BowelScreen
An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme

Standards for **Quality Assurance in Colorectal Screening**

Third Edition

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Acknowledgments

Foreword

BowelScreen is the HSE's national bowel screening programme, and operated by the National Screening Service. Bowel screening aims to detect signs of colorectal (bowel) cancer as early as possible, before there are symptoms.

The purpose of cancer screening is to detect pre-cancer or early-stage cancer in people who do not have symptoms so that timely diagnosis and early treatment can be offered, and can lead to better outcomes. The vast majority of bowel cancers are thought to arise from benign growths known as adenomas. BowelScreen can detect and remove these adenomas early, reducing the risk of bowel cancer developing.

Screening invites people who are asymptomatic in a target population to undergo testing. Under international screening criteria, the test should be simple, safe, precise, validated and acceptable to the population.

This document is the third edition of the BowelScreen Standards for Quality Assurance in Colorectal Screening. These standards are pivotal to the continued management of a high-quality screening programme, building on our experience of four completed screening rounds of the programme, with a fifth round near completion at time of writing.

Quality Assurance
It is crucial that screening programmes operate in accordance with rigorous standards. Quality assurance is the process of checking that standards are met, and ensuring continuous improvement is encouraged. BowelScreen regularly measures itself against these standards to make sure we are meeting our purpose.

Assuring and improving the quality of services is essential if population screening is to achieve its intended benefits to population health, while minimising unintended but known harms to those taking part.

Colorectal cancer in Ireland
Approximately 2,600 people are diagnosed with bowel cancer in Ireland every year. Bowel cancer is the second most common cancer in men and the third most common cancer in women in Ireland.

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.[1]

The number of new cases of colorectal cancer is expected to increase significantly over the next 10 years, due mainly to an increasing and ageing population.[2]

The BowelScreen programme
BowelScreen was introduced in October 2012 to provide free bowel cancer screening every two years. BowelScreen was initially available to all eligible men and women aged 60 to 69. In October 2023, the age range of people eligible for BowelScreen was lowered to include people aged 59. This is the first stage of our plans to expand the age range of bowel screening to people aged 55 to 74.

FIT test
We use the faecal immunochemical test (FIT) as our primary screening tool. It detects a level of blood in the stool, and it operates on an automated testing

platform. Ireland was one of the first countries to adopt this technology for organised population-based colorectal cancer screening. One of the advantages of using this test in a population-based screening programme is that people can do the test themselves, in their own homes.

No screening test is 100 per cent accurate. The FIT relies on a cancer or adenoma bleeding at the time of the test. Therefore, there will be false negatives when the FIT is negative and a lesion is present. There will also be false positives when the FIT is positive, and a subsequent colonoscopy shows no significant cause. In some of these cases it may be that the FIT detects blood from benign conditions, rather than adenomas linked to cancer.

Appreciation

BowelScreen is providing an essential service to the Irish public. This could not be achieved without the dedication and professionalism of the individuals who work to ensure that services are delivered to high standards, and the active participation of the thousands of people we invite to choose screening every year.

Quality assurance is at the heart of the BowelScreen programme and dictates every aspect of the screening journey. The Quality Assurance Committee for Colorectal Screening monitors standards for each part of the bowel screening programme, and I thank them for their ongoing work and support for the programme.

The BowelScreen Clinical Advisory Group sets quality standards and advises the BowelScreen Executive Management Team on clinical aspects of the programme. I thank past and present members of these groups for their ongoing professional dedication, input, and support. Subcommittees of the Clinical Advisory Group reviewed and assessed the existing BowelScreen standards, identified any potential gaps in comparison to international standards, recommended best practice, and ensured that the standards are appropriate and drive quality. The review was conducted in line with the NSS QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6). I am grateful also to the members of the international peer review panel who reviewed our quality assurance standards.

I would like to acknowledge the work of all colleagues who contributed to the development of this third edition. In particular, thank you to the BowelScreen Programme Manager, Clinical Director and the BowelScreen team, and those who provide leadership and advice in the Executive Management Team meetings.

Finally, it is important to note that the colonoscopy element of the BowelScreen programme would not be possible without the professional input of all the staff in the colonoscopy screening centres, who deliver excellent services in conjunction with the consultant endoscopists, surgeons, CTC, and histopathology laboratories.

I am greatly encouraged that the additional support provided by the National Endoscopy Working Group of the HSE, the Acute Hospitals Division, and the Department of Health, will ensure that the BowelScreen programme continues to progress and mature.

Fiona Murphy | Chief Executive
National Screening Service

References:

[1] Cancer in Ireland 1994-2014: Annual Report of the National Cancer Registry. Cork: National Cancer Registry; 2016.
[2] Cancer incidence projections for Ireland 2020-2045. National Cancer Registry

Preface

The primary goal of BowelScreen is to reduce mortality from colorectal cancer in men and women in Ireland.

Population-based screening for colorectal cancer is a layered, complex process involving a number of steps, including identification of the target population; ensuring equity of access; seeking to encourage the target population to choose screening; and identification of people whose initial screening test indicates a not normal result for colonoscopy.

Every aspect of BowelScreen is underpinned by quality assurance, with each step being fully quality assured. Quality assurance is process-driven, and specific steps help define and achieve screening goals.

This edition of *Standards for Quality Assurance in Colorectal Screening* sets out the specific quality standards, quality requirements and Key Performance Indicators (KPIs) for the programme.

This is the third edition of the *Standards* since the programme was established in 2012, and its publication follows significant work undertaken to review the previous edition. The review was conducted in line with the NSS *QA Policy Framework: Standard Setting & Revision Procedure* (NSS/S&F-6).

Quality assurance (QA) standards review subgroups were convened in 2022, with membership from the BowelScreen programme and the wider National Screening Service. The preparatory work involved the subgroup members independently reviewing and assessing the existing BowelScreen standards and identifying any potential gaps where a quality assurance standard may need to be developed.

The standards are grouped under the following principal components:

- BowelScreen programme and administration QA standards and requirements
- QA standards for faecal immunochemical test (FIT)
- QA standards and requirements for endoscopy
- QA requirements CT colonography
- QA standards and requirements histopathology
- Colorectal cancer treatment QA standards and requirements

This grouping enables everyone to readily assess the most relevant QA requirements for their roles within the screening programme. In developing this document, care has been taken to address the links between the QA components in the pathway.

A significant aspect of this quality assured colorectal screening programme is the role of the BowelScreen Clinical Advisory Group (CAG). The primary remit of the BowelScreen CAG is to set quality standards and make recommendations to the BowelScreen Executive Management Team on clinical pathways and protocols in the programme.

These standards have been set by the CAG. Ongoing monitoring of the programme's performance versus the standards is the remit of the Quality Assurance Committee.

These revised standards were reviewed by an international peer review panel, which included experts and practitioners in the delivery of colorectal cancer screening, endoscopy, radiology, histopathology and surgery.

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. This third edition of *Standards 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 the development of these standards. I also wish to thank the members of the CAG for bringing their acknowledged expertise and giving of their time to developing this edition.

Pádraic Mac Mathúna

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Introduction

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.

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 and requirements against which BowelScreen is measured, including standards for all aspects of the screening programme, including administration, the faecal immunochemical test (FIT), endoscopy, radiology, histopathology and treatment.

BowelScreen measures performance of screening units against Quality Assurance (QA) standards, providing regular reports for review and consideration, as well as conducting formal service provider audits. One of the aims of this review was to develop a framework whereby data is reviewed regularly at both programme and individual service level.

QA is an integral component of any population screening programme. In the HSE National Screening Service (NSS), the QA Policy Framework (1) outlines our approach to QA to safeguard and improve outcomes for participants in BowelScreen, BreastCheck, CervicalCheck and Diabetic RetinaScreen. This overarching policy framework supports the NSS commitment to quality by ensuring that the range of standards outlined by programmes are comprehensive, fit for purpose and informed by high quality evidence and best practice. We consistently assess the validity of our standards, working with all relevant stakeholders to support this work.

There are a suite of supporting documentation arising from the QA Policy Framework (2), (3), (4). They support the programme specific Standards for Quality Assurance, which set out the specific quality standards, quality requirements and Key Performance Indicator's (KPIs) for each programme. The NSS QA Manual (5) sets out the generic HSE NSS QA structures and processes, which support the delivery of quality assured population screening programmes, and should be read in conjunction with the programme-specific Standards for Quality Assurance.

1. Quality Assurance Policy Framework for NSS (NSS/S&F-1)
2. QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6)
3. QA Policy Framework: Governance (under development) (NSS/S&F-7)
4. QA Policy Framework: Standardised Language Procedure (under development) (NSS/S&F-8)
5. QA Policy Framework: QA Manual (NSS/S&F-9)

BowelScreen Quality Assurance (QA) Standards Review Process

A process has been developed whereby all BowelScreen QA standards are published and subject to formal review. The first edition of the BowelScreen Quality Standards in Colorectal Screening was published at the start of the programme in 2012, with the first formal review undertaken in 2017. One of the purposes of the BowelScreen Clinical Advisory Group is to review international standards, recommend best practice, and to ensure that standards are appropriate and drive quality improvement. The standards are kept under review and revised as necessary, as further evidence or data becomes available.

The QA standard review subgroups were convened in 2022. Membership of these groups included representatives drawn from the NSS and the BowelScreen programme (see page 11 for authors and contributors).

The preparatory work involved the subgroup members independently reviewing and assessing the existing BowelScreen standards and identifying any potential gaps where a QA standard may need to be developed. Meetings to further discuss proposals were arranged where deemed necessary. During

the review some QA standards were archived and replaced with new standards. Decisions for update included significant change to clinical practice, standards that did not have any outcome measures, and publication of new evidence. Where a current QA standard has been archived, but remains clinically relevant, data will continue to be collected to allow future analysis as required. Where there was no clear evidence, the agreed QA standards are derived from the opinion of the QA standard review subgroup. Before publication, the revised standards were reviewed and approved by a peer review panel, which included international and leading experts and practitioners in the delivery of colorectal cancer screening, endoscopy, radiology, histopathology and surgery.

New QA Standards
Any new QA standards will be developed in line with the following criteria:

- Overall importance – does the indicator address an area within the screening pathway that would significantly impact on the quality and outcome of service delivered?
- Evidence based – is the indicator based on high quality evidence, where this evidence exists?
- Measurability – is the indicator measurable? Are the required data items accessible and available for collection?

Quality Assurance - requirements and standards
Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

Quality requirements are stated as a description. There is no target associated with a requirement as service providers must fulfil the requirement. For many requirements, we propose that evidence to demonstrate that a requirement has been met will consist of a stated policy, indicating that the requirement has been incorporated into local practice, supported by results of periodic survey / audit activities to show that policy has been followed.

Quality standards are stated as a description of an activity with a measurable level of performance, with an associated performance threshold for achievement.

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Programme and administration standards

3.1 QA Standard

Name	Coverage by invitation
Description	Coverage by invitation: Proportion of eligible population on register invited for screening every 2 years
Rationale	There is evidence that population-based screening leads to a reduction in incidence and mortality from bowel cancer. There is evidence that effective invitation and subsequent recall maximises these benefits.[1]
Numerator	Number of unique participants who have had at least 1 invitation
Denominator	Total Number of eligible* participants
Caveats	* BowelScreen Exclusion Criteria (BSP/QP-001) Policy for definition of 'eligible individuals' Eligibility table will be published on the BowelScreen website.
Performance threshold	Minimum ≥95%, Achievable 100%
Data Source	Data from the COR register, Report name: *Coverage Report.*
Reporting period	Data on this standard is published in the programme's Round Report (see glossary for definition)

3.2 QA Standard

Name	Coverage by screening
Description	Proportion of eligible* individuals screened in the period (screening round) every 2 years
Rationale	There is evidence that population-based screening leads to a reduction in incidence and mortality from bowel cancer. An effective call-recall service increases the number of people returning the screening test.[2]
Numerator	Number of unique participants who have had at least 1 satisfactory** FIT test taken
Denominator	Total Number of eligible* participants
Caveats	* BowelScreen Exclusion Criteria (BSP/QP-001) Policy for definition of 'eligible individuals'. Eligibility table will be published on the BowelScreen website. **A satisfactory FIT is defined as 1 that is suitable for analysis that reaches a definitive FIT outcome: normal or abnormal
Performance threshold	Minimum ≥45%, Achievable ≥55%
Data Source	Data from the COR register, Report name: ***Coverage report***.
Reporting period	Data on this standard is published in the programme's Round Report (see glossary for definition)

3.3 QA Standard

Name	Uptake
Description	Proportion of invited individuals who returned a satisfactory (suitable for analysis) FIT (faecal immunochemical test) kit
Rationale	The death rates from bowel cancer can be reduced where around 60% of people take part in a population-based screening programme[2]
Numerator	The number of invited participants in the defined time period who returned a completed satisfactory FIT kit
Denominator	The total participants invited in the defined time period
Performance threshold	Minimum ≥50%, Achievable ≥60%
Caveats	If a participant returns a FIT that is inadequate and then returns a repeat test that is complete only the complete test should be counted. i.e. 1 result per participant returning FIT kit
Data Source	Data from the COR register, Report name: *PEU Cohort Uptake* and *FIT response on Invitation*. Note this report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard is published in the programme's Round Report (see glossary for definition)

Number	QA Requirement – Clinical Audit	Suggested evidence	Reporting period
3.4	The Hospital will have a process in place to conduct clinical audits on a regular basis. BowelScreen reserves the right to request the completion and reporting of further clinical audits in response to emerging clinical outcome data.	• Copy of planned audit schedule • Copies of Relevant audits available on request at the time of service provider audit if required	Reported on at each service provider audit

3.5 QA Standard

Name	Completeness of population register
Description	Completeness* of population register
Rationale	There is evidence that population-based screening leads to a reduction in incidence and mortality from bowel cancer[1]. To have an effective call-recall service, the population register must be as complete as possible. The National Census is the gold-standard against which population register can be validated. The Census is carried out every 5 years. The Census provides an opportunity to estimate the completeness and accuracy of the COR database.
Numerator	In any defined period of time, the number of eligible people listed on the register
Denominator	Relevant Central Statistics Office (CSO) census data
Performance Thresholds	Validation within 95% of census figures
Caveats	*Definition of completeness added to glossary
Data Source	Data from the COR register and census data, Report name: *Census Report*.
Reporting period	Data on this standard will be reported on after each Census.

Number	QA Requirement – Register Accuracy	Suggested Evidence	Reporting period
3.6	There must be processes in place to: • Identify participants with more than 1 record on the BowelScreen register and to merge the records into a single record. • Update the demographic details of participants on the register • Provide participants with opportunities to update their details on the register (ie. by phone, email or online)	• Copy of SOP	Compliance with the SOP to be assessed through internal quality audits

Number	QA Requirement – Informed Choice	Suggested Evidence	Reporting period
3.7	People who are offered screening must be given enough information in an appropriate format to enable an informed choice to be made. Information on the benefits and limitations of screening must be given.	• Programme letters and leaflets Copy of Standard Operating Procedure (SOP)	Assessed through internal quality audits Distribution acknowledgements of SOP.

Number	QA Requirement – Opt-out Process	Suggested Evidence	Reporting period
3.8	An opt-out process should be in place for participants who choose not to participate in the BowelScreen programme. BowelScreen should not issue correspondence to participants who choose to opt out.	• Copy of SOP	Assessed through internal quality audits Distribution acknowledgements of SOP.

3.9 QA Standard

Name	Invitation reminders
Description	Proportion of invited population who do not respond to invitations ≤8 weeks from the invitation date who are sent 1 reminder
Rationale	A high level of participation for all population groups will maximise the benefits of screening, mechanisms to identify non-responders and offer them a further opportunity to respond within the screening round will increase participation [1,2]
Numerator	Amongst participants who do not decline or are not excluded, the number issued with a reminder letter if they do not consent to screening in ≤8 weeks
Denominator	Amongst participants who do not decline or are not excluded, the number who do not consent to screening in ≤8 weeks
Caveats	Exclusions: • Participants who opt out • Participant excluded
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: ***BowelScreen Charter Report***, this report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time.
Reporting period	Data on this standard will be reported for each screening round

3.10 QA Standard

Name	Timely despatch of FIT kits
Description	Proportion of FIT kits despatched* in ≤3 working days when requested by participants
Rationale	A high level of participation for all population groups will maximise the benefits of screening, requests responded to in a timely fashion will increase the number of people returning the screening test.[3]
Numerator	The number of FIT kits despatched in ≤3 working days to participants who consent to screening.
Denominator	Number of FIT kits despatched to participants who consent to screening
Caveats	• *Measured from date file sent to service provider • Manual check that service provider issues FIT kit within 2 days of file sent
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.11 QA Standard

Name	FIT test reminders
Description	Proportion of participants who request and are sent FIT kits who are sent a reminder if FIT kit is not received at laboratory in ≤4 weeks
Rationale	There is evidence that population-based screening leads to a reduction in incidence and mortality from bowel cancer. An effective call-recall service increases the number of people returning the screening test, mechanisms to identify non-responders and offer them a further opportunity to respond within the screening round will increase uptake.[2]
Numerator	Number of participants, for whom it is possible* to return the FIT kit who are sent a reminder if FIT kit is not received at laboratory in ≤4 weeks.
Denominator	Number of participants for whom it is possible to return the FIT kit, who do not return the FIT kit in ≤4 weeks
Caveats	• *Exclusions are: • Participants who decline • Participants that are excluded • Post office returns or FIT kit service provider returns • Kits reported as lost or damaged • Where replacement kits are requested by provider
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.12 QA Standard

Name	Timeliness of result letters to participants
Description	Proportion of participant FIT result letters sent* in ≤5 working days of receipt of result from laboratory
Rationale	People who are waiting for their screening result may experience anxiety which can be reduced by providing them with timely information.[1,2]
Numerator	The number of FIT results where a satisfactory FIT kit was received from participants and the results letter file was sent to the Mail provider in ≤5 working days of the FIT result being received by NSS
Denominator	The number of satisfactory FIT test kits received from participants where the results letter file was sent to the Mail provider
Caveats	• *Measured from date file sent to mail provider • Manual check that mail provider issues letters within 2 days of file sent • FIT result letters are only generated to the participant for satisfactory results (see glossary for definition)
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.13 QA Standard

Name	Timeliness of result letters to GPs
Description	Proportion of FIT result GP letters sent* in ≤5 working days of receipt of result from from laboratory
Rationale	Providing GPs with timely information from the programme will ensure that they have the relevant information if participants contact them with queries regarding the result letter.[1]
Numerator	The number of FIT results where a satisfactory FIT kit was received from participants with a GP assigned where the results letter file was sent to the Mail provider in ≤5 working days of the FIT result being received by NSS
Denominator	The number of FIT results to GP letters where file sent to mail provider
Caveats	• *Measured from date file sent to mail provider • Manual check that mail provider issues letters within 2 days of file sent • FIT result letters are only generated to the participant for satisfactory results (see glossary for definition) • This standard only applies to participants where a GP was assigned to the participant record.
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.14 QA Standard

Name	Timeliness of positive FIT notification to endoscopy unit
Description	Proportion of positive FIT results notified to screening colonoscopy unit by NSS in ≤7 working days of receipt of result from laboratory
Rationale	There is evidence that waiting for colonoscopy creates increased anxiety, therefore the programme must ensure the time between notification of a positive FIT and the notification to the screening unit is minimised.[1,2]
Numerator	Number of positive FIT result participants notified to the preassessment list of screening colonoscopy unit ≤ 7 working days of result received from laboratory
Denominator	Number of participants with a positive FIT result notified to the screening colonoscopy unit
Caveats	None
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.15 QA Standard

Name	Timeliness of despatch of repeat test kits
Description	Proportion of repeat test kits sent* in ≤10 working days following receipt of unacceptable test kits by laboratory
Rationale	There is evidence to suggest that people who have submitted a test kit that is subsequently spoilt are less likely to continue participation in the programme, therefore repeat test kits must be issued in a timely fashion.[2]
Numerator	The number of repeat FIT test kits despatched to participants, who were contactable and satisfied for a replacement FIT kit to be sent, issued in ≤10 working days following receipt of unacceptable FIT kit by laboratory
Denominator	The number of repeat FIT test kits where participant was contactable and satisfied for a replacement to be issued
Caveats	• *Measured from date file sent to service provider • Manual check that service provider issues kits within 2 days of file sent • Participants who were not contactable or declined a replacement kit are not included in the measurement of the standard
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.16 QA Standard

Name	Timeliness of 'routine recall' letters no pathology taken
Description	Following index colonoscopy, the proportion of 'routine recall' result letters, where no pathology was taken are sent* in ≤11 working days of colonoscopy date
Rationale	People who are waiting for their colonoscopy result may experience anxiety which can be reduced by providing them with timely information.[3]
Numerator	The number of participants who had an index colonoscopy with no pathology taken as part of the colonoscopy and result classified as routine recall where the result is sent to the mail provider ≤ 11 working days
Denominator	The number of participants who had an index colonoscopy with no pathology taken as part of colonoscopy and result classified as routine recall where the result is sent to the mail provider
Caveats	*Measured from date file sent to mail provider • In the BowelScreen MOU, units are required to enter the post-procedure data on COR in 10 working days • Manual check that mail provider issues letters within 2 days of file sent
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: ***BowelScreen Charter Report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.17 QA Standard

Name	Timeliness of 'routine recall' letters where pathology taken
Description	Following index colonoscopy, the proportion of 'routine recall' result letters, where pathology was taken as part of the colonoscopy are sent* in ≤15 working days of colonoscopy date
Rationale	People who are waiting for their colonoscopy result may experience anxiety which can be reduced by providing them with timely information.[3]
Numerator	The number of participants who had an index colonoscopy where pathology taken as part of the colonoscopy and result classified as routine recall where the result is sent to the mail provider in ≤15 working days
Denominator	The number of participants who had an index colonoscopy where pathology was taken as part of colonoscopy and result classified as routine recall where the result is sent to the mail provider
Caveats	• *Measured from date file sent to mail provider • Manual check that mail provider issues letters within 2 days of file sent • In the BowelScreen MOU units are required to hold polyp conferences no less than every 2 weeks.
Performance Threshold	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: *BowelScreen Charter Report*. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.18 QA Standard

Name	Timeliness of 'routine recall' GP letters, no pathology taken
Description	Following index colonoscopy, the proportion of 'routine recall GP result letters', where no pathology was taken, are sent* in ≤11 working days of colonoscopy date
Rationale	Providing GPs with timely information from the programme will ensure that they have the relevant information if participants contact them with queries regarding the result letter.[1]
Numerator	The number of participants who had an index colonoscopy with no pathology taken as part of the colonoscopy and result classified as routine recall where the GP result letter is sent to the mail provider ≤ 11 working days
Denominator	The number of participants who had an index colonoscopy with no pathology taken as part of colonoscopy and result classified as routine recall where the GP result letter is sent to the mail provider
Performance Thresholds	Minimum ≥95% Achievable 100%
Caveats	*Measured from date file sent to mail provider • This standard only applies to participants where a GP was assigned to the participant record. • Manual check that mail provider issues letters within 2 days of file sent
Data Source	Data from the COR register, Report name: *BowelScreen Charter report*. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

3.19 QA Standard

Name	Timeliness of 'routine recall' GP letters, pathology taken
Description	Following index colonoscopy, the proportion of 'routine recall GP result letters', where pathology was taken, are sent* in ≤15 working days of colonoscopy date
Rationale	Providing GPs with timely information from the programme will ensure that they have the relevant information if participants contact them with queries regarding the result letter.[1]
Numerator	The number of participants who had an index colonoscopy where pathology was taken as part of the colonoscopy and result classified as routine recall where the GP result letter is sent to the mail provider in ≤ 15 working days
Denominator	The number of participants who had an index colonoscopy where pathology was taken as part of colonoscopy and result classified as routine recall where the GP result letter is sent to the mail provider
Caveats	*Measured from date file sent to mail provider. • Manual check that mail provider issues letters within 2 days of file sent • This standard only applies to participants where a GP was assigned to the participant record.
Performance Thresholds	Minimum ≥95% Achievable 100%
Data Source	Data from the COR register, Report name: ***BowelScreen Charter report***. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard will be reported for each screening round

References

1. New Zealand Government, National Bowel Screening Programme Interim Quality Standards (2017) *https://www.nsu.govt.nz/system/files/resources/national-bowel-screening-programme-interim-quality-standards-jul17v3.pdf*

2. Bowel Screening Wales, Quality Assurance Reference Manual (August 2021). *https://phw.nhs.wales/services-and-teams/screening/bowel-screening/information-resources-old/bsw-quality-manual-version-01d/*

3. HIS (Healthcare Improvement Scotland), NHS Scotland. Bowel Screening Standards (2015) *https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/bowel_screening_standards.aspx*

4

FIT Standards

QA standards for Faecal Immunochemical Test (FIT)

4.1 QA Standard

Name:	FIT results turnaround-time (TAT)
Description	Proportion of participants invited for a FIT test where the result received at NSS is ≤ 3 working days of receipt of sample in the laboratory
Rationale:	People who are waiting for their screening result may experience anxiety which can be reduced by providing them with timely information[1]. The timeliness of providing these results is important for both the person's experience, and potentially, for patient and clinical outcomes[2]
Numerator:	Number of participants invited for a FIT test where the result received at NSS is ≤ 3 working days of receipt of sample in the laboratory
Denominator:	Number of participants invited for a FIT test where the result received at NSS
Caveats:	No exclusions
Performance Thresholds:	Standard set at 100%
Data source:	The data source is the COR register. The BowelScreen programme will report on the standard using the BowelScreen Charter Report. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of participants over time
Reporting period	Data on this standard is published in the programme's Round Report see glossary for definition

4.2 QA Standard

Name:	Rate of unacceptable tests
Description	The proportion of unacceptable tests received by laboratory for measurement along with the reason deemed unacceptable. *Please note that the reporting of this standard is separated to ensure clear measurement of unacceptable tests received for: age, sex, overall total and reasons deemed unacceptable.*
Rationale	Number of samples rejected as not suitable for reporting are kept to the minimum levels. There is evidence that waiting for screening result can cause anxiety[3]
Numerator:	The number of invited participants who returned a FIT kit who had an "unacceptable" FIT result
Denominator:	The number of invited participants who returned a FIT kit
Caveats:	If a client returns a FIT that is unacceptable and then returns a repeat test that is acceptable, only the acceptable test should be counted. i.e., 1 result per unique participant returning FIT kit
Performance threshold:	Minimum ≤3% Achievable ≤1%
Data source:	The data source is the COR database. The BowelScreen programme will report on the standard using the FIT results on invitation report. This report is a Cohort Report (epidemiological report), that means it follows the same cohort of clients identified over time
Reporting period	Data on this standard is published in the programme's Round Report see glossary for definition

QA Requirements - FIT KIT Supplier

Number	QA Requirement – FIT KIT Design	Suggested Evidence	Reporting Period
4.3	The design of the FIT kit must be acceptable to the target population. The design of the collection device must ensure that contact with the sample is minimised when the device is being handled by the participant and the laboratory staff.	• Patient Reported Experience Measures (PREMs) feedback on FIT kit • Contract in place with service provider	Continuous monitoring by Programme of PREMs dashboard Service provider audit of the FIT kit supplier
Number	**QA Requirement- Postage and Transport**	**Suggested Evidence**	**Reporting Period**
4.4	The FIT kit must be safe and acceptable for the chosen method of transport and comply with EU/ Irish postal regulations and HSE guidelines for the preparation for transport of patient specimens and other biological samples.	• Written confirmation that completed FIT kits are suitable for delivery through the Irish Postal System.	Service provider audit

Number	QA Requirement- Labelling	Suggested Evidence	Reporting Period
4.5	The FIT kit must have barcodes that: • Provide a singular identity system that unambiguously identifies the participant • Identifies its expiration date	• Sample FIT kit with barcodes • Contract in place with service provider	Service provider audit

Number	QA Requirement- Stability of FIT kit device	Suggested Evidence	Reporting Period
4.6	The FIT kit supplier must supply the stability characteristics of the FIT kit. The FIT kit device must maintain the stability of the sample for up to 10 days at 35°C	• Copy of manufacturer's product information sheet and instructions on stability checks • Copy of published evidence that assesses and verifies stability	Service provider audit

Section 4 : QA requirements - Medical Laboratory Service Provider

Number	QA Requirement - Accreditation	Suggested Evidence	Reporting Period
4.7	The medical laboratory must be: • INAB accredited to ISO15189 'Requirements for quality and competence' • Scope of accreditation to include analysis of Faecal Immunochemical Test (FIT) samples	• Copy of INAB accreditation schedule and scope of accreditation certificate	On receipt of accreditation and after every renewal period. Service Provider Audit

Number	QA Requirement- Clinical Lead	Suggested Evidence	Reported Period
4.8	The service must be led by a consultant chemical pathologist who is medically qualified and has completed a structured, supervised, specialist training scheme prior to being entered on the Specialist Register of the Medical Council.	• Consultant Chemical Pathologist name • Confirmation of medical council number	Service provider audit or change of Clinical Lead

Number	QA Requirement- Laboratory Service Management	Suggested Evidence	Reporting Period
4.9	A senior medical scientist must be designated to oversee the service on a day-to-day basis. This individual must: • be registered with CORU • participate in continuing professional development (CPD) • be subject to Fitness to Practice process • undergo structured appraisal mandated by the ISO 15189 standard.	• Confirmation of Senior Medical Scientist name • Evidence that staff qualifications, CORU registration, training and competence assessment records are maintained by the service provider	Annually Service provider audit or change of Senior Medical Scientist

Number	QA Requirement- Training	Suggested Evidence	Reporting Period
4.10	All medical laboratory staff must receive relevant training in the processing of FIT kit samples. This must include: • induction training • assessment of competence • annual updates • 'top-up' training as needed • structured appraisals • participation in CPD. Note: Staff should not have access to client data (protected by password) until trained.	• Name of designated staff to be provided • Evidence that staff qualifications, training and competence assessment, records of appraisals completed and ongoing CPD participation are maintained by the service provider • A copy of the staff training SOP	Annually Service provider audit

Number	QA Requirement- End-to-End Processes	Suggested Evidence	Reporting Period
4.11	The end-to-end BowelScreen processes and procedures must be documented as part of the medical laboratory Quality Management System and in line with ISO requirements. The documentation must include: • pre-laboratory processes • intra-laboratory processes • post-laboratory processes • process flow algorithm • detailed standard operating procedures	• Copy of local SOP	Service provider audit Note: Copy of SOPs to be resubmitted after every local review

Number	QA Requirement- Pre-analytic process	Suggested Evidence	Reporting Period

4.12	Medical laboratory must use barcode or similar technology to enter the test order electronically on the laboratory information management system (LIMS).
	
	• The BowelScreen specific pre-analytic process must be documented and include detail on:
	
	• the use of the barcodes to enter the test order electronically on LIMS
	
	• the use of unique accession numbers for each sample logged
	
	• the process to automatically reject samples received including all rejection reasons as agreed with the BowelScreen programme
	
	• the BowelScreen specific reconciliation report process
	  • Number of FIT samples physically received
	  • Results authorised
	  • Results rejected
	  • Results transmitted
		• Copy of local SOP	Service provider audit
			
			Note: Copy of SOP to be resubmitted after every local review.

Number	QA Requirement- Test Method verification	Suggested Evidence	Reporting Period
4.13	• The analytical method must be reliable, automated, quantitative, CE marked and In-Vitro Medical Device Regulation (IVDR) compliant. • Equipment must be validated, and test method verified and accredited in accordance with ISO requirements (Equipment validation and test method verification requirements are documented in the ISO standard and INAB PS24). • The stability characteristics for samples collected in the test device should be known and subject to periodic assessment by monitoring stability checks using agreed methodology. • When more than 1 analyser is used to meet demand or as contingency there must be a documented procedure in place for regular inter-instrument comparison.	• Copy of OC Sensor verification report or master verification plan • Copy of inter-instrument comparison reports to BowelScreen monthly	Service provider audit Monthly

Number	QA Requirement- Automation and contingency plans	Suggested Evidence	Reporting Period
4.14	The analytical method is an automated process that ensures a sufficient throughput to deal with the required number of BowelScreen samples within the agreed turnaround time (TAT). There must be always a contingency plan in place to ensure the turnaround time is met if an analytical machine is not available.	• Confirmation of number of analytical machines in operation for BowelScreen samples • Copy of Contingency Plan	Service provider audit

Number	QA Requirement- Internal Quality Control	Suggested Evidence	Reporting Period
4.15	Ensuring quality of test results including: • Internal quality control (IQC) material must be sourced from approved suppliers • QC material must cover the clinically relevant range, clinical decision value and be analysed at appropriate intervals • There must be a documented procedure for batch acceptance of reagents, consumables and QC material • The Mean and Standard Deviation must be established by the laboratory • Warning and rejection rules must be applied • The procedure for troubleshooting of IQC failure must be documented including the procedure for prevention of result release and reanalysis of patient samples and review of results • There must be a procedure for ongoing IQC review and results reported to BowelScreen	• Copy of local SOP • Results of IQC, Positivity rates and Levy-Jennings charts to be reported to BowelScreen	Service provider audit Monthly

Number	QA Requirement- External Quality Assessment	Suggested Evidence	Reporting Period
4.16	FIT testing must be subject to an approved external quality assessment (EQA) scheme. There must be a documented process for EQA participation including: • Criteria for selection of EQA scheme based on clinical relevance, the number of participants, robust interpretation and pre- and post-analytical considerations • review of EQA performance by relevant trained local laboratory personnel • actions taken in response to results (including trends, shifts, out of specification results and inter-instrument variability) • reporting to the relevant persons and discussion at multidisciplinary meeting (MDM) • immediate escalation locally and to BowelScreen of performance concerns • routine 6 monthly reporting of performance results to BowelScreen. Using secure electronic circulation and review of quality assurance data, the laboratory team must participate in a multidisciplinary quality assurance review (service provider audit) that includes the NSS and other representatives.	• Submission of result of EQA to BowelScreen every 6 months • Copy of local SOP • Copy of MDM agenda	Every 6 months Service provider audit

Section 4 : QA Requirements - Medical Laboratory Service Provider

Number	QA Requirement – Reporting results	Suggested Evidence	Reporting period
4.17	Results must be authorised for release by designated senior medical scientists and provided electronically in a format agreed with BowelScreen. There must be a BowelScreen specific local policy for electronic reporting of results, this policy to include: • the concentration at which a positive test is reported (determined by the NSS) • how the results released by authorised person are subsequently stored on a laboratory information system (LIMS). • The process for reporting results above the limit of quantitation (LoQ), within the analytical measuring range (AMR) are reported numerically with specified units • The Interface and transmission of the results file validation process and how it is verified at regular intervals or when any changes are made.	• Copy of local SOP • Copy of validation and verification schedule	Service provider audit

Number	QA Requirement – Technical Audits	Suggested Evidence	Reporting Period
4.18	BowelScreen processes must be included in the horizontal and vertical audit schedule as required by ISO standard. Additional audits may be required on request	• Copy of audit schedule with BowelScreen processes listed • Copy of BowelScreen audits	Every 6 months Service provider audit

Number	QA Requirement – Equipment	Suggested Evidence	Reporting Period
4.19	Scheduled and unscheduled downtime of equipment used for BowelScreen samples must be monitored on an ongoing basis	• Copy of service reports and any maintenance or repair reports of this equipment to be submitted to BowelScreen.	Annually and if any unscheduled downtime experienced/ Service provider audit

References

1. HIS (Healthcare Improvement Scotland), NHS Scotland. Bowel Screening Standards (2015) *https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/bowel_screening_standards.aspx*

2. HIS (Healthcare Improvement Scotland), NHS Scotland. Bowel screening- Draft Standards, (2023) *https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/bowel_screening_standards.aspx*

3. New Zealand Government, National Bowel Screening Programme Interim Quality Standards (2017) *https://www.nsu.govt.nz/system/files/resources/national-bowel-screening-programme-interim-quality-standards-jul17v3.pdf*

5

Endoscopy standards

QA Requirements Endoscopy

Number	QA Requirement- Accreditation	Suggested Evidence	Reporting period
5.1	All service providers performing bowel screening are JAG accredited or have plans to achieve accreditation. All service providers performing bowel screening undertake GRS-Ireland twice yearly census returns.	• Submission of certificate or letter from JAG re up-to-date accreditation • Letter clarifying plans to achieve accreditation • Proof of 6-monthly GRS submissions	Annually Service review Service provider audit

Number	QA Requirement- Ongoing Experience of Endoscopists	Suggested Evidence	Reporting period
5.2	A minimum number of colonoscopy procedures performed per endoscopist per annum is determined by the Clinical Advisory Group (CAG). This is reviewed annually.	• Signed BowelScreen audit certificate from Clinical Lead • NQAIS data	Annually Service review Service provider audit

Number	QA Requirement- Participant's Experience	Suggested Evidence	Reporting period
5.3	Routine measurement of participant's reported experience measures (PREMs) after colonoscopy.	• Reports from the PREMs Dashboard • Quality Improvement action in response to PREMs report	Continuously Service review Service provider audit

Number	QA Requirement- Pre-Assessment	Suggested Evidence	Reporting period
5.4	All participants for colonoscopy are pre-assessed that they are clinically suitable prior to receiving an appointment and bowel preparation. All participants having a colonoscopy are provided with information about the colonoscopy/ CT colonography, e.g bowel preparation and medication management, etc.	• Agreed BowelScreen pre-assessment process • Documented local procedure describing how they conduct this process • Copy of BowelScreen pre-assessment in participant's chart	Service provider audit

Number	QA Requirement- Participant information and consent	Suggested Evidence	Reporting period
5.5	Participants are consented in line with HSE national guidance for consent. Service providers ensure that information is provided explaining. • what the colonoscopy involves, • benefits, risks and limitations of colonoscopy. A copy of the BowelScreen consent form to be posted to participants with the appointment letter. On the day of procedure, prior to the participant entering the examination room the consent form must be signed.	• Documented local procedure in place describing the consent process. • Audit at least every 3 years of the consent process with results discussed at Endoscopy User Group (EUG) meetings. • Copy of BowelScreen Consent form in the participant's chart	Service provider audit

Number	QA Requirement- Advanced polypectomy procedures	Suggested Evidence	Reporting period
5.6	Advanced polypectomy procedures include Endoscopic mucosal resection (EMR) and Endoscopic submucosal resection (ESD) EMR and ESD procedures should be done in endoscopy units with access to appropriate surgical backup[1]	• Documented local procedure in place for the agreed pathway to refer to another BowelScreen unit with the appropriate expertise, if required • Surgical transfer protocol • Audit at least every 3 years of the agreed pathways and procedures with results discussed at EUG	Service provider audit

Number	QA Requirement- Endoscopy Safety Checklist	Suggested Evidence	Reporting period
5.7	A safety checklist is used for colonoscopy procedures Guidance for the implementation of a safety checklist for gastrointestinal endoscopic procedures[2]	• Documented local procedure in place describing the use of safety checklist for colonoscopy procedures • Regular local audit of the local procedure with results discussed at EUG • Sample of anonymised completed safety checklist for a colonoscopy procedure	Service provider audit

Number	QA Requirement- Medication	Suggested Evidence	Reporting period
5.8	Medication is given as per current National GI Endoscopy Quality Improvement Programme guidelines.[1]	• Programme/ NQAIS data • Locally agreed medication policy • Audit at least every 3 years of medication usage with results discussed at EUG • Copy of EUG Minutes where NQAIS medication discussed	Service provider audit

Number	QA Requirement- Caecal Intubation	Suggested Evidence	Reporting period
5.9	Service providers undertaking bowel screening can demonstrate achievement of programme requirement for photographic evidence of the ileo-caecal valve (ICV), the terminal ileum or the appendix orifice to support completion of a colonoscopy[3]. Whole bowel examination is a prerequisite for complete and reliable inspection of the mucosa in search of lesions. A low caecal intubation rate is associated with an increased risk of interval colorectal cancer [4,5,6]	• Processes and protocols in line with national guidance relating to the agreement within the endoscopy room between endoscopists and nurses that caecal intubation has been reached[1] • Audit at least every 3 years of processes and protocols with results discussed at EUG	Service provider audit

Number	QA Requirement- Process to manage underperformance and support Endoscopists	Suggested Evidence	Reporting period
5.10	The Service Provider's Clinical Lead or Clinical Director will have a process to: • identify underperformance • manage underperformance of screening endoscopists against BowelScreen QA standards and requirements, and National GI Endoscopy Quality Improvement Programme.[1] The Service Provider should audit the agreed process.	• Documentation of agreed process to manage underperformance and support endoscopists • Documented clinical governance structure within the hospital and the Hospital Group.	Service provider audit

QA Endoscopy Standards

QA Standard 5.11

Name:	Colonoscopy waiting times
Description:	• Please note, the reporting of this standard is separated to ensure clear measurement of: • Percentage of pre-assessments initiated ≤20 working days • Proportion of participants offered a colonoscopy appointment date that occurs ≤20 working days from when the participant was deemed clinically suitable following pre-assessment
Rationale	To reduce anxiety for participants with an abnormal FIT result, it is important they are offered an appropriate diagnostic procedure in a timely manner [7].
Numerator:	Number of pre-assessments initiated ≤20 working days within a date range
Denominator:	Number of pre-assessment initiated within a date range
Caveat:	None
Performance threshold:	Minimum standard ≥75% Achievable standard ≥90%
Numerator:	Number of participants who are offered a colonoscopy appointment ≤ 20 working days from when participant was deemed clinically suitable following pre-assessment
Denominator:	Number of colonoscopies scheduled
Caveat:	Exclusions • participants who decline procedure • participants who declined first appointment offered
Performance threshold:	Minimum standard ≥90% Achievable standard 100%
Data Source:	Data measured at unit level Programme database
Reporting period:	Quarterly, rolling 12-month data reported 3 months in arrears. Service Reviews/ Service provider audits
Comment	Please note that BowelScreen will monitor the time from positive FIT to colonoscopy appointment.

QA Standard 5.12

Name:	Bowel cleanliness at colonoscopy
Description	Proportion of colonoscopy procedures with bowel preparation described as excellent or adequate within a reporting period.
Rationale	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.[3,5] Inadequate bowel preparation results in increased costs and inconvenience as the examination must be rescheduled or alternative investigations have to be organized.[4]
Numerator:	Number of colonoscopy procedures with bowel preparation described as excellent or adequate within a reporting period.
Denominator:	Total number of colonoscopy procedures within the reporting period.
Caveat:	None
Performance threshold:	Minimum standard ≥90% Achievable standard ≥95%
Data Source:	Data measured at unit Programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service reviews/ Service provider audit
Comment	Colonic cleansing protocols should be in place and the effectiveness of these should be monitored continuously by the Endoscopy User Group[1]. The Programme recommends polyethylene glycol-electrolyte solutions for bowel preparations.

QA Standard 5.13

Name:	Acceptance rate for colonoscopy after positive FIT
Description	Percentage of participants with positive FIT results who undergo a colonoscopy procedure
Rationale	Improving the acceptance rate for colonoscopy will maximise the population health impact of the screening programme[3]
Numerator:	The number of index colonoscopies that were performed
Denominator:	The number of participants referred for an index colonoscopy
Caveat:	None
Performance threshold:	Minimum standard ≥85% Achievable standard >90%
Data Source	Data measured at unit and programme level Programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.

QA Standard 5.14

Name:	Surveillance colonoscopy
Description	Proportion of participants who accepted surveillance colonoscopy who underwent the procedure on or within 3 months of becoming due for colonoscopy
Rationale	Optimise attendance for surveillance procedures[3]
Numerator:	Number of suitable participants who accepted surveillance colonoscopy who underwent the procedure on or within 3 months of becoming due for colonoscopy
Denominator:	Number of surveillance colonoscopies that have taken place within specified date range.
Caveat:	Exclusions • Participants who decline procedure • Participants who declined first appointment offered
Performance threshold:	Minimum standard ≥85% Achievable standard >90%
Data Source:	Data measured at unit and programme level Programme database
Reporting period:	Quarterly, rolling 12-month data reported 3 months in arrears. Service reviews/ Service provider audits

QA Standard 5.15

Name:	Comfort Score
Description	Proportion of colonoscopy procedures with comfort score ≤3
Rationale	Minimise harm to screening population and optimise patient experience.[3]
Numerator:	Number of colonoscopy procedures with comfort score ≤3
Denominator:	Total number of colonoscopies (includes both complete and incomplete procedures)
Caveat:	None
Performance threshold:	Minimum standard ≥90% should have a comfort score of 1, 2 or 3
Data Source:	Data measured at unit level Programme database
Reporting period:	Quarterly, rolling 12-month data reported 3 months in arrears. Service reviews/ Service provider audits
Comment:	Participants comfort is measured during a colonoscopy procedure with the use of a Gloucester Score[1]. Where the score of 1 indicates no discomfort; 2, Minimal; 3, Mild; 4, Moderate and 5, severe discomfort. Screening colonoscopy units should conduct rolling audits of sedation practice, patient comfort scores and the use of reversal agents in line National GI Endoscopy Quality Improvement Programme.[1] Participants comfort should be assessed by the Endoscopist, and the endoscopy nurses present during the procedure. The comfort score should be agreed on by those present before it is recorded in the ERS.[1]

QA Standard 5.16

Name:	Use of reversal agents
Description	Proportion of colonoscopy procedures where reversal agent was used.
Rationale	The use of reversal agents should be recorded as a participants safety incident and should trigger review of the case in line with local hospital escalation policy.[1] The use of specific reversal agents usually indicates that the participants has been given a relative overdose of benzodiazepine or opiate.[1]
Numerator:	Number of colonoscopy procedures where reversal agent was used.
Denominator:	Number of colonoscopy procedures both complete and incomplete.
Caveat:	None
Performance threshold:	Minimum standard <1%
Data Source:	Data measured at unit level Programme database NQAIS data (Service reviews/IQA)
Reporting period	• Quarterly, rolling 12-month data reported 3 months in arrears. • Service reviews/ Service provider audits
Comment:	Self-reported by endoscopist onto endoscopy reporting systems/ National Quality Assurance Intelligence System (NQAIS).

QA Standard 5.17

Name:	Caecal Intubation Rate (CIR)
Description	Proportion of colonoscopy procedures when the ceacum was reached
Rationale & Evidence:	The CIR is a marker of full colonoscopy; when supported by the other performance measures, it contributes to a high-quality, participant centred outcome. Whole bowel examination is a prerequisite for complete and reliable inspection of the mucosa in search of lesions. A low caecal intubation rate is associated with an increased risk of interval colorectal cancer. Incomplete colonoscopy leads to increased costs and inconvenience as the examination has to be repeated [4,5,6] Ensure the entire colon is visualised, marker of quality of colonoscopy.[3]
Numerator	Number of complete colonoscopy procedures
Denominator	Number of colonoscopy procedures both complete and incomplete.
Caveat	Exclusions • Planned limited procedures
Performance threshold:	Minimum standard ≥90% Achievable standard ≥95%
Data Source:	NQAIS
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Comment:	• Self-reported by endoscopist into the service provider's electronic reporting system • Photographic evidence of appendix orifice, ICV, terminal ileum or anastomosis is required to document complete intubation (See requirement 5.9)

QA Standard 5.18

Name:	Adenoma Detection Rate (ADR)
Description	Proportion of index colonoscopy procedures where adenomas were detected. The reporting of this standard is separated to ensure clear measurement of: 1. Individual endoscopist ADR 2. Unit ADR
Rationale	Identification of adenomas (precursors to colorectal cancer (CRC)) is a marker of quality of colonoscopy.[3] ADR reflects adequate inspection of the bowel mucosa. ADR is associated with interval CRC and CRC death, with improvement in the ADR lowering the risk for CRC and CRC death.[3,4,5,6]
Numerator:	Number of index colonoscopy procedures where at least one histologically-confirmed adenoma was detected
Denominator:	Number of index colonoscopy procedures
Caveat:	Exclusions • surveillance procedures • planned repeat procedures
Performance threshold:	Minimum standard ≥45% Achievable standard ≥50%
Data Source:	Data measured at individual endoscopist and unit level Programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service reviews/ Service provider audits
Comment	The ADR includes any adenomas detected at the same time that cancer is detected or during incomplete intubation.[3]

QA Standard 5.19

Name:	Participants discussed at multidisciplinary team meetings (MDT)
Description	Proportion of procedures discussed at multidisciplinary meeting. The reporting of this standard is separated to ensure clear measurement of: 1. Procedures discussed at polyp multidisciplinary meeting following histological diagnosis 2. Procedures discussed at cancer multidisciplinary meeting following histological diagnosis Note: rectal cancer and colon cancer will be reported separately
Rationale	Evidence suggests that participants managed by multidisciplinary teams have better outcomes. Discussion prior to clinical decisions being made provide reassurance that participants have been managed appropriately.[8]
Numerator:	Number of procedures with histological findings discussed at polyp multidisciplinary meeting
Denominator:	Number of procedures with histological findings
Numerator:	Number of procedures with histologically confirmed colon cancer discussed at cancer multidisciplinary meeting
Denominator:	Number of procedures with histologically confirmed colon cancer
Numerator:	Number of procedures with histologically confirmed rectal cancer discussed at cancer multidisciplinary meeting
Denominator:	Number of procedures with histologically confirmed rectal cancer
Caveat:	To ensure all procedures are discussed at least once, the data from this standard will be reviewed in conjunction with QA requirement 8.5 Post-surgery Multidisciplinary Meeting (MDM)
Performance threshold:	Minimum standard ≥95%
Data Source:	Data measured at unit level Programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service reviews/ Service provider audits

QA Standard 5.20

Name:	Perforation rate
Description	Proportion of colonoscopy procedures with colonic perforation
Rationale	Perforation is defined as evidence of air, luminal contents or instrumentation outside the GI tract. It may result from direct mechanical trauma to the bowel wall during insertion.[1]
Numerator:	Number of participants undergoing colonoscopy procedures and colonic perforation was reported during that Endoscopy admission.
Denominator:	Number of colonoscopy procedures
Caveat:	None
Performance threshold	Minimum standard <1 per 1,000 colonoscopies
Data Source:	Data measured at programme level Programme database
Reporting period	Round Report
Comment	Screening colonoscopy units should conduct rolling audits of adverse events/ incidents in line National GI Endoscopy Quality Improvement Programme.[1]

QA Standard 5.21

Name:	Post-polypectomy perforation rate
Description	Proportion of polypectomy procedures with colonic perforation.
Rationale	Perforation is defined as evidence of air, luminal contents or instrumentation outside the GI tract. It may result from direct mechanical trauma to the bowel wall during insertion.[1]
Numerator:	Number of participants undergoing colonoscopy procedures, where at least one polyp was excised, and colonic perforation was reported during that Endoscopy admission.
Denominator:	Number of participants undergoing colonoscopy procedures, where at least one polyp excised
Caveat:	None
Performance threshold:	Minimum standard <2 per 1,000 colonoscopies where polypectomy is performed
Data Source	Data measured at programme level Programme database
Reporting period	Round Report
Comment:	Screening colonoscopy units should conduct rolling audits of adverse events/ incidents in line with National GI Endoscopy Quality Improvement Programme.[1]

QA Standard 5.22

Name:	Post-polypectomy bleeding (PPB) requiring transfusion
Description	Proportion of colonoscopy procedures which resulted in post-polypectomy bleeding require transfusion
Rationale	Minimise harm to screening population.[3] Bleeding is the most frequent adverse event following polypectomy. The risk of bleeding increases with the size of polyp and location, in particular polyps larger than 2cm and located in the right colon.[1]
Numerator:	Number of colonoscopy procedures which resulted in post-polypectomy bleeding require transfusion
Denominator:	Number of colonoscopy procedures where number of polyps excised ≥1
Caveat:	None
Performance threshold:	Minimum standard <1% colonoscopies where polypectomy is performed
Data Source	Data measured at programme level Programme database
Reporting period	Round Report
Comment:	Includes endoscopic mucosal resection (EMR), endoscopic submucosal dissection and all other polypectomies at colonoscopy. Rates of post-polypectomy bleeding are higher for ESD and EMR.

QA Standard 5.23

Name:	Referral rates for CT colonography
Description	Proportion of participants referred to CT colonography; 1. Of all colonoscopy and CT colonography procedures 2. Following pre-assessment 3. Following Incomplete colonoscopy
Rationale	CT colonography is recommended as the completion test of screening in specific clinical scenarios. These include; if there is a failed colonoscopy or incomplete study; in those where a repeat colonoscopy is unlikely to be successful as the completion test; for those who are medically unfit for colonoscopy.[4,9]
Numerator:	Number of CT colonography procedures
Denominator:	Number of colonoscopy and CT colonography procedures
Performance threshold:	Minimum standard ≤5%
Numerator:	Number of participants referred to CT colonography following pre-assessment
Denominator:	Number of colonoscopy and CT colonography procedures
Performance threshold:	Minimum standard ≤5%
Numerator:	Number of participants referred to CT colonography following incomplete colonoscopy
Denominator:	Number of colonoscopy and CT colonography procedures
Performance threshold:	Minimum standard ≤5%
Caveat:	No exclusions
Data Source	Data measured at programme level Programme database
Reporting period	Round Report

QA Standard 5.24

Name:	CT Colonography follow-up (suspected cancers)
Description	Proportion of CT Colonography procedures for suspected cancers with follow-up colonoscopy or MDT within 15 working days
Rationale	Communication of results from radiology to the screening unit must be clear. Referral into the MDT and symptomatic service in the event of abnormal findings should comply with local policies on communication/escalation of significant findings.[7]
Numerator:	Number of CT Colonography procedures for suspected cancers with follow-up colonoscopy or MDT within 15 working days
Denominator:	Number of CT Colonography procedures for suspected cancers with follow-up colonoscopy or MDT
Caveat:	None
Performance threshold	Minimum standard ≥95% Achievable standard ≥98%
Data Source	Data measured at programme level Programme database
Reporting period	Round Report

QA Standard 5.25

Name:	CT Colonography follow-up (suspected polyps)
Description	Number of CT Colonography procedures for suspected polyps with follow-up colonoscopy or MDT within 30 working days
Rationale	Communication of results from radiology to the screening unit must be clear. Referral into the MDT and symptomatic service in the event of abnormal findings should comply with local policies on communication/escalation of significant findings.[7]
Numerator:	Number of CT Colonography procedures for suspected polyps with follow-up colonoscopy or MDT within 30 working days
Denominator:	Number of CT Colonography procedures for suspected polyps with follow-up colonoscopy or MDT
Caveat:	None
Performance threshold	Minimum standard ≥95% Achievable standard ≥98%
Data Source	Data measured at programme level Programme database
Reporting period	Round Report

QA Standard 5.26

Name	Post-colonoscopy colorectal cancer (PCCRC) rate
Description	A post-colonoscopy colorectal cancer (PCCRC) is the diagnosis of a CRC within 36 months of last colonoscopy, (reported as normal or completion of polypectomy) as defined in the BowelScreen MOU. Likewise, a CRC diagnosed at the next screening colonoscopy is considered to be a PCCRC if it occurs within 3 years of the participants going over the eligible age.[3]
Rationale	PCCRC's 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.[3] Evidence from a UK study PCCRC rates vary from 2.5 to 8.5%.
Numerator	Number of false negative colonoscopy procedures[3]
Denominator	Number of true positives and false negative colonoscopy procedures[3]
Caveat	None
Performance threshold	2.5% to 8.5%
Data Source	National Cancer Registry Ireland (NCRI) Notification from hospitals who will complete the Notification of Post-Colonoscopy Colorectal Cancer (PCCRC) form and return it to BowelScreen for recording possible PCCRC's.[10]
Reporting period	Round Report
Comment	The Screening Unit has policies and procedures in place in line with national guidelines and BowelScreen Memorandum of Understanding.

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6

CT colonography standards

CT colonography standards

QA Requirements CT Colonography

Number	QA Requirements – Referral protocol	Suggested Evidence	Reporting period
6.1	Documented local policy/procedure in place for referral of BowelScreen cases. Radiology departments should audit their compliance with local policy at regular intervals (at least every 3 years).	• Copy of referral process • Copy of audit	Service provider audit

Number	QA Requirements- Participant information and consent	Suggested Evidence	Reporting period
6.2	Documented local consent policy/ procedure in-line with the latest HSE National Consent policy. Radiology departments should audit their compliance with local policy at regular intervals (at least every 3 years).	• Copy of consent policy • Copy of audit	Service provider audit

Number	QA Requirements – Participant Safety	Suggested Evidence	Reporting period
6.3	Radiology department must have a policy that includes: 1. Identification and management of the following key complications: • perforation • abdominal pain • blurred vision • hypotension or vasovagal syncope • extravasation • anaphylaxis 2. Communication of complications back to both referring clinicians and the programme • Radiology department should audit their compliance with local policy, at regular intervals (at least every 3 years).	• Copy of policy • Copy of audit	Service provider audit

Number	QA Requirements – Pathway for communication of radiological findings	Suggested Evidence	Reporting period
6.4	Radiology department must have a policy that includes: 1. Two-way communication of findings (CTC and endoscopy) between radiology department and referring endoscopy team 2. Escalation process to ensure that, Critical, Urgent and Unexpected or Clinically Significant radiological findings are communicated to, and an acknowledgement received from, the referring clinician.[1] Radiology departments should audit their compliance with local policy, at regular intervals (At least every 3 years).	• Copy of policy • Copy of audit	Service provider audit

Number	QA Requirements – Participant Experience	Suggested Evidence	Reporting period
6.5	Participants Reported Experience Measures (PREMs) after CT colonography should be routinely measured using validated scales and/or validated questionnaires.	• Reports from the PREMs dashboard • Quality improvement actions in response to PREMs results	Continuously Service review/ Service provider audit

Number	QA Requirements – Ongoing experience of reporting radiologists	Suggested Evidence	Reporting period
6.6	Minimum number of CT colonography procedures performed per radiologists per annum ≥100	• Signed BowelScreen audit certificate from Clinical Lead	Annually Service review/ Service provider audit

QA Standards CT colonography

6.7 QA Standard

Name	Image Quality
Description	Proportion of 'adequate' CT colonography procedures with bowel preparation and distension
Rationale	It is important that people attending for CT colonography have their bowel examined as thoroughly as possible, to maximise the finding of adenomas and cancers. Accurate interpretation of CTC depends on high-quality image acquisition.[2]
Numerator	Number of CTCs with bowel preparation and distension of 'adequate'
Denominator	Number of CTCs
Caveat	No Exclusions
Performance threshold	≥90%
Data Source	Data measured at Service Provider level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears Service Reviews/ Service Provider Audit
Comment	Includes all CTCs, multiple CTCs per participant, CTCs where consent was withdrawn during the procedure and incomplete CTCs.

6.8 QA Standard

Name	Perforation rate of CT colonography
Description	Number of perforations out of the total number of CT Colonography procedures performed
Rationale	The most serious adverse event of CTC is colonic perforation which occurs in fewer than 1 in 3,000 CTC examinations.[3]
Numerator	Number of screening CT Colonography procedures where a perforation was recorded
Denominator	Number of screening CT Colonography procedures
Caveats	No Exclusions
Performance threshold	<1 in 3,000 CT colonography procedures
Data Source	Data measured at programme level Data source is the COR database
Reporting period	Round Reporting
Comment	**Definition-** Perforation is defined as extraluminal gas introduced at the time of CTC.[2]

6.9 QA Standard

Name	CT colonography radiation dose recorded
Description	Median radiation dose for participants undergoing CT colonography should correspond to a dose-length product (DLP) of <950 mGy.cm.[4]
Rationale	Given both an individual participant'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.[3]
Definition	The median radiation dose for participants undergoing CT colonography
Caveats	No exclusions
Performance threshold	Minimum DLP of <950 mGy.cm Achievable DLP of <600 mGy.cm
Data source	Data should be measured at Service Provider level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears Service Reviews/ Service Provider Audit
Comment	Prospective reporting by the radiologist at the time of CT colonography interpretation

6.10 QA Standard

Name	Polyp identification rate- PIR (visualised and recorded)
Description	The proportion of CT colonography examinations with at least 1 polyp measured at CT colonography of ≥6mm
Rationale	Removal of polyps prevents future cancers. Recommend referral for endoscopic polypectomy in participants with at least 1 polyp ≥6mm detected at CT Colonography.[5]
Numerator	Number of CT colonography examinations where at least 1 polyp measured at CT colonography of ≥6mm
Denominator	Number of CT colonography examinations
Caveats	Exclusions: Equivocal reports (for example, 'possible polyp') should not be included
Performance threshold	Minimum >13% Achievable >20%
Data source	Data should be measured at unit level (all radiologists) and for each individual radiologist Data source is the programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears Service Reviews/ Service Provider Audit
Comment	Radiologists should provide clear guidance regarding the presence or absence of polyps and/or colorectal cancer. Equivocal reports should be avoided where possible. If a finding is genuinely equivocal, this should be accompanied by a clear recommendation for either endoscopy, repeat CTC (and at what time interval) or no action.[2]

6.11 QA Standard

Name	CT colonography appointment waiting time
Description	The proportion of participants who are offered a CT colonography appointment within 30 working days of referral date.
Rationale	It is important to minimise anxiety for participants in the programme who are referred for CT colonography.
Numerator	Number of participants who are offered a CT colonography appointment within 30 working days of referral date
Denominator	Number of CTC examinations performed
Caveats	No exclusions
Performance threshold	Minimum ≥95% Achievable 100%
Data source	Data measured at Service Provider level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears Service Reviews/ Service Provider Audit

6.12 QA Standard

Name	CT colonography report turnaround times
Description	Proportion of CT colonography reports where the elapsed time between 'date examination completed' and 'date report signed off' falls within 10 working days, out of the number of CT colonoscopy reports
Rationale	To reduce anxiety, it is important for participants who have a CT colonography, that results are reported in a timely manner.[6]
Numerator	Number of CT colonography reports where the elapsed time between 'date examination completed' and 'date report signed off' falls within 10 working days
Denominator	Number of CT colonography examinations reported on by a BowelScreen approved radiologist
Caveats	No exclusions
Performance threshold	Minimum 90% Achievable 100%
Data source	Data should be measured at Service Provider level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears Service Reviews/ Service Provider Audit

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7

Histopathology standards

QA Requirements Histopathology

Number	QA Requirements - Pathology reporting	Suggested Evidence	Reporting period
7.1	Pathology specimens should be reported according to the latest: • UK Bowel cancer screening: pathology guidance on reporting lesions • Royal College of Pathologists Dataset for histological reporting of colorectal cancer • ICCR Colorectal cancer datasets Pathology departments to audit their reports at regular intervals (at least every 3 years).	• Copy of local audits • Anonymised histopathology reports	Service Provider Audit

Number	QA Requirements- External Quality Assurance (EQA) scheme	Suggested Evidence	Reporting period
7.2	Pathologists reporting BowelScreen histopathology specimens participate in the UK BSCP diagnostic External Quality Assurance (EQA) scheme.	• Evidence of participation	To be set

Number	QA Requirements - INAB accreditation	Suggested Evidence	Reporting period
7.3	Histopathology laboratories must achieve and maintain Irish National Accreditation Board (INAB) accreditation. The programme must be notified about any changes of accreditation status**.**	• Copy of INAB certificate	Annually Service review / Service provider audit

Number	QA Requirements - National Histopathology Quality Improvement (NHQI) Programme	Suggested Evidence	Reporting period
7.4	Histopathology laboratories must participate in the National Histopathology Quality Improvement (NHQI) programme	• Evidence of participation	Service review / Service provider audit

Number	QA Requirements - Reporting Histopathologists	Suggested Evidence	Reporting period
7.5	BowelScreen cases where lesions (polyps /biopsies) are removed at endoscopy must be reported on by a named BowelScreen Histopathologist	• Programme database	Quarterly, rolling 12-month data, reported 3 months in arrears. Service review / Service provider audit

Number	QA Requirements-Double reporting of Polyp cancer cases	Suggested Evidence	Reporting period
7.6	Double reporting of all polyp cancers (stage pT1) is required to minimise overdiagnosis of adenocarcinoma and ensure accuracy of reporting early-stage cancer.[1] At least one reporter should be a BowelScreen approved histopathologist and both reporters should be named on the histopathology report. This standard relates to: • polyp cancers excised at endoscopy • polyp cancers resected at transanal surgery	• Programme database	Quarterly, rolling 12-month data, reported 3 months in arrears. Service review / Service provider audit

Number	QA Requirements - Unusual or difficult cases	Suggested Evidence	Reporting period
7.7	There must be a local policy for discussion of polyps or other lesions that are difficult to diagnose. Laboratory should audit their compliance with local policy at regular intervals (at least every 3 years).	• Copy of policy • Copy of audit of policy	Service provider audit

Number	QA Requirements – Median number of lymph nodes examined	Suggested Evidence	Reporting period
7.8	The number of lymph nodes examined should be as high as possible. The median number of lymph nodes examined should be greater than or equal to 15 per specimen. Exclusion: • Cases who have received pre-operative therapy	• Programme database	Quarterly, rolling 12-month data, reported 3 months in arrears. Service review / Service provider audit

7.9 QA Standard

Name	Pathology turnaround time (TAT)
Description	Proportion of samples where the time between 'date sample received' and 'date sample reported' falls ≤5 working days.
Rationale	Turnaround time of pathology reports should allow participants who have had lesions removed at endoscopy to be managed appropriately.[1]
Numerator	Number of results reported ≤5 working days
Denominator	Number of results reported
Caveats	No exclusions
Performance threshold	Minimum standard ≥90% Achievable standard 100%
Data source	Data measured at unit level Programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Comment:	TAT is calculated based on working days and does not include weekends or bank holidays. For TAT calculations 'day 0' is counted as the date of receipt of sample in the laboratory and the end point is counted as the day the report is authorised.

7.10 QA Standard

Name	Adenoma with high grade dysplasia
Description	Proportion of adenomas reported as high-grade dysplasia
Rationale	Adenomas with high grade dysplasia fulfil the new criteria for advanced colorectal polyp.[1] BSG surveillance guidelines recommend surveillance of adenomas with high grade dysplasia, due to risk of developing future colorectal cancer.[2]
Numerator	Number of adenomas reported as high-grade dysplasia
Denominator	Number of adenomas reported
Caveats	No exclusions
Performance threshold	Minimum standard ≤5%
Data source	Data measured at unit level Programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears
Comment	Includes all endoscopy procedures (index, surveillance, or planned procedures)

7.11 QA Standard

Name	Sessile serrated lesion with dysplasia
Description	Proportion of sessile serrated lesions (SSLs) with dysplasia
Rationale	It has been suggested that SSLs with dysplasia may be associated with faster progression to colorectal cancer than 'classical' adenomas.[1] BSG surveillance guidelines recommend surveillance for SSLs containing dysplasia, as they are considered pre-malignant.[2]
Numerator	Number of sessile serrated lesions (SSLs) containing dysplasia
Denominator	Number of SSLs
Caveats	No exclusions
Performance threshold	Minimum standard ≤10%
Data source	Data measured at unit level Programme database
Reporting period	Quarterly, rolling 12-month data, reported 3 months in arrears
Comment	Includes all endoscopy procedures (colonoscopy, flexible sigmoidoscopy and limited colonoscopy) **Note:** This is a new standard; varying evidence exists regarding the most appropriate performance threshold for sessile serrated lesions showing dysplasia. Therefore, the threshold may be revised to take account of new evidence or as further data becomes available. A review of the performance threshold to take place in 12 months.

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8

Colorectal cancer treatment standards

QA requirements Colorectal Cancer

Number	QA Requirement- Ongoing experience of surgeons (Colon cancer surgery)	Suggested Evidence	Reporting period
8.1	Minimum number of colon cancer resections per surgeon per annum ≥20. Includes when named as a second consultant involved in an operation. Exclusions: • No exclusions	• Signed audit certificate from clinical lead	Annually Service provider audit / Service review

Number	QA Requirement- Ongoing experience of surgeons (Rectal cancer surgery)	Suggested Evidence	Reporting period
8.2	Minimum number of rectal cancer resections per surgeon per annum ≥10. Includes when named as a second consultant involved in an operation. Exclusions: • No exclusions	• Signed audit certificate from clinical lead	Annually Service provider audit / Service review

Number	QA Requirement- Initial staging– Colon Cancer	Suggested Evidence	Reporting period
8.3	CT chest, abdomen and pelvis to be performed for the initial staging of participants diagnosed with colon cancer.[1] Exclusions: • Patients who decline investigations • Patients who undergo emergency surgery • Patients who die before staging scan completed	• Programme database	Quarterly, rolling 12-month data reported 3 months in arrears Service provider audit / Service review

Number	QA Requirement- Initial staging– Rectal Cancer	Suggested Evidence	Reporting period
8.4	CT chest, abdomen and pelvis plus MRI pelvis to be performed for the initial staging of patients diagnosed with rectal cancer.[2] Exclusions: • Patients who decline investigation • Patients who undergo emergency surgery • Patients with a contraindication to MRI • Patients who die before staging scans completed.	• Programme database	Quarterly, rolling 12-month data reported 3 months in arrears. Service provider audit /Service review

Number	QA Requirement- Post-surgery Multidisciplinary Meeting (MDM)	Suggested Evidence	Reporting period
8.5	Participants with colorectal cancer to be discussed at MDM after resection surgery Exclusions: • No exclusions	• Programme database	Quarterly, rolling 12-month data reported 3 months in arrears Service provider audit / Service review

Number	QA Requirement- Position of Rectal Tumour	Suggested Evidence	Reporting period
8.6	Participants newly diagnosed with rectal cancer should have a rigid sigmoidoscopy performed to determine the position of the tumour prior to treatment.[2] Exclusions: • Patients who decline investigation • Patients who undergo emergency surgery • Patients who die before rigid sigmoidoscopy.	• Programme database	Quarterly, rolling 12-month data reported 3 months in arrears. Service provider audit / Service review

8.7 QA Standard

Name	Time-to-Treatment - Colorectal cancer surgery
Description	Proportion of participants with colon cancer with an admission date for surgery ≤ 20 working days from decision to treat Please note, the reporting of this standard is separated to ensure clear measurement of time-to-treatment for both: I. Colon cancer surgery II. Rectal cancer surgery
Rationale	Colorectal cancer surgery services are delivered through eight cancer centres. Services must ensure access to safe, timely, quality-assured, person-centred care.[3] Timely high-quality care following a diagnosis of cancer contributes to a better patient experience by reducing anxiety and uncertainty and improved outcomes.[4]
Numerator	Number of participants with colon cancer with an admission date for surgery ≤20 working days from decision to treat
Denominator	Number of participants with colon cancer with an admission date for surgery
Numerator	Number of participants with rectal cancer with an admission date for surgery ≤20 working days from decision to treat
Denominator	Number of participants with rectal cancer with an admission date for surgery
Caveats	Exclusion: • Participants who require pre-operative chemotherapy and/ or radiotherapy • First appointment declined as requested by participant • The 10% tolerance within this standard is designed to account for clinical appropriateness
Performance threshold	Minimum standard ≥ 90% Achievable standard 100%
Data source	Data measured at unit level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service review / Service provider audit
Comment:	For time-to-treatment calculations ‘day 0’ is counted as the date of discussion in which the patient and clinician agree the treatment plan and the end point is counted as the date of admission.

8.8 QA Standard

Name	Time-to-Treatment - Neo-adjuvant systemic anti-cancer therapy (SACT) / radiotherapy
Description	Proportion of participants with rectal cancer whose neoadjuvant systemic anti-cancer therapy or radiotherapy is started ≤20 working days from decision to treat
Rationale	Services must ensure access to safe, timely, quality-assured, person-centred care.[3] Timely high-quality care following a diagnosis of cancer contributes to a better patient experience by reducing anxiety and uncertainty and improved outcomes.[4] Systemic anti-cancer therapy is one of three main treatment modalities alongside radiotherapy and surgery.[5]
Numerator	Number of participants with rectal cancer whose neoadjuvant systemic anti-cancer therapy or radiotherapy is started ≤20 working days from decision to treat
Denominator	Number of participants with rectal cancer who started neoadjuvant systemic anti-cancer therapy or radiotherapy
Caveats	Exclusions: • First appointment declined as requested by participant • The 10% tolerance within this standard is designed to account for clinical appropriateness
Performance threshold	Minimum standard ≥90% Achievable standard 100%
Data source	Data measured at unit level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service review / Service Provider Audit
Comment:	For neoadjuvant systemic anti-cancer therapy or radiotherapy: time-to-treatment calculations 'day 0' is counted as the date of discussion in which the participants and clinician agree the treatment plan and the end point is counted as the date of admission.

8.9 QA Standard

Name	Abdominoperineal resection
Description	Proportion of participants with rectal cancer who had an abdominoperineal resection (APR)
Rationale	Choice of rectal resection should be tailored to the individual patient, focussing on achieving complete resection, low morbidity and restorative procedures in appropriate cases.[6] Abdominoperineal resection may decrease quality of life due to the formation of a permanent stoma.[4]
Numerator	Number of participants with rectal cancer who had an abdominoperineal resection
Denominator	Number of participants who undergo major resection surgery for rectal cancer
Caveats	No exclusions
Performance threshold	Minimum standard <20% Achievable standard <10%
Data source	Data measured at Programme level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service review / Service Provider Audit
Comment	Major resection for rectal cancer means a surgical operation when part or all of the rectum is removed, including anterior resection and abdominoperineal resection.[7]

8.10 QA Standard

Name:	Anastomotic leak
Description	Proportion of participants with colorectal cancer who undergo a surgical resection involving anastomosis of the colon or rectum having anastomotic leak requiring any intervention (medical, endoscopic, radiological or surgical). Note: The specifications of this standard are separated to ensure clear measurement of patients who undergo: (i) Colonic anastomosis; and (ii) Rectal anastomosis (anterior resection).
Rationale	Anastomotic leakage is one of the most significant and potentially fatal complication of colorectal cancer surgery, and measures to minimise it should be taken. [1,2,6,7,8]
Numerator	Number of participants with colon cancer who undergo a surgical resection involving anastomosis of the colon having anastomotic leak requiring any intervention (medical, endoscopic, radiological or surgical)
Denominator	All participants with colon cancer who undergo a surgical resection involving anastomosis of the colon
Caveats	No exclusions
Performance Thresholds	Minimum standard <8% Achievable standard <5%
Numerator	Number of participants with rectal cancer who undergo a surgical resection involving anastomosis of the rectum (anterior resection) having anastomotic leak requiring any intervention (medical, endoscopic, radiological or surgical).
Denominator	All participants with rectal cancer who undergo a surgical resection involving anastomosis of the rectum (anterior resection).
Caveats	No exclusions
Performance threshold	Minimum standard <8% Achievable standard <5%
Data source	Data measured at programme level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service review / Service Provider Audit

8.11 QA Standard

Name	Re-operation rate
Description	Proportion of participants who undergo surgical resection for colorectal cancer with an unplanned return to theatre during hospital stay.
Rationale	It is important to minimise morbidity and mortality related to the treatment of colorectal cancer.[8] Reoperation after colorectal surgery is associated with serious post-operative complications and therefore may offer a possible indicator of surgical quality.[9]
Numerator	Number of participants who undergo surgical resection for colorectal cancer with an unplanned return to theatre during hospital stay.
Denominator	Number of participants with colorectal cancer who undergo surgical resection
Caveats	No exclusions
Performance threshold	Minimum standard ≤10% Achievable standard ≤5%
Data source	Data measured at unit & programme level Data source is the programme database
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears. Service review / Service Provider Audit

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Glossary of terms, definitions and abbreviations

Glossary of terms, definitions and abbreviations

ADR	Adenoma Detection Rate
Call, Re-call	Initially inviting and subsequently recalling the eligible population to bowel screening
CIR	Caecal Intubation Rate
Cohort Report	Cohort Report is an epidemiological report, that means it follows the same cohort of participants over time
Completeness of population register	The National Census is the gold-standard against which the population register can be validated, the comparison report is used as a snapshot to estimate the completeness and accuracy of the COR register at that time.
COR register	BowelScreen data is stored in a SQL Server® database known colloquially as 'COR'. COR is a bespoke, event-driven application which respects a logical order and follows the development of the screening process
CT	Computed Tomography
EQA	External quality assessment/assurance
FIT	Faecal Immunochemical Test
Horizontal audit	A horizontal audit follows a process across many departments in the organisation
IQC	Internal quality control
IVDR	In-Vitro Medical Device Regulation
JAG	Joint Advisory Group on GI Endoscopy
LIMS	Laboratory information system
LoQ	Limit of quantitation
MDM	Multidisciplinary meeting
MOU	Memorandum of understanding
NSS	National Screening Service
PCCRC	Post-colonoscopy colorectal cancer
PEU	Programme Evaluation Unit
PREMS	Patient Reported Experience Measures
Round Report	BowelScreen offers screening on a two-yearly cycle, the report produced after each two-year cycle is called the Round Report.
Satisfactory FIT result	is defined as reaching a definitive FIT outcome, either normal or abnormal (from potentially multiple test kits).
SOP	Standard Operating Procedure
SSLs	Sessile Serrated Lesions
Vertical audit	A vertical audit involves assessing all processes undertaken by a department

Appendix

Appendix 1

Review and development of the Standards for Quality Assurance in Colorectal Screening Third Edition

Multi-stakeholder involvement is a key requirement for the effective review and development of quality assurance standards as outlined in the Authors & Contributors page 11. The review was undertaken in line with QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6) with the governance set out in the Introduction chapter 2 page 13. The process for this review and development is outlined below in the BowelScreen QA standards review and development process:

Budget and Resource Implication

This revision of the standards document considered feedback and change requests and any new screening guidance issued since the last revision of the standards in 2017. No new technologies have been recommended in this revision. To monitor compliance to these standards and requirements, additional resources in the form of QA visit teams and enhanced data provision are required. These costs and resources are incorporated into the strategic planning projects for BowelScreen. Stakeholder Resourcing is their responsibility and is defined within the terms of Memorandums of Understanding (MOUs), Service Level Agreements (SLA), and contracts with stakeholders.

Implementation plan

Stakeholders are notified and are provided with the new revision of the standards when they are published. Stakeholders are required by contract or MOU to ensure that their staff are aware of and trained on implementing the standards and requirements relevant to their area of practice. On-going assistance is provided by the clinical coordinators in BowelScreen. In general, a lead in period of three months is provided before monitoring commences against new or amended standards. To assist with implementation a summary of the changes made to this revision will be shared with the relevant stakeholders.

Communication and Dissemination

Internal to NSS:

This document is a controlled document and dissemination internally is managed via the distribution list assigned on the NSS Quality Management Information system (Q pulse). The system will automatically email each person on the distribution list, and they must acknowledge they have read and understood the document.

External to NSS:

The NSS communications team will update the website with the new revision. Stakeholders are provided with a copy of the revised standards once approved for implementation within the NSS, initially

via soft copy and then in hard copy once printed.

Governance and approval

Each chapter of the document was revised in line with documented governance arrangements as outlined in the BowelScreen QA standards review and development process below.

Monitoring, Evaluation and Audit

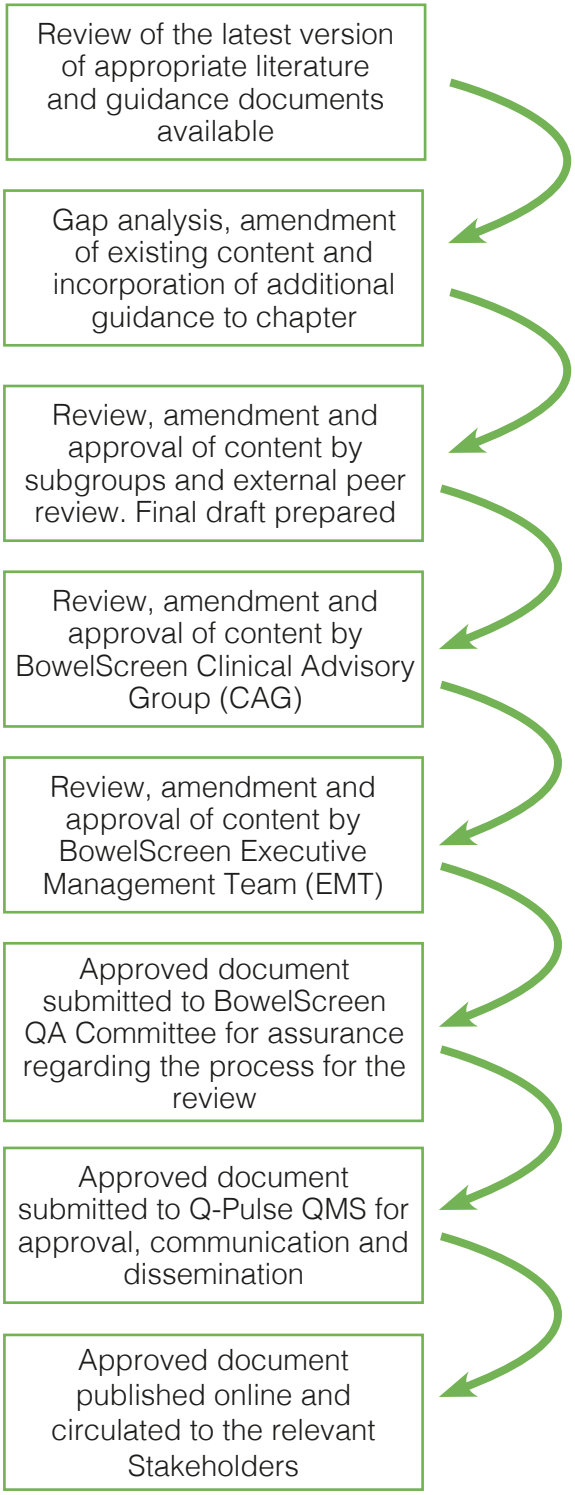
This document outlines the standards and requirements for the BowelScreen programme, a schedule of both internal and service provider audits against the standards are planned and organised on a rolling basis. The frequency of audits conducted are in line with the NSS QA Policy Framework: QA Manual (NSS/S&F-9), and NSS Audit SOPs.

Review and Update

A formal review will be carried out at in line with the NSS QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6) within a minimum of 5 years unless there is a change informed by legislation, best practice, the Regulator, or EU Directives etc., which would identify the need to update the standards sooner.

Internally within the NSS, an alert is sent to the document owner when a review is due via NSS Quality Management Information system (Q pulse). The standards will be kept under review and comments and feedback are welcome to inform this process. Any change requests raised against the document throughout the period of each revision is stored on NSS Quality Management Information system (Q pulse).

BowelScreen QA standards review and development process



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BowelScreen

An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

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The National Bowel Screening Programme