BowelScreen
An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme

Guidelines for **Quality Assurance in Colorectal Screening**

Second Edition

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Foreword

Part of the Health Service Executive (HSE), the National Screening Service (NSS) has significant expertise and a strong national and international reputation in the development, implementation and delivery of successful population-based screening programmes in Ireland.

The NSS delivers four screening programmes: BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme and BowelScreen – The National Bowel Screening Programme. This document is the second edition of the NSS's guidelines for assuring the quality of the BowelScreen programme.

Colorectal cancer in Ireland

In Ireland, colorectal cancer, also known as bowel cancer, is the second most-common newly diagnosed cancer in men and the third most-common newly diagnosed cancer in women. An average of 2,489 new cases of colorectal cancer were diagnosed each year between 2012 and 2014.[1] The number of new cases of colorectal cancer has increased in Ireland since 1994 and is expected to increase significantly over the next 10 years due to an ageing population and increasing life expectancy. Despite improvements in diagnosis and treatment, colorectal cancer remains the second most-common cause of cancer death in Ireland; only 57 per cent of colorectal cancer patients are alive 10 years after their diagnosis.[2]

Population-based screening

Screening is a means of detecting disease before symptoms appear. In screening for cancer, disease can be detected at an early stage, which can often increase treatment options and reduce the invasiveness of the treatment. The aim of screening is to improve survival rates, limit morbidity and improve the quality of life of those who have developed cancer.

Population-based call, re-call screening programmes provide a consistent, high-quality and standardised approach to identifying the population most at risk from a particular disease, through to diagnosis and referral for treatment.

By detecting cancer early and reducing mortality, organised screening programmes have obvious advantages. However, for screening programmes to reap acceptable clinical benefits, consistent repeat participation is necessary, and this is why adherence to biennial screening is an important element of the BowelScreen programme.

Colorectal screening

Population-based screening for colorectal cancer is potentially one of the most effective public health interventions in the Irish healthcare system.[3] The primary objective of colorectal cancer screening is to detect pre-cancerous adenomas in the lining of the bowel with a view to preventing the development of colorectal cancer. This has the effect of reducing the burden of disease on both the individual and the health system.

The BowelScreen programme

First offered in October 2012, the BowelScreen programme was established to provide free screening on a two-yearly cycle, initially to all eligible men and women aged 60 to 69 and ultimately to the full 55 to 74 age group. The first round was carried out over approximately three years so that hospitals could be recruited and efficiencies in postal and laboratory systems could be tested. While the first phase targeted men and women aged 60 to 69, it is important to note that the maximum benefit for the population in terms of reducing mortality and cost-effectiveness will occur only when the programme targets the full 55 to 74 age population.

In its first screening round, from October 2012 to December 2015, BowelScreen invited 488,628 eligible people, screened 196,238 clients, performed 8,058 colonoscopies and detected 521 cancers. This represents a screening uptake rate of 40.2 per cent and a cancer detection rate of 2.63 per 1,000 people screened. In addition, approximately 13,000 adenomas were removed. Adenomas are abnormal tissue growths that can become cancerous at a later stage. The removal of pre-cancerous adenomas greatly reduces the risks associated with future bowel cancer development.

The programme's primary screening tool is the faecal immunochemical test (FIT), which uses an automated analytical platform. From an international perspective, Ireland was an early adopter of this technology for organised population-based colorectal cancer screening. One of the advantages of this test in a population-based screening programme is that it can be self-administered in the privacy of the individual's own home.

The NSS has learned extensively from the experience of implementing the first round of the programme. Throughout the second and subsequent rounds, the NSS will continue to work with the HSE Acute Hospitals Division and its screening colonoscopy partner hospitals to ensure sufficient and high-quality endoscopy capacity is in place to meet the needs of the programme. Given that the uptake rate is much lower than that being achieved by other screening programmes, the future focus will be on advertising and promoting the programme and identifying and removing perceived barriers to screening uptake.

The NSS is cognisant of the importance of quality assurance within the screening pathway. To ensure that the BowelScreen programme is effective and adheres to the highest international standards, each step of the screening process must be fully quality assured, monitored and assessed. These 'Guidelines for Quality Assurance in Colorectal Screening' are pivotal to the management of a high-quality screening programme. I am delighted that we are now in a position to publish this second edition of the guidelines, which builds on our experience of the first completed screening round of the programme and encompasses the latest international standards.

We would like to thank all those involved in the implementation of the BowelScreen programme for their dedication. We would also like to thank those who have been part of this revision of the guidelines, which will enable us to continue to provide world-class screening services.

Charles O'Hanlon
Head of Screening, National Screening Service

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1. Cancer projections for Ireland 2015-2040. Cork: National Cancer Registry; 2014.
2. Cancer in Ireland 1994-2014: Annual Report of the National Cancer Registry. Cork: National Cancer Registry; 2016.
3. HIQA. Health technology assessment (HTA) of a population-based colorectal cancer screening programme in Ireland [online], 2009, available: https://www.hiqa.ie/sites/default/files/2017-01/HTA_population_based_colorectal_cancer_screening_programme.pdf [accessed 23 May 2017].

Preface

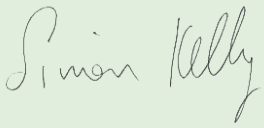
The primary goal of BowelScreen is to reduce mortality from colorectal cancer in men and women in Ireland. Starting with men and women aged 60 to 69 and targeting men and women aged 55 to 74 in the future, the programme is being implemented on a phased basis. Organised population-based screening for colorectal cancer is a layered, complex process involving a number of steps, including identification of the target population, attraction of the target population into the programme, delivery of a suitable screening test, analysis of the screening test, identification of people whose initial screening test indicates an abnormality and provision of referral, where required, for further treatment and diagnosis.

Each aspect of the screening process must be fully quality assured. Quality assurance is process-driven, and specific steps help define and achieve screening goals. A significant aspect of this quality-assured colorectal screening programme is the continuing oversight of quality by the NSS Quality Assurance Committee for Colorectal Screening (referred to below as the QA Committee).

The QA Committee's purpose is to review international standards, recommend best practice, monitor and evaluate achievement of the recommended standards and monitor and support adherence by service providers. The QA Committee reports to the Colorectal Executive Management Team (CR EMT), which, in turn, reports to Head of Screening, National Screening Service, who has overall responsibility for quality assurance in NSS programmes.

One of the main principles to adhere to when developing quality assurance standards for a screening programme is that the programme should deliver optimal outcomes for all its users. It is imperative, therefore, that the members of the QA Committee disregard constraints or difficulties in the area when developing the standards. To ensure continual adherence to the standards across every aspect of BowelScreen, the programme's written, auditable standards need to be updated continually to take into account changes in technology, operation or clinical expectations. The QA Committee, which considered this revision of the standards, comprises a multidisciplinary team of experts drawn from the fields of endoscopy, radiology, histopathology, surgery and programme operation and administration. Before publication, the revised standards were reviewed and approved by an international peer review panel, which included leading experts and practitioners in the delivery of colorectal cancer screening, endoscopy, radiology, histopathology and surgery.

This second edition of 'Guidelines for Quality Assurance in Colorectal Screening' represents best practice. Rigorous adherence to best practice will ensure that BowelScreen has a greater impact on reducing mortality from colorectal cancer in Ireland. I wish to thank the members of the international panel for devoting their time to this very important exercise. I also wish to thank the members of the QA Committee for bringing their acknowledged expertise and giving of their time to developing this edition of the standards.



Simon Kelly
Chairperson, NSS Quality Assurance Committee
for Colorectal Screening

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International peer review

As part of the development of the Guidelines for Quality Assurance in Colorectal Screening (2nd edition), an external international peer review took place in March 2017.

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Introduction

1 Introduction

The purpose of BowelScreen is to identify the population most at risk from colorectal cancer and to target those most likely to benefit from early detection and treatment. The benefit of BowelScreen is that, over time, the rate of mortality from colorectal cancer will reduce, which will result in lower numbers attending for cancer treatment in hospitals. In the absence, to date, of any large-scale randomised controlled trials of colorectal cancer screening using the faecal immunochemical test (FIT), the best estimate of mortality reduction is 36 per cent after 10 years of offering screening to men and women aged 55 to 74 years. However, there is uncertainty around this estimate due to the heterogeneity in diagnostic performance among different tests used in the model.[1] The NSS intends to extend the BowelScreen screening age group from the current 60 to 69 years of age to 55 to 74 years of age.

The NSS is working with the National Endoscopy Working Group of the HSE, the Acute Hospitals Division of the HSE, the Department of Health and the National Treatment Purchase Fund to develop a national strategy for endoscopy services. BowelScreen is committed to working in partnership with the National Endoscopy Working Group to promote and drive service improvements across all hospital groups. The work streams identified by the group will include developing support plans for capacity and demand, standardised referral pathways, validation and scheduling, quality assurance and training.

Strategic planning for the development and implementation of BowelScreen is provided by the Colorectal Executive Management Team (CR EMT). The programme's QA Committee developed the guidelines documented in this publication. A clinical advisory group supports the ongoing clinical development of the programme and provides medical policy and clinical advice to the CR EMT.

The establishment of BowelScreen as an organised population-based screening service for colorectal cancer was a complex and layered process. The second round of the programme began in January 2016, and the data collected from each round will inform the future direction of the service.

The programme operates on a call, re-call basis. The target population is identified using data extracted from the Department of Social Protection and self-registrants. All eligible individuals are issued with an invitation to participate in the programme within the two-year cycle. Individuals who wish to take part in the programme call a freephone customer information line to consent to participation, and a FIT is then forwarded to them by post.

The easy-to-use FIT includes step-by-step instructions for self-administration of the test at home. The client sends the completed test by Freepost to an accredited laboratory for analysis. Approximately 96 per cent of people will receive a normal test result and will be sent another home test kit in the next two-year cycle while they remain within the eligible age range.

Approximately four per cent of people will receive an abnormal result following the home test kit and will require an additional test – a colonoscopy – to investigate the lining of the bowel. The colonoscopy will be offered at a hospital-based unit contracted by the NSS to provide this service. Each person will be contacted by a suitably qualified nurse, who will assess the person's suitability for colonoscopy and then guide them through the colonoscopy process. In conjunction with the National Cancer Control Programme (NCCP), defined pathways have been developed for those who may require further treatment or surgery.

Each part of the screening process must be fully quality assured and monitored to ensure it adheres to the highest international standards and gives rise to the best possible outcomes. The following chapters set out the quality standards against which BowelScreen is measured, including standards for all aspects of the screening programme, including administration, FIT, endoscopy and radiology, histopathology and surgery.

References

1. HIQA. Health technology assessment (HTA) of a population-based colorectal cancer screening programme in Ireland, p.37 [online], 2009, available: https://www.hiqa.ie/sites/default/files/2017-01/HTA_population_based_colorectal_cancer_screening_programme.pdf [accessed 23 May 2017].

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Summary of quality standards

2 Summary of quality standards

For ease of reference, a summary table of quality standards from the guidelines specified throughout this report is given below. Please note that the numbering of the standards is not indicative of importance. All targets are continually reviewed in the light of experience and revised accordingly with respect to results achieved and best clinical practice. Targets given refer to people aged 60 to 69 years of age attending the BowelScreen programme. Some standards will not be measured for some time as data are collected over a period of years.

Each standard specified in the table below is cross-referenced in superscript to a section in the relevant chapter where the standard can be seen in context.

	Quality standard	Minimum standard	Achievable standard
2.1	Completeness of population register[3.3.1]	Within 95% of census figures	
2.2	**Coverage by invitation**: Proportion of eligible population on register invited for screening every two years[3.1.1]	≥95%	100%
2.3	**Coverage by screening**: Proportion of eligible individuals screened in the period (screening round) every two years[3.1.2]	≥45%	≥55%
2.4	**Uptake**: Proportion of invited individuals who returned a satisfactory FIT kit[3.1.3]	≥50%	≥60%
2.5	Proportion of invited population who do not respond to invitations within eight weeks who are sent one reminder[3.4.2]	≥95%	100%
2.6	Proportion of FIT kits and instructions despatched within five working days to clients who request them[3.5.1]	≥95%	100%
2.7	Proportion of clients who request and are sent test kits who are sent a reminder if test kit is not received at laboratory within four weeks[3.5.2]	≥95%	100%
2.8	Proportion of FIT samples tested within two working days of receipt in laboratory[4.4.5]	100%	
2.9	Proportion of results of FIT samples tested by the laboratory made available to NSS within three working days of receipt of samples in laboratory[4.5.1]	100%	
2.10	Proportion of positive FIT results notified to screening colonoscopy unit by NSS within seven working days of receipt of result from laboratory[3.5.3]	≥95%	100%
2.11	Proportion of FIT result letters to clients despatched to clients within five working days of receipt of result from laboratory[3.5.4]	≥95%	100%
2.12	Proportion of FIT result letters to general practitioners despatched within five working days of receipt of result from laboratory[3.5.5]	≥95%	100%
2.13	Proportion of unacceptable tests received by laboratory for measurement (related to 2.14 below)[4.5.3]	≤3%	≤1%
2.14	Proportion of repeat test kits despatched to clients within 10 working days following receipt of unacceptable test kits by laboratory (related to 2.13 above)[3.5.6]	≥95%	100%
2.15	Proportion of clients offered a colonoscopy appointment date that occurs within 20 working days from when client was deemed clinically suitable following pre-assessment[3.5.7]	≥90%	100%
2.16	Minimum number of colonoscopies (symptomatic and screening) undertaken annually by each screening colonoscopist[5.2.2]	>300	

	Quality standard	Minimum standard	Achievable standard
2.17	Bowel cleanliness at colonoscopy: bowel preparation described as excellent or adequate[5.2.3]	≥90%	≥95%
2.18	Acceptance rate for colonoscopy after positive FIT[5.2.4.1]	≥85%	>90%
2.19	Colonoscopic comfort is recorded[5.2.6]	80% should have a comfort score of 1 or 2 from Gloucester Scale	
2.20	Medication used for comfort during lower gastrointestinal (GI) endoscopy is recorded[5.2.6.1]	Auditable outcome	
2.21	Use of reversal agents is recorded[5.2.6.2]	<1%	
2.22	Caecal intubation rate (CIR) with photographic evidence (adjusted only for obstructing lesions)[5.2.7]	≥90%	≥95%
2.23	Perforation rate of colonoscopy[5.3.1]	<1 per 1,000 colonoscopies	
2.24	Post-polypectomy perforation rate[5.3.2]	<2 per 1,000 colonoscopies where polypectomy is performed	
2.25	Post-polypectomy bleeding (PPB) requiring transfusion[5.3.3]	<1% colonoscopies where polypectomy is performed	
2.26	Percentage of individuals scheduled for surveillance colonoscopy who undergo that procedure within three months of scheduled date[5.2.4.2]	≥85%	>90%
2.27	Adenoma detection rate (ADR), measured in terms of both individual endoscopist and screening colonoscopy unit[5.2.8]	≥45% of colonoscopies	≥50% of colonoscopies
2.28	Following colonoscopy, the proportion of "no abnormality detected" result letters despatched to clients within 10 working days of colonoscopy date[3.5.8]	≥95%	100%
2.29	Following colonoscopy, the proportion of result letters to general practitioners despatched within 10 working days of receipt of result from screening colonoscopy unit[3.5.9]	≥95%	100%
2.30	Referral rates for CT (computed tomography) colonography of all clients referred for colonoscopy following a positive FIT[5.4.1, 6.2.2]	≤10%	
2.31	Minimum number of CT colonography cases read per consultant radiologist per year[6.5.1]	≥100	
2.32	Proportion of CT colonography clients offered a CT colonography appointment date that occurs within 30 working days of receipt of referral[6.5.9]	≥95%	100%
2.33	Proportion of CT colonography procedures that are complete/ adequate[6.5.2]	≥90%	
2.34	Perforation rate of CT colonography[6.4.1, 6.5.3]	<1 per 3,000 CT colonography examinations	
2.35	Other major complications of CT colonography recorded[6.5.4]	Auditable outcome	
2.36	CT colonography radiation dose recorded[6.5.5]	Auditable outcome	
2.37	Large polyps (≥10mm) visualised and recorded during CT colonography[6.5.6]	Auditable outcome	
2.38	Cancers visualised and recorded on CT colonography[6.5.7]	Auditable outcome	
2.39	Prevalence of extracolonic lesions that warrant additional investigation recorded[6.5.8]	Auditable outcome	

	Quality standard	Minimum standard	Achievable standard
2.40	Turnaround time for report being issued to the programme after CT colonography examination is performed[6.5.10]	≤15 working days	≤10 working days
2.41	Clients in receipt of abnormal CT colonography report with a CRADS classification of C4 (or other equivalent classification) will have follow-up colonoscopy within 15 working days or be referred to multidisciplinary team (MDT) for a date that occurs within 15 working days[5.4.2]	≥95%	≥98%
2.42	Clients in receipt of abnormal CT colonography report with a CRADS classification of C3 (or other equivalent classification) will have follow-up colonoscopy within 30 working days or be referred to MDT for a date that occurs within 30 working days[5.4.3]	≥95%	≥98%
2.43	Proportion of patients with C3 or C4 CT colonography findings who subsequently have biopsy or lesion removed at colonoscopy who were discussed at MDT meetings[5.4.4]	≥95%	≥98%
2.44	Proportion of histopathology reporting consistent with Faculty of Pathology, RCPI guidelines and including a clear indication of main diagnosis[7.1.2]	≥95%	100%
2.45	Proportion of pathologists participating in a national external quality assurance scheme for colorectal screening pathology[7.1.3]	100%	
2.46	Proportion of histopathology laboratories holding CPA/INAB accreditation or equivalent[7.1.4]	100%	
2.47	Proportion of histopathology laboratories participating in RCPI national histopathology quality assurance scheme[7.1.5]	100%	
2.48	Proportion of histopathology screening results validated by a named screening pathologist[7.1.6]	100%	
2.49	Proportion of polyp cancers with double reporting[7.1.7]	100%	
2.50	Median number of lymph nodes retrieved in non-neoadjuvant treated cases[7.1.9]	>12	
2.51	Proportion of lesions reported as high-grade dysplasia[7.1.10]	≤10%	
2.52	Proportion of polyp pT1 cancer (removed by polypectomy or local excision) identified as poor differentiation[7.1.11]	≤20%	
2.53	Proportion of histopathological biopsy reports authorised and relayed to referrer within five working days of receipt of specimen in laboratory[7.1.1]	≥90%	100%
2.54	Proportion of colon cancer referrals to a surgeon at a designated cancer centre taking place within 10 working days of histological diagnosis[8.2.1]	≥90%	100%
2.55	Proportion of colon cancer patients offered an admission date for surgery that occurs within 20 working days of histological diagnosis.[8.2.2] This will not apply to the small number of patients who require pre-operative chemoradiotherapy.	≥90%	100%
2.56	Minimum number of colon cancer resections per surgeon per annum[8.2.3]	≥20	
2.57	Proportion of rectal cancer referrals to a surgeon at a designated cancer centre that take place on a date that occurs within 10 working days of histological diagnosis[8.3.1]	≥90%	100%

	Quality standard	Minimum standard	Achievable standard
2.58	Proportion of rectal cancer patients offered admission date for surgery on a date that occurs within 20 working days of histological diagnosis where surgery is to be the primary treatment[8.3.2]	≥90%	100%
2.59	Minimum number of rectal resections per surgeon per annum[8.3.3]	≥20	
2.60	Proportion of rectal cancer patients whose neoadjuvant therapy is initiated within 30 working days of histological diagnosis where surgery is not the initial treatment[8.3.4.1]	≥90%	100%
2.61	Overall proportion of resectable rectal cancer treated by abdomino-perineal excision (APE)[8.3.4.2]	<30%	<25%
2.62	Symptomatic anastomotic leakage rate for each surgeon[8.3.5.1]	<8%	<5%
2.63	Crude length of stay (date of admission to date of discharge)[8.4]	Auditable outcome	
2.64	Unadjusted operative and procedural 30-day mortality from date of patient's operation or stent[8.4]	Auditable outcome	
2.65	Return to theatre rate during hospital stay (for any reason)[8.4]	Auditable outcome	
2.66	Neoadjuvant and adjuvant radiotherapy/chemotherapy use (% neoadjuvant, % adjuvant)[8.4]	Auditable outcome	
2.67	Readmission rate within 30 days of operation (for any reason apart from planned readmissions for chemotherapy or radiotherapy)[8.4]	Auditable outcome	
2.68	The following[8.4] is recorded for all surgeries: · Radiologic stage of cancer at time of presentation based on CT and/or MRI scans · ASA (American Society of Anesthesiologists) grade · Position of tumour at rigid sigmoidoscopy (0-5, 6-10, 11-15cm) (rectal cancer only)	Auditable outcome	
2.69	Post-colonoscopy colorectal cancers (PCCRC)[5.5.2]	≤8.6%	≤2.5%

3

Programme and administration standards

3 Programme and administration standards

3.1 Programme standards

The BowelScreen programme standards are set to ensure overall quality in a national population-based screening programme.

	Quality standard	Standard
3.1.1	**Coverage by invitation**: Proportion of eligible* population on register invited for screening every two years	Minimum ≥95% Achievable 100%
3.1.2	**Coverage by screening**: Proportion of eligible* individuals screened in the period (screening round) every two years	Minimum ≥45% Achievable ≥55%
3.1.3	**Uptake**: Proportion of invited individuals who returned a satisfactory (suitable for analysis) FIT (faecal immunochemical test) kit	Minimum ≥50% Achievable ≥60%
3.1.4	All complaints pertaining to the programme recorded and responded to within the timeframes set out in the NSS client feedback process	HSE Your Service, Your Say, 100%

* In this context, 'eligible' refers to the known target population less those excluded by the programme for certain eligibility criteria. Ineligible clients include clients who have been diagnosed with colon or rectal cancer and are currently being followed up with colonoscopies in the symptomatic service as part of their treatment, clients who have had the large bowel totally removed, clients who are not within the current age range and clients whose invitation letters are returned by An Post.

3.2 Clinical audit

Multidisciplinary clinical audits should be conducted on a regular basis by the relevant hospital. BowelScreen retains the right to request evidence of such audits (by exception) to ensure high standards of clinical governance.

3.3 Population register

	Quality standard	Standard
3.3.1	Completeness of population register	Validation within 95% of census figures**
3.3.2	Each client registered will have a unique identifier number.	Minimum ≥95% Achievable 100%

** In any defined period of time, the number of eligible people listed on the register (numerator) expressed as a percentage of relevant Central Statistics Office (CSO) census data (denominator).

3.4 Call, re-call process

	Quality standard	Standard
3.4.1	Consent for participation from each client of the screened population obtained and recorded prior to issue of first FIT	100%
3.4.2	Proportion of invited population who do not respond to invitations within eight weeks who are sent one reminder	Minimum ≥95% Achievable 100%

3.5 Screening process

There are a number of key steps in the screening process. The eligible population who respond to the invitation to take part will be offered screening by a home test kit – the FIT.

Approximately 96 per cent of people screened as part of the programme will receive a normal FIT result and will be invited for routine screening again in another two years if they remain within the eligible age range (3.5.1 to 3.5.6).

Approximately four per cent of people screened will receive a result that will require a colonoscopy for which they will be referred to one of the screening colonoscopy units accredited to provide colonoscopies to the BowelScreen programme (3.5.7 to 3.5.9).

	Quality standard	Standard
3.5.1	Proportion of FIT kits and instructions despatched within five working days to clients who request them	Minimum ≥95% Achievable 100%
3.5.2	Proportion of clients who request and are sent test kits who are sent a reminder if test kit is not received at laboratory within four weeks	Minimum ≥95% Achievable 100%
3.5.3	Proportion of positive FIT results notified to screening colonoscopy unit by NSS within seven working days of receipt of result from laboratory	Minimum ≥95% Achievable 100%
3.5.4	Proportion of FIT result letters to clients despatched to clients within five working days of receipt of result from laboratory	Minimum ≥95% Achievable 100%
3.5.5	Proportion of FIT result letters to general practitioners despatched within five working days of receipt of result from from laboratory	Minimum ≥95% Achievable 100%
3.5.6	Proportion of repeat test kits despatched to clients within 10 working days following receipt of unacceptable test kits by laboratory	Minimum ≥95% Achievable 100%
3.5.7	Proportion of clients offered a colonoscopy appointment date that occurs within 20 working days from when client was deemed clinically suitable following pre-assessment	Minimum ≥90% Achievable 100%
3.5.8	Following colonoscopy, the proportion of "no abnormality detected" result letters despatched to clients within 10 working days of colonoscopy date	Minimum ≥95% Achievable 100%
3.5.9	Following colonoscopy, the proportion of result letters to general practitioners despatched within 10 working days of receipt of result from screening colonoscopy unit	Minimum ≥95% Achievable 100%

3.6 Communications

One of the hallmarks of an effective population-based screening programme is the accessibility of clear, high-quality information for the eligible population, the general population and other stakeholders. Information should be easy to understand, available in a number of formats, relevant and timely.

	Quality standard	Standard
3.6.1	Standard written communications (letters and information leaflets) from the programme to individual clients will be written in a manner that is clear, relevant and approved by the National Adult Literacy Agency (NALA).	100%
3.6.2	Standard written communications will be reviewed on an annual basis.	100%
3.6.3	Individuals invited for screening will be given standardised information explaining the benefits, risks and limitations of screening and the significance of both positive and negative screening test results.	100%
3.6.4	The NSS and BowelScreen websites will be monitored annually to ensure information is updated.	Yes
3.6.5	Freephone information calls will be randomly audited and monitored every week to ensure customer care and the quality of information are of a high standard.	Yes
3.6.6	Freephone staff will receive appropriate training annually.	Yes

3.7 Information communications technology

	Quality standard	Standard
3.7.1	Data will be held in a secure manner.	Evidence of annual network audit
3.7.2	Virtual private network (VPN) or secure email systems will be used to transfer personal health data between the programme and third-party service providers. Data transferred will be encrypted and subject to file transfer protocols (FTPs).	Yes

4

FIT standards

4 FIT standards

4.1 FIT standards subgroups

The BowelScreen programme will use the faecal immunochemical test (FIT) to carry out biochemical testing designed to detect faecal occult blood.

The FIT standards are grouped into four sections:

- Standards for pre-laboratory processes
- Standards for laboratory organisation
- Standards for the analytical method
- Standards for post-laboratory processes

4.2 Standards for pre-laboratory processes

4.2.1 Faecal sampling/collection system for the client

The design of the collection device/kit should be acceptable to the target population. The kit should include a clear and simple instruction sheet.

The design of the collection device should ensure that contact with the sample is minimised when the device is being handled by the client or laboratory staff.

4.2.2 Sample identity

The sample identity should unambiguously identify the client by name, barcode and other means (such as health number).

4.2.3 Stability

The stability characteristics for samples collected in the test device should be known and subject to periodic assessment by monitoring population positivity rates and stability checks using agreed methodology. The stability of biological samples stored at 20˚C should show no more than 30 per cent loss of analyte within two days of the sample being collected. No sample should be assayed if the time between its collection and analysis is greater than 10 days.

4.2.4 Transport

The proposed sample should be safe and acceptable for the chosen method of transport and should comply with EU/Irish postal regulations.

4.2.5 Electronic test ordering

Using barcode or similar technology, the laboratory should be able to enter the test order electronically on the laboratory information system.

4.3 Standards for laboratory organisation

4.3.1 Laboratory accreditation

The FIT service will be carried out in a clinical laboratory that is accredited to the ISO15189 ('Medical laboratories – Requirements for quality and competence') or CPA standard.

4.3.2 Overall laboratory direction

The service should be led by a consultant chemical pathologist or an appropriately qualified clinical chemist/scientist who is trained and experienced in the techniques used for analysis and clinical quality assurance procedures.

4.3.3 Operational management

A senior member of the scientific staff should be designated to oversee the service on a day-to-day basis and should be required to participate in structured appraisal and appropriate continuing professional development schemes.

All staff should receive relevant training in the BowelScreen programme, including induction training and periodic updates. Staff should not have access to client data (protected by password) until trained. Regular updates ('top-up' training) should be provided.

4.3.4 Quality manual

The FIT service should be described in a quality manual. The manual should cover all pre-laboratory, intra-laboratory and post-laboratory processes and should be supported by detailed standard operating procedures.

The overall service should be documented in a screening algorithm.

4.4 Standards for the analytical method

4.4.1 Analytical principle

The analytical principle of the method for the determination of blood in stool specimens is immunochemical.

4.4.2 Method validation

The method should be easy and reliable to undertake. It should be quantitative and should demonstrate compliance with the manufacturer's standards for analytical sensitivity, specificity and reproducibility.

4.4.3 Cut-off point

The laboratory must be able to specify and adjust the concentration at which a positive test is reported. The concentration will be determined by the NSS.

4.4.4 Automation

It should be possible to automate the method on an automated analyser from a reliable commercial provider that can handle the numbers of samples expected in a population-based screening programme (approximately 120,000 to 180,000 samples per annum).

Results should be authorised for release by designated senior members of the scientific staff only and subsequently stored on a laboratory information system.

4.4.5 Turnaround time (TAT)

The samples should be analysed without delay to prevent further sample denaturation and an increase in false negative results. An intra-laboratory and whole-process TAT should be specified and agreed with laboratory service providers.

	Quality standard	Standard
4.4.5.1	Proportion of FIT samples tested within two working days of receipt in laboratory. If a sample is not tested within one day of receipt, it should be stored in the fridge.	100%

4.4.6 Internal quality control

The assay should be controlled using readily available internal quality control (IQC) materials at a number of clinically significant concentrations, including the chosen threshold for positivity. Rigorous IQC procedures should be applied to all analytical batches. Given the difficulty in providing good biological data for quality control/quality assurance (QC/QA), duplicate measurements for a selected few samples should be performed. Acceptance testing for all products should be carried out as follows:

- Population positivity rates should be monitored continually and assessed against agreed performance criteria (for example, weekly).
- Mean and a dispersion parameter SD (standard deviation) of SEM (standard error of the mean) for the measured Hb concentration should be calculated.
- Measuring and monitoring of Levy-Jennings charts and Westgard rules (or equivalent) should be considered.

4.4.7 External quality assurance

The laboratory should be an active participant and demonstrate satisfactory performance in approved clinical chemistry external quality assurance schemes and, when developed, specific EU/international faecal occult blood schemes.

Using secure electronic circulation and review of quality assurance data, the laboratory team should participate in a multidisciplinary quality assurance review that includes the NSS and other representatives.

4.5 Standards for post-laboratory processes

4.5.1. Reporting

Protocols should be implemented to facilitate rapid, standardised and reliable classification of the test result into negative and positive categories.

	Quality standard	Standard
4.5.1.1	Proportion of results of FIT samples tested by the laboratory made available to NSS within three working days of receipt of samples in laboratory	100%

4.5.2. Electronic reporting

The laboratory should be capable of providing electronic reports in a format agreed with the NSS.

4.5.3. Unacceptable tests

	Quality standard	Standard
4.5.3.1	Proportion of unacceptable tests received by laboratory for measurement	Minimum ≤3% Achievable ≤1%

4.5.4. Technical audit

Horizontal and vertical audits should be conducted in a manner and frequency compatible with laboratory accreditation or on specific request, including analytical performance and technical failure rate.

5

Endoscopy standards

5. Endoscopy standards

5.1 Colonoscopy

Colonoscopy quality standards form a central part of the BowelScreen programme. The standards described in this section emerged following a detailed critical appraisal of best practice with particular reference to Irish[1], UK[2] and European guidelines[3] and US Preventive Services Task Force recommendations[4].

As part of a screening investigation, colonoscopy requires public and professional acceptance to ensure the screening programme continues to be successful. Until an appropriate Irish process is in place, quality assurance in colonoscopy is being supported through the UK JAG (Joint Advisory Group on GI Endoscopy) accreditation process.[2]

5.2 Quality indicators

5.2.1 Quality assurance guidelines

Colonoscopy quality assurance guidelines set out:

- The objective to be achieved in each area of activity
- The measure used to evaluate whether or not that objective is being achieved
- The minimum standard expected of each screening colonoscopy unit (or, for certain standards, each colonoscopist)

5.2.2 Minimum number of colonoscopies

To support the maintenance of colonoscopists' clinical competence, a minimum number of screening colonoscopies should be undertaken each year.[5] In addition, one hour should be set aside for each screening colonoscopy.

Quality measure	Minimum number of colonoscopies undertaken annually by each screening colonoscopist
Objective	Minimise harm and maximise benefit to screening population
Standard	>300 colonoscopies (symptomatic and screening) per annum
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit

5.2.3 Bowel preparation

Good bowel preparation supports improved adenoma detection and caecal intubation. Poor bowel preparation is associated with failure to reach the caecum and hinders the detection of lesions.[6, 7]

Quality measure	Bowel cleanliness at colonoscopy
Objective	Maximise pathology detection and minimise need for additional procedures
Standard	Bowel preparation described as excellent or adequate · Minimum ≥90% · Achievable ≥95%
Accountability	· Screening colonoscopy unit · Recorded on BowelScreen database by screening colonoscopy unit

5.2.4 Response rate (acceptance rate) for colonoscopy

Maximising the response for colonoscopy in this cohort is a core challenge for the programme as a whole. The effectiveness of the BowelScreen programme is compromised by low uptake, which makes monitoring and optimising colonoscopy attendance rates a key priority.

5.2.4.1 Index screening programme colonoscopy

Quality measure	Acceptance rate for colonoscopy after positive FIT
Objective	Investigate individuals with positive FIT results
Standard	Percentage of individuals with positive FIT results who undergo colonoscopy: · Minimum ≥85% · Achievable >90%
Accountability	· Screening colonoscopy unit · Recorded on BowelScreen database by screening colonoscopy unit

5.2.4.2 Surveillance colonoscopy

Quality measure	Surveillance attendance[8]
Objective	Optimise attendance for surveillance procedures
Standard	Percentage of individuals scheduled for surveillance colonoscopy who undergo that procedure within three months of scheduled date: · Minimum ≥85% · Achievable >90%
Accountability	· Screening colonoscopy unit · Recorded on BowelScreen database by screening colonoscopy unit

5.2.5 Pre-assessment for colonoscopy

Quality measure	Pre-assessment for colonoscopy
Objective	Ensure clients and screening colonoscopy unit have sufficient information so that client can make informed decisions and screening colonoscopy unit can safely perform colonoscopy
Standard	Adequate information[5.2.5.1] is exchanged between screening colonoscopy unit and client in a minimum of 98% of cases
Accountability	· Screening colonoscopy unit · Recorded on BowelScreen database by screening colonoscopy unit

5.2.5.1 Adequate information for pre-assessment for colonoscopy

The process starts after a positive FIT. The nurse will contact individuals by phone and will coordinate the pre-assessment process, taking into account:

- Comorbidity (for example, insulin-dependent diabetes mellitus (IDDM), chronic obstructive pulmonary disease (COPD))
- Use of anticoagulants or antiplatelet drugs
- Allergies
- A clear and realistic explanation of the procedure
- Possible discomfort, the risks and benefits and a discussion of potential adverse events
- The possibility of late adverse events and how to seek help

5.2.6 Sedation

It is essential that colonoscopy is performed to a high standard and is both safe and comfortable. This requires appropriate sedation. All sedation used should be recorded so that it can be audited at a later stage.

Quality measure	Colonoscopic comfort[9]
Objective	Minimise harm to screening population and optimise patient experience
Standard	80% should have a comfort score of 1 or 2[1]
Accountability	· Colonoscopist · Recorded on BowelScreen database by screening colonoscopy unit
Comment	Gloucester comfort score should be employed as per Guidelines for the Implementation of a National Quality Improvement Programme in GI Endoscopy.[1]

Screening colonoscopy units should conduct rolling audits of sedation practice, patient comfort scores and the use of reversal agents in line with Global Rating Scale (GRS – Ireland) requirements.

5.2.6.1 Medications used

Quality measure	Medication used for comfort during lower GI endoscopy[9]
Objective	Minimise harm to screening population and optimise patient experience
Standard	Auditable outcome
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit
Comments	· For guidance on sedation, refer to Guidelines for the Implementation of a National Quality Improvement Programme in GI Endoscopy.[1] · The use of propofol should be limited to exceptional cases, and the reason for its use should be documented.

5.2.6.2 Use of reversal agents

Quality measure	Use of reversal agents[9]
Objective	Minimise harm to screening population and optimise patient experience
Standard	<1%
Accountability	· Colonoscopist · Recorded on BowelScreen database by screening colonoscopy unit

5.2.7 Caecal intubation rate (CIR)

Complete examination of the colon is a fundamental objective of colonoscopy and a quality standard. An intention-to-scope figure of at least 90 per cent has been set as the programme standard (adjusted only for obstructing lesions).[10] The CIR is a marker of full colonoscopy; when supported by the other performance measures, it contributes to a high-quality, patient-centred outcome. Photographic evidence of the ileo-caecal valve (ICV), the terminal ileum or the appendix orifice must be available to support completion of a colonoscopy.

Quality measure	Caecal intubation rate (CIR)
Objective	Ensure the entire colon is visualised; marker of quality of colonoscopy
Standard	90% CIR with photographic evidence (adjusted only for obstructing lesions) · Minimum ≥90% · Achievable ≥95%
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit
Comment	Photographic evidence of appendix orifice, ICV, terminal ileum or anastomosis is required to document complete intubation.

5.2.8 Adenoma detection rate (ADR)

ADR is a robust and key metric for the quality of colonoscopy.[11, 12, 13, 14, 15, 16] Based on data from the first screening round, the minimum standard detection rate has been set at greater or equal to 45 per cent and the achievable at greater or equal to 50 per cent. ADR standards may need to be reviewed during incident rounds of screening and will be adjusted accordingly.

Quality measure	Adenoma detection rate (ADR), measured in terms of both individual endoscopist and screening colonoscopy unit
Objective	Identification of adenomas, prevention of cancer; marker of quality of colonoscopy
Standard	Histologically confirmed adenomas detected in colonoscopies · Minimum standard ≥45% · Achievable standard ≥50%
Accountability	· Colonoscopist · Recorded on BowelScreen database by screening colonoscopy unit
Comments	· Surveillance procedures and repeat endoscopic procedures are excluded. · The ADR includes any adenomas detected at the same time that cancer is detected or during incomplete intubation.

5.2.9 Polypectomy and endoscopic mucosal resection (EMR)

The BowelScreen programme recognises that there is considerable therapeutic expertise within the wider endoscopy community. However, some endoscopists may not wish to provide conventional screening but instead may provide an enhanced therapeutic endoscopic service (tertiary referral). EMRs[16, 17] should be carried out only by expert and experienced endoscopists who have access to appropriate surgical backup.

5.2.10 Cases for discussion at multidisciplinary team meetings

Cases where cancers or intermediate- or high-risk adenomas are detected during colonoscopy will be discussed at multidisciplinary team meetings.

Three or four small adenomas (<10mm) or at least one adenoma ≥10mm and <20mm detected in a patient would be considered to be intermediate risk.

Five or more small adenomas (<10mm) or at least one adenoma ≥20mm detected in a patient would be considered to be high risk.

Sessile serrated lesions (SSL) of any size are to be counted as adenomas for these purposes.

5.3 Adverse events

5.3.1 Perforation rate

Quality measure	Perforation rate[18, 19, 20, 21]
Objective	Minimise harm to screening population
Standard	<1 per 1,000 colonoscopies
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit
Comments	· Includes all colonoscopy, whether diagnostic or therapeutic · Perforation rate needs to be interpreted carefully as some colonoscopists will appropriately perform advanced therapeutic procedures (which may carry higher perforation rates).

5.3.2 Post-polypectomy perforation rate

Quality measure	Post-polypectomy perforation rate
Objective	Minimise harm to screening population
Standard	<2 per 1,000 colonoscopies where polypectomy is performed
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit
Comment	Perforation rate needs to be interpreted carefully as some colonoscopists will appropriately perform advanced therapeutic procedures (which may carry higher perforation rates).

5.3.3 Post-polypectomy bleeding (PPB)

Quality measure	Post-polypectomy bleeding (PPB) requiring transfusion[18, 22, 23]
Objective	Minimise harm to screening population
Standard*	<1% colonoscopies where polypectomy is performed
Accountability	· Colonoscopist · Self-reported by colonoscopist to screening colonoscopy unit
Comment	Includes endoscopic mucosal resection (EMR), endoscopic submucosal dissection and all other polypectomies at colonoscopy

* Individual performance standard

5.4 Endoscopy standards relating to interchange with CT colonography

	Quality standard	Standard
5.4.1	Referral rates for CT colonography of all clients referred for colonoscopy following a positive FIT	≤10%
5.4.2	Clients in receipt of abnormal CT colonography report with a CRADS (colonography reporting and data system) classification of C4 (or other equivalent classification) will have follow-up colonoscopy within 15 working days or referred to MDT for a date that occurs within 15 working days	Minimum ≥95% Achievable ≥98%
5.4.3	Clients in receipt of abnormal CT colonography report with a CRADS classification of C3 (or other equivalent classification) will have follow-up colonoscopy within 30 working days or be referred to MDT for a date that occurs within 30 working days	Minimum ≥95% Achievable ≥98%
5.4.4	Proportion of patients with C3 or C4 CT colonography findings who subsequently have biopsy or lesion removed at colonoscopy who were discussed at MDT meetings	Minimum ≥95% Achievable ≥98%

5.5 Interval and post-colonoscopy colorectal cancers

BowelScreen is a FIT-based screening programme: An individual who has a positive FIT is offered a screening colonoscopy. In this context, the definitions given below for interval colorectal cancer and post-colonoscopy colorectal cancer will apply.

5.5.1 Interval colorectal cancer

An interval colorectal cancer (CRC) is one diagnosed following a negative FIT and before the next screening FIT or within three years of the client going over the eligible age.

5.5.2 Post-colonoscopy colorectal cancer (PCCRC)

A post-colonoscopy colorectal cancer (PCCRC) is the diagnosis of a CRC within three years of a negative screening colonoscopy. Likewise, a CRC diagnosed at the next screening colonoscopy is considered to be a PCCRC if it occurs within three years of the most recent colonoscopy.

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

PCCRC rate is a key quality measure of colonoscopy. Within the context of the BowelScreen programme, it will be a number of years before the PCCRC rate can be calculated. Evidence from a UK retrospective study involving both screening and non-screening colonoscopies indicated PCCRC rates varying from 2.5 per cent to 8.6 per cent.[24] Within the BowelScreen programme, it would be expected that the PCCRC rate 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.[24]

5.6 Rolling clinical audits

Rolling clinical audits of quality standards (e.g. of caecal intubation rate and adherence to surveillance guidelines) will be carried out in each screening centre in accordance with periodic guidance issued by the programme. The responsibility to adhere to agreed standards rests primarily with the individual endoscopists. Supported by the hospital, the clinical lead ensures audits are performed at least quarterly. Identified underperformance is addressed locally, and overall performance data are returned to BowelScreen at agreed intervals.[25] The NSS reserves the right to carry out additional audits to verify high clinical standards.

5.6.1 Failure to meet agreed quality standards

The local clinical lead or director will manage compliance with quality assurance guidelines for all colonoscopists and will, in the first instance, address non-compliance issues. Measures to deal with underperformance, particularly that associated with missed cancers, will be implemented locally, with regional support, if necessary, following close coordination with BowelScreen. Such measures may include repeat colonoscopy in a selected cohort of patients and suspension of an endoscopist with or without retraining.

5.7 References

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6

CT colonography standards

6. CT colonography standards

6.1 Role of CT colonography in BowelScreen

In the context of the BowelScreen programme[1, 2], computed tomography (CT) colonography should be available (1) as a completion test to patients who have had an incomplete or unsuccessful colonoscopy and for whom a repeat colonoscopy is unlikely to be successful and (2) to those who are medically unfit for colonoscopy.[3, 4]

6.2 Patient eligibility for CT colonography

6.2.1 Patient referral

Following a positive FIT (faecal immunochemical test), patients in category 1 above will be referred for CT colonography while patients in category 2 above may be referred for CT colonography. Patients who are unlikely to be fit for CT colonography or further intervention such as surgery should not automatically be referred for imaging. Instead, the options should be explained to the patient and appropriate further management decided at this time.

See the standard operating procedures as agreed by the CT Colonography Steering Group.[5, 6]

6.2.2 Referral protocols

Clear referral protocols should govern the direct referrals from the screening programme at the point of colonoscopy pre-assessment. Referral rates for CT colonography should be less than or equal 10 per cent of all those referred for colonoscopy following a positive FIT.

See the standard operating procedures as agreed by the CT Colonography Steering Group.[5, 6, 7]

6.3 Patient information and consent

- The physician or nurse who obtains the consent should be fully informed about the risks and benefits of CT colonography.
- The contact details of an experienced CT colonography team member should be made available to the patient so that any additional questions that the patient might have can be answered prior to the day of the examination.
- Patient referral forms for CT colonography should include completed information regarding suitability for bowel preparation (such as allergy to iodinated contrast usually administered intravenously). See the standard operating procedures as agreed by the CT Colonography Steering Group[8, 9, 10]

6.4 Safety, risks and patient experience

6.4.1 Colonic perforation

The most serious adverse effect of CT colonography is colonic perforation, which occurs in fewer than 1 in 3,000 CT colonography examinations.

6.4.2 Other complications

All members of the CT colonography team must be trained to recognise and deal appropriately with complications arising before, during and after procedures and should follow clearly documented protocols in managing complications.

A history of allergy to iodinated contrast usually administered intravenously should be sought at the time of referral by an experienced practitioner before prescribing bowel preparation.

After the procedure, patients should be provided with information regarding common minor symptoms that they may experience, including advice on what to do if symptoms persist or worsen. Patients should be advised to seek medical attention if they develop painful blurred vision (possible glaucoma).

See the standard operating procedures as agreed by the CT Colonography Steering Group.[6, 7, 10]

6.4.3 Radiation dose

Given both an individual patient's radiation exposure and population radiation doses in a screening programme, low dose techniques must be adhered to. Effective doses should be monitored locally and dose modulation should be used where available.

6.5 Quality assurance in CT colonography

The following quality standards will be required of each CT colonography unit:

	Quality standard	Standard
6.5.1	Minimum number of CT colonography cases read per consultant radiologist per year	≥100
6.5.2	Proportion of CT colonography procedures that are complete/ adequate	≥90%
6.5.3	Perforation rate of CT colonography	<1 in 3,000 CT colonography examinations
6.5.4	Other major complications of CT colonography recorded	Auditable outcome
6.5.5	CT colonography radiation dose recorded	Auditable outcome
6.5.6	Large polyps (≥10mm) visualised and recorded	Auditable outcome
6.5.7	Cancers visualised and recorded	Auditable outcome
6.5.8	Prevalence of extracolonic lesions that warrant additional investigation recorded	Auditable outcome
6.5.9	Proportion of CT colonography clients offered a CT colonography appointment date that occurs within 30 working days of receipt of referral	Minimum ≥95% Achievable 100%
6.5.10	Turnaround time for report being issued to the programme after CT colonography examination is performed	Minimum ≤15 working days Achievable ≤10 working days

6.6 References

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7

Histopathology standards

7 Histopathology standards

7.1 Standards [1, 2]

	Quality standard	Standard
7.1.1	Proportion of histopathology biopsy reports authorised and relayed to the referrer within five working days of receipt of specimen in laboratory	Minimum ≥90% Achievable 100%
7.1.2	Proportion of histopathology reporting is consistent with the Faculty of Pathology, Royal College of Physicians of Ireland (RCPI) guidelines as applicable to the specimen type being reported and should include a clear indication of the main diagnosis. All specimens should be identified using the unique identifier of the screening participant.	Minimum ≥95% Achievable 100%
7.1.3	Proportion of pathologists participating in a national external quality assurance scheme for colorectal screening pathology	100%
7.1.4	Proportion of histopathology laboratories holding CPA/INAB* accreditation or equivalent	100%
7.1.5	Proportion of histopathology laboratories participating in RCPI national histopathology quality assurance scheme	100%
7.1.6	Proportion of histopathology screening results validated by a named screening pathologist	100%
7.1.7	Proportion of polyp cancers with double reporting	100%
7.1.8	There must be a pathway for discussion of polyps or other lesions that are difficult to interpret	Auditable outcome
7.1.9	Median number of lymph nodes retrieved in non-neoadjuvant treated cases	>12
7.1.10	Proportion of lesions reported as high-grade dysplasia	≤10%
7.1.11	Proportion of polyp pT1 cancer (removed by polypectomy or local excision (most will be pT1NX)) identified as poor differentiation	≤20%

* Clinical Pathology Accreditation/Irish National Accreditation Board

7.2 References

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8

Surgery standards

8. Surgery standards

8.1 Management of screen-detected colorectal cancer

The management and pre-operative staging of colon and rectal cancer is not materially different from that of the management of symptomatic disease. These standards are based on the Irish Association of Coloproctology's Recommendations for the Future Development of Colorectal Cancer Surgery in Ireland and Guidelines for the Management of Rectal Cancer in Ireland[1] and on evidence-based international guidelines.[2, 3]

8.2 Colon cancer

Colon cancer surgery should be performed in designated cancer centres within defined timeframes, as specified below.

	Quality standard	Standard
8.2.1	Proportion of colon cancer referrals to a surgeon at a designated cancer centre taking place within 10 working days of histological diagnosis	Minimum ≥90% Achievable 100%
8.2.2	Proportion of colon cancer patients offered an admission date for surgery that occurs within 20 working days of histological diagnosis. This will not apply to the small number of patients who require pre-operative chemoradiotherapy.	Minimum ≥90% Achievable 100%
8.2.3	Minimum number of colon cancer resections per surgeon per annum	≥20

8.2.4 Colon cancer surgery

All cases should be discussed at a multidisciplinary team meeting both prior to and after surgery (see Appendix 4 of the Irish Association of Coloproctology (IACP) framework[1]). The meeting should be attended by a named surgeon working within a team, a colorectal nurse and, where appropriate, a stoma therapist. The designated cancer centre will collect a minimum data set of information and will follow the IACP framework (see Appendix 1 of the framework). The NCCP is producing additional standards (in draft form at the time these guidelines were being revised) that may supersede the requirements of Appendix 1.

8.3 Rectal cancer

Rectal cancers are tumours where the lower margin is 15cm or less from the dentate line.

Rectal cancer surgery should be performed only in designated cancer centres that meet the criteria laid down by the IACP.[1]

	Quality standard	Standard
8.3.1	Proportion of rectal cancer referrals to a surgeon at a designated cancer centre that take place on a date that occurs within 10 working days of histological diagnosis	Minimum ≥90% Achievable 100%
8.3.2	Proportion of rectal cancer patients offered admission date for surgery on a date that occurs within 20 working days of histological diagnosis where surgery is to be the primary treatment	Minimum ≥90% Achievable 100%
8.3.3	Minimum number of rectal resections per surgeon per annum	≥20

8.3.4 Neoadjuvant therapy

Local recurrence of rectal cancer is reduced by adjuvant chemoradiotherapy, which, when given pre-operatively, is superior to post-operative treatment. All cases of rectal cancer should be considered for pre-operative radiotherapy, plus or minus concomitant chemotherapy.

	Quality standard	Standard
8.3.4.1	Proportion of rectal cancer patients whose neoadjuvant therapy is initiated within 30 working days of histological diagnosis where surgery is not the initial treatment	Minimum ≥90% Achievable 100%

While abdomino-perineal excision (APE)[2, 3] should be avoided, where possible, in favour of anterior resection, it is necessary in certain low rectal cancers, especially where the sphincter is involved or where an insufficient distal resection margin exists. It is recommended that the overall proportion of resectable rectal cancer treated by APE should be between 25 and 30 per cent.

	Quality standard	Standard
8.3.4.2	Overall proportion of resectable rectal cancer treated by APE	Minimum <30% Achievable <25%

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) recommends that surgeons should audit their leak rate, which should be less than eight per cent.[3] Anastomotic leakage is associated with poorer survival and a significant increase in the local recurrence rate.

8.3.5 Leak rate

	Quality standard	Standard
8.3.5.1	Symptomatic anastomotic leakage rate for each surgeon	Minimum <8%[3] Achievable <5%

8.3.6 Management of complications of colonoscopy

Screening colonoscopy units should be able to deal with the complications that might occur. The units should be able to provide emergency admission with general surgical service and operating theatre availability, cross match and provide blood for transfusion and provide emergency angiographic and radiology services.

8.4 Minimum key performance indicators for colorectal cancer surgery

(Adapted from Appendix 5 of 'Recommendations for the Future Development of Colorectal Cancer Surgery in Ireland and Guidelines for the Management of Rectal Cancer in Ireland'[1])

A. Core data:

1. Radiologic stage of cancer at time of presentation based on CT and/or MRI scans
2. ASA (American Society of Anesthesiologists) grade
3. Position of tumour at rigid sigmoidoscopy (0-5, 6-10, 11-15cm) (for rectal cancer only)

B. Key performance indicators:

1. Crude length of stay (date of admission to date of discharge)
2. Unadjusted operative and procedural 30-day mortality (all causes of mortality in the 30 days from the date of the patient's operation or stent)
3. APE (abdomino-perineal excision) rate (for rectal cancer only)[8.3.4.2]
4. Return-to-theatre rate during hospital stay (for any reason)
5. Symptomatic anastomotic leak rate[8.3.5.1]
6. Radiotherapy/Chemotherapy use (% neoadjuvant, % adjuvant)
7. Readmission rate within 30 days of operation for any reason apart from planned readmissions for chemotherapy or radiotherapy

8.5 References

1. Irish Association of Coloproctology. Recommendations for the Future Development of Colorectal Cancer Surgery in Ireland and Guidelines for the Management of Rectal Cancer in Ireland. Prepared by Deborah McNamara MB (Hons) MD FRCSI (Gen), Secretary, Irish Association of Coloproctology (IACP). 2010.
2. European Commission. European guidelines for quality assurance in colorectal cancer screening and diagnosis [online], 2010, available: http://www.euref.org/european-guidelines/4th-edition [accessed 23 May 2017].
3. Association of Coloproctology of Great Britain and Ireland (ACPGBI). Guidelines for the management of colorectal cancer (3rd edition) [online], 2007, available: http://www.acpgbi.org.uk/content/uploads/2007-CC-Management-Guidelines.pdf [accessed 23 May 2017].

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