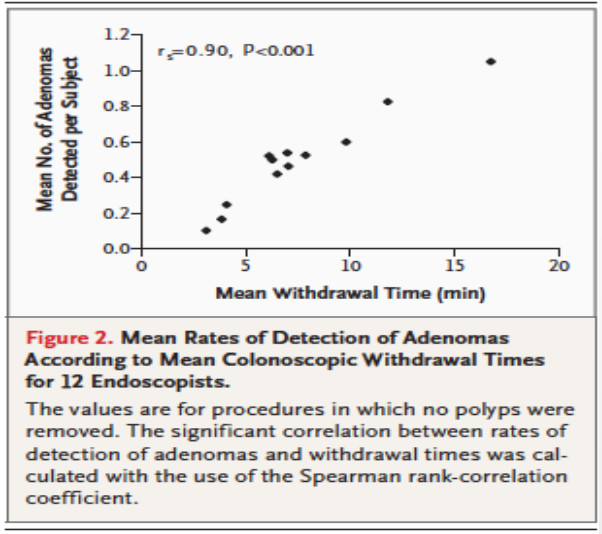


Figure 2. Mean Rates of Detection of Adenomas According to Mean Colonoscopic Withdrawal Times for 12 Endoscopists.

The values are for procedures in which no polyps were removed. The significant correlation between rates of detection of adenomas and withdrawal times was calculated with the use of the Spearman rank-correlation coefficient.

Longer mean colonoscopy withdrawal time is associated with increased adenoma detection

TJ Lee et al Endoscopy 2013, 45; 20-26

NHS BCSP in England, from 8/06-8/09.

31, 088 colonoscopies. 147 BSP Colonoscopists

(>100 procedures, >90% CIR, >20% ADR in last 12 months = "Driving License").

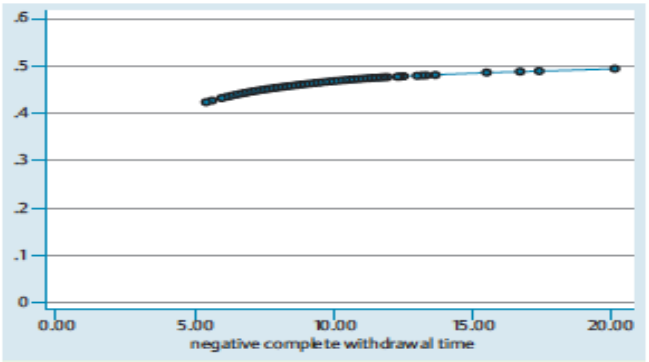


Fig. 1 Adenoma detection rate (ADR) against mean withdrawal time in complete colonoscopies with negative findings (mean nc-CWT). Logistic regression model using data on 147 colonoscopists who performed 31 088 colonoscopies in the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) in England.

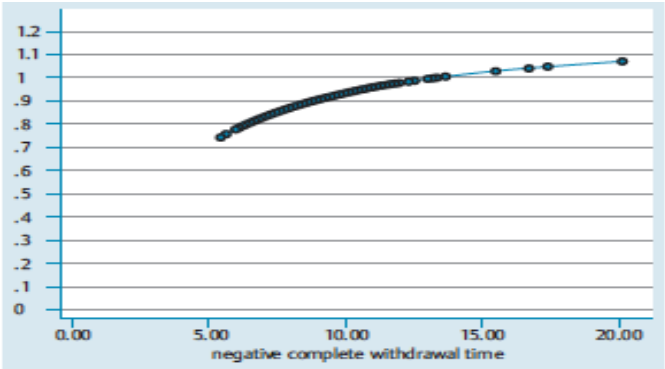


Fig. 2 Adenomas detected per procedure against mean withdrawal time in complete colonoscopies with negative findings (nc-CWT). Logistic regression model using data on 147 colonoscopists who performed 31 088 colonoscopies in the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) in England.

WT > 9mins = 11% ↑ no. of procedures with adenomas & 25% ↑total number adenomas removed.

WT > 11 mins found 50% more Rt adenoma cf. WT <7 mins.

EGGNZ Individual Standard 1: Experience of Colonoscopist

Previous level of Experience & Performance

- **Aspirational**
  - 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.

EGGNZ Individual Standard 1: Experience of Colonoscopist

Skills

- **Essential**
  - 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.
- **Aspirational**
  - Level 4 (EMR) polypectomy should probably be undertaken by designated experts only

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

Essential

- The Colonoscopist is responsible for ensuring that:
  - The patient understands the procedure
  - The patient understands the associated risks
  - Correct documentation is completed
  - The patient is given an opportunity to ask the endoscopist any questions
- The consent document should have an indication that, at a minimum, the following aspects have been discussed:
  - Sedation risk
  - Perforation (suggest quoting a rate of 1 in 1000)
  - Bleeding rate (suggest post polypectomy rate of 1 in 100)
  - Missed clinically important lesion rate (published rates are wide, so no particular rate is given, consensus that it is probably 1-10%)
- Permission to dispose of or return tissue is indicated
- 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

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

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

Essential

- In order to maintain as high a standard as possible we believe that those colonoscopists performing BCS should undertake a minimum of:
    - One endoscopy list per week (not necessarily of all BSP 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.
    - Withdrawal time minimum of >6 mins in >90% of negative (non-interventional) colonoscopies,
    - Caecal Intubation Rate (CIR, unadjusted) minimum >95%
    - Adenoma Detection Rate (ADR) >35% **
    - Polyp retrieval rate minimum >95% (unadjusted)

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

Procedural Techniques that Increase ADR

- Position change
  - Uncertain. Maybe if a difficult procedure, maybe right colon best seen in left lateral.
- Mechanical Devices
  - Short caps; PDR increased , ADR not.
  - Endocuff; RCT = No increase in ADR or MAP
- Retroflexion in rectum
  - Increase in ADR of 0.3-2% (total patients in studies = 3600)
  - Rectal perforation 0.01% (n= 40,000)

EGGNZ Clinical Practice recommendations: Retroflexion should be attempted.

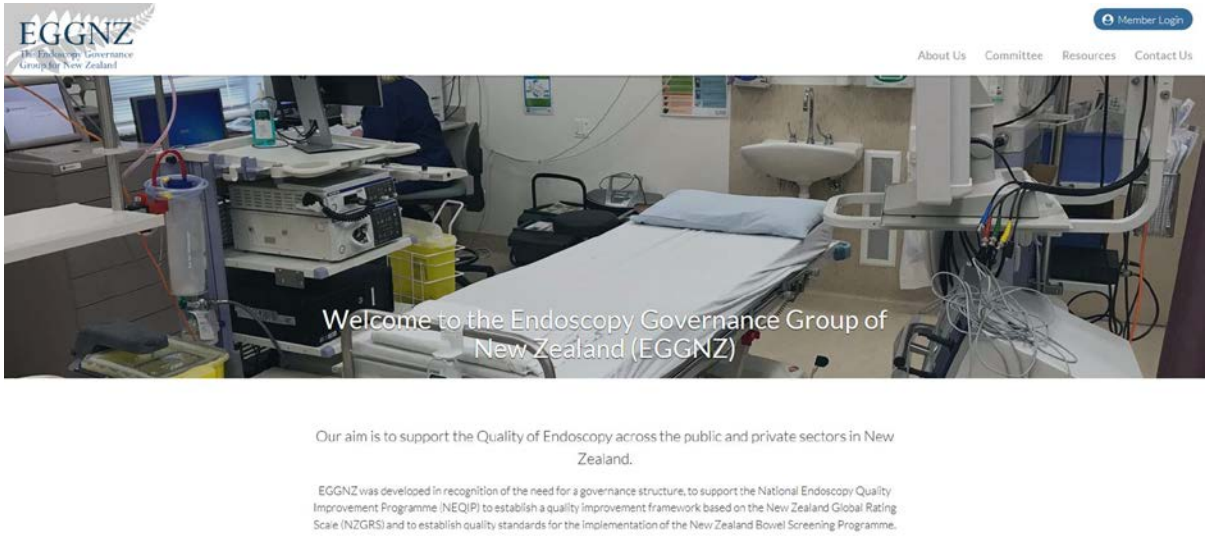
EGGNZ Individual Standard 7 (Auditable Outcome): Continuing Endoscopic Medical Education (CME-E)

Essential

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

Quality Standards for Bowel Cancer Screening

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



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Case study 1.

- 2011 FIT Bowel Cancer screening is introduced Nationally.
- 2014; 2 Post Colonoscopy Colorectal Cancers from BCSP patents are reported at Centre X.
- Local enquiry shows their BCSP Colonoscopies performed by the same endoscopist within previous 9 months.
- 2015; Local then national Review.
  - 615 patients offered repeat colonoscopies.
  - 384 colonoscopies undertaken
- 13 total interval cancers found
- 67 patients had surveillance initiated/altered.

Case Study , Part 2.

- Endoscopist's KPIs:
  - CIR = 91% for 2013.
  - ADR = 23.65% (National BCSP target 25-35%)
- Individual record review finds no objective evidence of Caecal intubation in 30% of BCSP colonoscopies

- PCCRC rate varies by population and indication and screening method.
- International Published rates 2.5-8.6%
- Taking PCCRC of 8.6 % there could have been 7 Interval Cancers.

Case study.
Health Safety Commission Enquiry 2017

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Recommendations (abridged)

- National Quality Improvement Programme for Endoscopy
- BSP Quality Assurance Guidelines should be updated with latest figures (including ADR thresholds)
- The Endoscopy services, in conjunction with professional bodies, must develop competency framework
- Quality of BSP should be audited at local and national level
- Process to notify BSP PCCRC
- National figures of BSP and non-BSP PCCRC should be determined