Expert Reference Group

Interval Cancer Report BowelScreen

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An tSeirbhís Náisiúnta Scagthástála
National Screening Service

BowelScreen
An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme

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Foreword

BowelScreen began in 2012, as the youngest of the National Screening Service's three cancer screening programmes. Its aim is twofold: to detect colorectal (bowel) cancer as early as possible and to identify and remove benign polyps (growths) in the colon before they might evolve into cancers. Screening is a two-step process: a stool sample is tested for a level of blood (the FIT test), which, if positive, would result in a patient being referred for a colonoscopy. The screening tests are not available for retrospective audit, instead, the Programme relies on accredited colonoscopy units' key performance indicators to assure that they are functioning according to acceptable standards. Fortunately, interval cancers arising between colonoscopies (post colonoscopy colorectal cancer, PCCRC) have been rare in Ireland.

The Expert Reference Group on Clinical Audit of Interval Cancers in the CervicalCheck and BowelScreen population was established in 2019 to address one element of quality assurance: how best to conduct audit by clinical experts of interval cancers arising between screening visits. It has been my privilege to chair the Expert Reference Group, which comprised representatives from professional disciplines, international expertise and patient and public members. I would like to thank all participants, for the time and energy they devoted to this complex project, especially the patients and public members.

Our work focused on learning from international practice, through reviewing the published literature, conducting a survey of the approach to audit in well-established screening programmes and discussions with international experts. In Ireland, we considered patient and public expectations, HSE policies, the National Screening programme data, Irish legislation and lessons learned from reports related to issues arising in 2018 from an audit in CervicalCheck.

We learned that there is no international consensus or standard on clinical audit. In international jurisdictions, colorectal cancer screening has been implemented much later than cervical or breast cancer screening. Some countries do not have an audit process for interval cancers. For those countries who audit, the methodology varies and most countries do not disclose results of audit to patients. In some jurisdictions, there is legislative protection from disclosure of audit findings.

Our final recommendations have three main themes:

Patients with an interval cancer will, at time of diagnosis, have their clinical situation explained to them by their treating consultant in the hospital setting. Should a patient request a review of their clinical data from screening and care at any point in the future, this will be provided and a meeting offered.

The BowelScreen programme record all post colonoscopy colorectal cancers from multiple sources. Key performance indicators will continue to be monitored to ensure the endoscopy screening units meet agreed standards.

The national annual post colonoscopy colorectal cancer rate will be a new programmatic key performance indicator and will be monitored against an agreed standard.

BowelScreen has the potential to reduce deaths from colorectal cancer by 36% after 10 years of screening, but only if there is growth in participation of men and women. This effective and affordable programme is sustainable. Its full benefits will be realised as uptake grows from 41% today to a much higher proportion of the eligible population.

Professor Susan O'Reilly

MB, BCh, BAO, FRCPC, FRCPI

Glossary of terms, definitions and abbreviations

Term	Definition
ADR	Adenoma Detection Rate
Clinical Audit	As defined by the Health Service Executive (HSE), "Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements". It should be noted that the term is also frequently used for generic quality review processes.[1]
CIR	Caecal Intubation Rate
CRCs	Colorectal Cancers
CS	Colonoscopy Screening
EQI	Endoscopy Quality Improvement
False Negative	The test result is negative, although the disease is actually present.
FIT	Faecal Immunochemical Test
FS	Flexible Sigmoidoscopy
GDPR	General Data Protection Regulation
GP	General Practitioner
gFOBT	guaiac Faecal Occult Blood Test
HSE	Health Service Executive
IARC	International Agency for Research on Cancer
Interval Cancer	Colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam.[2]
JAG	Joint Advisory Group on GI Endoscopy
KPI	A key performance indicator (KPI) within BowelScreen is a predefined parameter by which the performance of a bowel screening programme is assessed.
MOU	Memorandum of Understanding
NCRI	National Cancer Registry Ireland
NHS	National Health Service
NSS	National Screening Service
PCCRC	Post-Colonoscopy Colorectal Cancer
PEU	Programme Evaluation Unit
RCOG	Royal College of Obstetricians and Gynaecologists (UK)
RCPI	Royal College of Physicians of Ireland
RCSI	Royal College of Surgeons in Ireland
SOP	Standard Operating Procedure
SSLs	Sessile Serrated Lesions
TOR	Terms of Reference
UK	United Kingdom

Section One: Executive Summary

Bowel cancer in Ireland

In Ireland, almost 3,000 people are diagnosed with bowel cancer every year. The *2019 Annual Report of the National Cancer Registry Ireland* shows that, on average, 1,731 men and 1,205 women are diagnosed with bowel cancer each year. [3]

Bowel cancer (colorectal cancer) is one of the most common types of cancer diagnosed in Ireland. It is the second most common cause of cancer death in Ireland. Recent studies have shown that cancer survival rates for colorectal cancer are poorer in Ireland than in other countries, with survival rates of 61.8% for colon cancer and 62.4% for rectal cancer.[4]

The annual number of cases of bowel cancer is projected to increase by approximately 100% by 2045 when compared with the 2015 figures.[5] Identification of precancerous lesions will usually mean cure without further treatment, and if bowel cancer is detected at an early stage, it is easier to treat and there is a better chance of recovery or cure.

Bowel cancer screening

Population-based bowel cancer screening aims to reduce deaths from colorectal cancer by 36% after 10 years of offering faecal immunochemical test (FIT) bowel screening to men and women aged 55–74 years.

Interval cancers

The Colorectal Cancer Screening Committee of the World Endoscopy Organization has proposed a definition of an interval cancer as a “colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam”.[2]

Colonoscopy (after a positive FIT test) is the cornerstone of colorectal screening. The quality of the colonoscopy, which includes the performance of the endoscopist, is considered an important determinant of post-colonoscopy colorectal cancer (PCCRC). Therefore, the PCCRC rate is an important measure of the overall quality of colorectal cancer screening programmes. The PCCRC rate has been shown to vary depending on the calculation methodology employed, and a standardised approach is required in order to allow meaningful comparison with other programmes.

Interval cancers, including false negative cancers, are a known feature of all screening programmes. Screening programmes work continuously to improve their processes and techniques in order to keep the number of interval cancers as low as possible.

While bowel screening programmes will not detect all cancers, there is mounting evidence in support of FIT screening as the initial test for population based bowel screening programmes. The sensitivity of faecal occult blood testing is known to be poor. However, the newer method of testing employed by BowelScreen (FIT) has better analytical and clinical sensitivity for colorectal cancer and is also better at detecting advanced adenomas.[5] Neither the FIT nor a colonoscopy is 100% accurate. While a number of countries monitor interval cancers post-FIT screening, post-colonoscopy interval cancers are considered a more meaningful measure of programme performance.[6]

BowelScreen – The National Bowel Screening Programme

BowelScreen – The National Bowel Screening Programme began in October 2012 and is offered on a biennial cycle to all eligible adults in Ireland aged 60–69 years who are known to the programme. The intention is to extend the eligibility to those aged 55–74 years. The first cycle, or 'round', was carried out over approximately 3 years, from 1 October 2012 to 31 December 2015, starting with men and women aged 60–69 years. A catch-up for clients who were within this age bracket on the date the programme was launched, allowed some screening participants who were over 70 years old during the first round of the programme to be invited in this round. The programme will be expanded over time until the full 55–74 age group is reached. The maximum benefit in terms of reduction in mortality will occur only when the programme targets the full population between the ages of 55 and 74.

In its second screening round from 2016 to 2017, BowelScreen invited 546,767 eligible people, screened 226,374 clients, performed 6,523 colonoscopies and detected 410 cancers. This represents a screening uptake rate of 41.4% and a cancer detection rate of 1.81 per 1,000 people screened. In addition, 12,367 adenomas or polyps were removed. These are abnormal tissue growths that can become cancerous at a later stage. The removal of precancerous polyps greatly reduces the risk of future bowel cancer development. Furthermore, 879 sessile serrated lesions (SSLs) were detected. SSLs are flat, precancerous polyps that can develop into bowel cancer[6]

Expert Reference Group

In 2019, the Health Service Executive (HSE) established two Expert Reference Groups: one for BreastCheck and one for both CervicalCheck and BowelScreen. These groups were asked to:

"define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice." (Appendix 1)

The Expert Reference Groups and their respective Working Groups considered the current review practices and the patient information and consent processes, agreed the principles relating to clinical audits, and conducted two projects to determine international practices in regard to the audit of interval cancers: an international literature review, and a survey of practices in established national or regional cancer screening programmes which serve a population equal to or larger than Ireland's. Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through

systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.[1]

Quality assurance in BowelScreen

In order to ensure that the BowelScreen programme is effective and adheres to the highest international standards, each step of the screening process is quality assured, monitored and assessed. BowelScreen has published *Guidelines for Quality Assurance in Colorectal Screening,* which are pivotal to the management of a high-quality screening programme.[7] Each BowelScreen unit is accredited by the United Kingdom's Joint Advisory Group on GI Endoscopy (JAG). In addition, BowelScreen endoscopists are monitored at unit and individual level under the Gastrointestinal Endoscopy National Quality Improvement Programme.

International practice

The management of interval cancers varies between international bowel screening programmes. Some international programmes do not examine interval cancers at any level. However, among programmes that do examine interval cancers, they focus on the post-FIT/guaiac faecal occult blood test interval cancer rate and the PCCRC rate.

Open disclosure

The HSE Open Disclosure Policy has been in operation for BowelScreen since 2013, and it is fully endorsed and implemented for patient safety clinical incidents or harms which are "unintended or unanticipated".[8]

In keeping with the majority of international screening programmes, BowelScreen has not considered interval cancers as unintended or unanticipated incidents, as they are an accepted, unavoidable occurrence in population screening programmes. As such, a universal disclosure policy has not been implemented for interval cancers by BowelScreen except where harm has been attributed to programme failings. This was most notable following a patient safety incident in one of the programme's endoscopy units in 2014. The management of that incident and the quality assurance measures in place within the BowelScreen programme were reviewed by an external expert following the incident. The BowelScreen programme was found to have implemented open disclosure in an appropriate manner, and this was also cited in the 2018 *Scoping Inquiry into the CervicalCheck Screening Programme* (Scally Report): "There is evidence that disclosure can be done well from another cancer screening issue in Ireland involving the BowelScreen programme".[9] The report goes on to quote the review of BowelScreen incidents in Wexford, which concluded that "disclosure was handled in an appropriate and timely manner".[10]

BowelScreen Expert Reference Group Recommendations

Recommendation 1: Participants should continue to be provided with all the information they require in order to make an informed choice to consent to participate in the BowelScreen programme. Informational materials should be revised to strengthen the information on the benefits and limitations of screening. These materials should include explicit information on the occurrence of interval cancers and information on the opportunity to discuss their case should a patient develops a PCCRC. Expanded content on data sharing arrangements between BowelScreen and the National Cancer Registry Ireland (NCRI) should be included. A standardised colonoscopy consent form should be employed throughout all endoscopy units participating in the BowelScreen programme. The revised consent form developed by the BowelScreen Working Group should be piloted for this purpose (Appendix 6a).

Recommendation 2: Implementation of the recommendations of the Scally Report should ensure that communication with NCRI is strengthened to enable a more timely validation of interval cancers and the calculation of the interval cancers rate in the BowelScreen programme.

- Processes should be put in place to calculate the PCCRC rate in BowelScreen. The rate should be calculated as follows:

$$\frac{\text{no.of PCCRCs (false negative colonoscopies)}}{\text{no.of PCCRCs (false negatives)+detected Colorectal Cancers (true positives)}} \times \frac{100}{1}$$

- The maximum rate should be set at 8% and an achievable rate of 5%.
- Notwithstanding capacity concerns, the BowelScreen Working Group recommends calculation of the post-FIT interval cancer rate to inform the determination of the FIT threshold, and to inform international scientific opinion on the sensitivity/specificity of FIT screening. Because of the known limitations of FIT as a screening test, the BowelScreen Working Group does not recommend individual case review or open disclosure of post-FIT interval cancers.

Recommendation 3: BowelScreen will record PCCRCs from multiple sources; screening units, symptomatic units and the NCRI to allow calculation of the PCCRC rate and monitoring of PCCRC. In compliance with GDPR, BowelScreen will no longer process or review any other patient identifiable information following notification of a PCCRC. Rather, the local Clinical Director/Endoscopy Lead will be responsible for the conduct and disclosure of reviews. The local Clinical Director/Endoscopy lead will be responsible for the escalation of any concerns arising following a review of PCCRC. The programme will continue to monitor KPIs independently of PCCRC notification.

Recommendation 4: In accordance with the BowelScreen MOU with local screening units, the local unit will continue to openly discuss the diagnosis, treatment plan and review of the screening colonoscopy with the patient following diagnosis of a PCCRC. The Screening Unit will respond to any request from the patient to conduct a review of their screening colonoscopy and to meet for full disclosure of the findings of that review.

Recommendation 5: The HSE should continue to build and promote understanding of, and public trust in, BowelScreen and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Participants should be made aware that they may, separately from any review process, request access to their records at any time.

Recommendation 6: The necessary resources should be provided to BowelScreen in order to implement these recommendations. An implementation team should be established in order to ensure continued implementation of disclosure according to the outlined recommendations. Processes should be continually monitored in the context of updates to the Patient Safety Bill 2018, the GDPR, and emerging international practice.

Consideration of implications of recommendations

- This document provides the "operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population", as required by its Terms of Reference with specific reference to the assessment of overall programme performance, the conduct of patient-requested case reviews of interval cancers, consent, and open disclosure (Appendix 1).
- As noted in the recommendations above, the HSE should proceed with the establishment of an implementation team to immediately progress these recommendations. The implementation team should also monitor the effects of the recommendations on all aspects of the functioning of BowelScreen, including the ongoing delivery of the programme, public trust, patient safety, efficacy and cost-effectiveness.
- The recommendations of this report provide for immediate and ongoing access to patient-requested case reviews of interval cancers with disclosure under a BowelScreen MOU following notification of a PCCRC. However, there is no standardised, reproducible review methodology and it involves communication with symptomatic units, treating clinicians, pathologists and other members of the multidisciplinary team. GDPR precludes the disclosure of individual endoscopist's NIQAS data as part of patient-requested case review and further discussion with the National Endoscopy Programme will be required in this regard under the implementation plan.
- The Expert Reference Group wishes to highlight that the implementation of these recommendations will have significant resource implications if BowelScreen is to meet the needs of patients, their families, and clinicians as outlined in the main report.

Section Two: Background

Background and introduction

Bowel cancer in Ireland

In Ireland, almost 3,000 people are diagnosed with bowel cancer every year. The 2019 *Annual Report of the National Cancer Registry Ireland* [3] shows that, on average, 1,731 men and 1,205 women are diagnosed with cancer each year (Table 1)

Table 1. Estimated annual average incidence, rate and cumulative risk of colorectal cancer, 2017–2019[3]

	Case count			Rate*/100,000 population		Risk** to age 75 1 in:	
	Male	Female	All	Male	Female	Male	Female
Colorectum and anus	1,731	1,205	2,936	63.8	40.2	21	33

*Rates are standardised to the 1976 European standard population.
**Cumulative risk of dying of a cancer before age 75 expressed as a proportion, e.g. 1 in 10.

Colorectal cancer was the second most common cause of cancer death overall (third most common in females), with an average of 998 deaths per year or 10% of cancer deaths in females and 12% of cancer deaths in males.

Colorectal cancers are infrequent before age 40, but the incidence rises progressively thereafter to 3.7/1,000 people per year by age 80. The lifetime incidence for patients at average risk in the United States is 4.4%,[11, 12] with 90% of cases occurring after age 50,[13] although a recent study [14] indicates increasing incidence in the under-50 age group. In Ireland, the risk for men up to age 75 is 1 in 21, and for women it is 1 in 33 (Table 1).

Almost 1,000 people die of colorectal cancer each year in Ireland (Table 2). If bowel cancer is found early, it is easier to treat and there is a better chance of recovery. The most recent statistics from the National Cancer Registry Ireland (NCRI) show that colorectal cancer is most often detected at an advanced stage in Ireland, with approximately 57% of cases being diagnosed at late stage (stage III/IV), and approximately 25% being diagnosed at the distant metastatic stage (stage IV). It is anticipated that the proportion of cases being diagnosed at late stage will begin to fall in the years ahead as a result of the initiation of the national BowelScreen programme in 2012.

Table 2. Annual average mortality attributable to colorectal cancer, 2014–2016[3]

	Deaths			Rate*/100,000 population		Risk** to age 75 1 in:	
	Male	Female	All	Male	Female	Male	Female
Cancer of colorectum and anus	584	415	999	23.4	13.4	68	118

*Rates are standardised to the 1976 European standard population.
**Cumulative risk of dying of a cancer before age 75 expressed as a proportion, e.g. 1 in 10.

The NCRI's 2019 annual report makes comparisons between seven developed countries: Australia, Canada, Norway, Denmark, New Zealand, the United Kingdom (UK) and Ireland. Between 2010 and 2014, Ireland ranked sixth for colon and rectal cancer survival, but third and second, respectively, for improvement over the full period between 2010 and 2014. At the end of 2017, there were approximately 21,000 people in Ireland living with bowel cancer (Table 3).

Table 3. Fixed duration and estimated complete prevalence of colorectal cancer: number of cancer survivors at the end of 2017[3]

	Fixed duration (1994–2017)	Complete to end of 2017	%*
Colorectal cancer	19,707	21,271	11.8%

Introduction to population-based screening

Cancer screening involves tests that look for early signs of disease before any symptoms have developed in order to enable prevention and/or early diagnosis, intervention and management of a treatable condition. Population-based screening programmes offer screening to all individuals in a target group deemed to be at higher risk of disease, usually defined by age or sex, as part of an organised programme. The screening test identifies people likely to have the disease in question and who are in need of further investigation and testing, which may lead to a cancer diagnosis.[15, 16]

Certain criteria must be met before a disease is considered suitable for screening, such as the seriousness of the disease, how common it is, the availability of treatment, and the availability and acceptability of a suitable screening test. These criteria were first defined by the World Health Organization more than 50 years ago and are known as the Wilson and Jungner criteria.[17] A summary of these criteria outlined by the World Health Organization[18] can be found in Appendix 2.

Population-based screening programmes are complex, and when "they are of high standard…target all the population at risk in a given geographical area with high specific cancer burden and everyone who takes part is offered the same level of screening, diagnosis and treatment services".[19] An organised, population-based approach provides an operating model that is "conducive to effective management of performance and continuous improvement of the screening process and outcomes. This is achieved, for example, through linkage of screening registry data with data in population and cancer registries, for optimization of invitation to screening and for evaluation of screening performance and impact".[20]

The *European guidelines for quality assurance in colorectal cancer screening and diagnosis,* in advocating for population-based screening, state: "In order to maximise the impact of the intervention and ensure high coverage and equity of access, only organised screening programmes should be implemented, as opposed to case finding or opportunistic screening as only organised programmes can be properly quality assured".[21]

In summary, screening is the process of identifying people who may be at increased risk of a disease in a wider population of healthy people. Once identified, those people can be offered further tests and beneficial interventions. A screening programme needs to offer more benefit than harm, and at a reasonable cost to the health service.[22]

Limitations of screening

No screening test is 100% accurate, and there is a delicate balance between the benefits and harms associated with screening. The screening test indicates that a disease may be present, but is not a diagnostic test. The bowel screening test looks only for blood in a stool sample. If the amount of blood is below the screening limit, however, this does not guarantee that bowel cancer is not present. This is because not all cancers or polyps bleed all the time.

All population-based screening programmes yield false positive and false negative results. Screening programmes are monitored in order to minimise the number of false positive and false negative results, and performance is judged against predefined guidelines.

The development of an interval cancer (defined as a colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam), including a missed cancer, is a potential harm associated with colorectal screening. This is common to all screening programmes. Similar to other screening programmes, screening for colorectal cancer may directly harm participants. There may be direct harms associated with colonoscopy, including over-sedation, colonic perforation, or bleeding precipitated by polypectomy. Indirect harm may be caused by surgical intervention for cancer which would not have presented clinically if left in situ.[23]

Introduction to bowel screening

Bowel screening aims to detect signs of bowel cancer at an early stage when there are no symptoms. BowelScreen – The National Bowel Screening Programme was established in the Republic of Ireland in October 2012. It is a free, population-based screening programme offered on a biennial cycle to all eligible adults aged 60–69 years who are known to the programme.[24] All eligible clients in the BowelScreen database receive an invitation letter requesting that they contact the BowelScreen programme in order to join the programme. Having contacted the BowelScreen programme, they are sent an explanatory letter, information sheet and home test kit. The intention is to expand the eligible screening age range to include the full 55–74 age group.

The purpose of BowelScreen is to identify the population most at risk from colorectal cancer that is 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 decline. This will also result in fewer patients attending hospitals for cancer treatment. In the absence, to date, of any large-scale randomised controlled trials of colorectal cancer screening using the faecal immunochemical test (FIT), the best estimate of mortality reduction is 36% after 10 years of offering bowel screening to men and women aged 55–74 years.[7]

The first round of the programme was carried out over approximately 3 years in order to recruit hospitals and test efficiencies in postal and laboratory systems. While the first round targeted men and women aged 60–69 years, it is important to note that the maximum benefit for the population in terms of reducing mortality and for cost-effectiveness will occur only when the programme targets the full 55–74 age group.

In its second screening round from 2016 to 2017, BowelScreen invited 546,767 eligible people, screened 226,374 clients, performed 6,523 colonoscopies, and detected 410 cancers. This represents a screening uptake rate of 41.4% and a cancer detection rate of 41.4% per 1,000 people screened. In addition, 12,367 adenomas were removed.[6]

Interval cancers

Interval cancers are an inevitable consequence of any cancer screening programme. Irrespective of quality assurance measures implemented in order to ensure the most effective and sensitive screening programme, a proportion of cancers diagnosed each year will include interval cancers.[25]

Neither the FIT nor colonoscopy is 100% accurate. While a number of countries monitor interval cancers post-FIT screening, post-colonoscopy colorectal cancers (PCCRCs) are considered a more meaningful measure of programme performance.[7]

Some individuals may undergo a colonoscopy which is negative for cancer but subsequently be diagnosed with cancer (i.e. PCCRC). These are sometimes referred to as interval cancers in the context of screening programmes. The Colorectal Cancer Screening Committee of the World Endoscopy Organization has proposed a definition of an interval cancer as a “colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam”.[2] It is acknowledged that “Colorectal cancers (CRCs) diagnosed within a few years after an index colonoscopy can arise from missed lesions or the development of a new tumour”.[26]

BowelScreen – The National Bowel Screening Programme

The BowelScreen programme began in October 2012. The purpose of BowelScreen is to identify the population most at risk of colorectal cancer and to target those most likely to benefit from early detection and treatment. Over time, full participation in the BowelScreen programme should result in a reduction in mortality from colorectal cancer and fewer patients requiring cancer treatment in hospitals. The first cycle, or ‘round’, of the programme was carried out over approximately 3 years, from 1 October 2012 to 31 December 2015, starting with men and women aged 60–69 years. A catch-up for clients who were within this age bracket on the date the programme was launched allowed some screening participants who were over 70 years old during the first round of the programme to be invited in this round. The programme will be expanded over time until the full 55–74 age group is reached. The maximum benefit in terms of reduction in mortality will occur only when the programme targets the full population between the ages of 55 and 74.

The programme's primary screening tool is the FIT, which analyses stool samples for the presence of blood using a mono- or polyclonal antibody to human haemoglobin. The FIT analysis process is automated and allows quantitative analysis of stool blood content. From an international perspective, Ireland was an early adopter of this technology for organised population-based colorectal cancer screening. One of the advantages of this test in a population-based screening programme is that it can be self-administered in the privacy of an individual's own home.

A home test kit is sent by post every 2 years to eligible women and men aged 60–69 years who consent to take part in the programme. This test can detect minute levels of blood in the stool specimen and is therefore used to select the group of patients who may be at a higher risk of precancerous growths and cancers in the colon. The current threshold for triggering a colonoscopy invitation is 45 µg of haemoglobin per gram of faeces. Patients with positive FIT results are then sent to one of 13 screening colonoscopy units to undergo a screening colonoscopy.

Colonoscopy is the main diagnostic test used to identify colorectal cancer. A colonoscopy is a fibre-optic examination of the bowel which looks for growths (adenomas) or other signs of disease in the lining of the bowel. During a colonoscopy, polyps or adenomas may be removed. Otherwise, surgery may be indicated for removal of colonoscopic abnormalities.

Adenomas are abnormal tissue growths that can become cancerous at a later stage. The removal of precancerous adenomas during colonoscopy greatly reduces the risks associated with future bowel cancer development. Although the main aim of bowel screening is to reduce the incidence of colon cancer by removing precancerous adenomas, colorectal cancers are also detected and treated. This is especially true of the prevalent round (first round) of screening where clients have never had a colonoscopy before.[27]

Colonoscopy is known to be highly effective in both detecting established cancer and preventing colorectal cancer by endoscopically removing precancerous growths.[28] As such, it is both a screening tool and a diagnostic test.[29]

Establishment of the Expert Reference Group

In Ireland, each of the three cancer screening programmes (BreastCheck, CervicalCheck and BowelScreen) operates independently within the National Screening Service. Each programme has different timelines and technologies specific to the cancer being screened for, and therefore has different strategies for managing interval cancers. Clinical audit in CervicalCheck comprises the programmatic review of cervical cytology in women with invasive cervical cancers. Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.[1] BreastCheck publishes interval cancer rates benchmarked against European guidelines and facilitates patient-requested case reviews of interval cancers. BowelScreen is the most recently established programme and has not yet collated sufficient data to publish interval cancer rates, but it does conduct case reviews of notified interval cancers (outlined in detail in Section Three).

In January 2019, the Health Service Executive (HSE) commissioned two Expert Reference Groups to, as outlined in its Terms of Reference "define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice." (Appendix 1) The governance and membership of the Expert Reference Groups, along with the Terms of Reference, are provided in Appendix 1.

Guiding Principles for Clinical Audit

In accordance with the Clinical Audit of Interval Cancer in the Screened Population Terms of Reference, the CervicalCheck/BowelScreen Expert Reference Group and its respective Working Groups agreed on the following principles:

1. Population screening refers to a test that is offered to all individuals in a target group (usually defined by age) as part of an organised programme, with the overall aim of prevention or early detection of the disease and thereby reducing mortality from the disease in that population. Well-organised and systematically conducted screening, with rigorous internal and external quality control, is effective at the population level and must continue to be offered to the eligible public in Ireland.
2. In line with the Wilson and Jungner criteria,[26] which state that the cost of case-finding (including diagnosis and treatment of diagnosed patients) should be economically balanced in relation to the possible expenditure on medical care as a whole, the recommendations of our Expert Reference Group should not jeopardise the overall cost-effectiveness of screening programmes.[1]
3. The purpose of clinical audit in screening programmes is quality assurance and quality improvement (professional education and development) in order to provide rigorous internal and external quality control.
4. Within each screening programme, an evidence-based definition of an interval cancer must be clearly defined.
5. The rate of interval cancers in each screening programme should be determined using a defined numerator and denominator.
6. Public and stakeholder information and communications regarding the audit processes must be informed by international practice.
7. Public and stakeholder information must clearly state the benefits and limitations of population screening programmes.
8. Communications with patients diagnosed with invasive cancers must be respectful and open, reflecting the HSE values of care and compassion.
9. Recommendations for future clinical audit of interval cancers should be informed by international practice.
10. A standardised, reproducible approach to clinical audit must be established for each screening programme.
11. For the purpose of this work, the clinical audit of interval cancers should focus on two different circumstances:
    a. Planned programmatic reviews as part of a quality assurance process in order to identify areas of improvement, action and implementation, and
    b. Individual case reviews.
12. Acceptable facilities and resources to conduct the clinical audit of interval cancers should be available.

1 Cost-effectiveness analysis (CEA) is defined as an analytical technique intended for the systematic comparative evaluation of the overall cost and benefit generated by alternative therapeutic interventions for the management of a disease.(WHO Guide to Cost-Effectiveness Analysis, 2003)

Section Three: Current Practice in the BowelScreen Programme

Quality assurance in the BowelScreen programme

Governance structures for Quality Assurance and including oversight for key performance indicators and any audit are well established within the screening programme. Details can be found in Appendix 3. All screening programmes report to the Chief Executive Officer of the National Screening Services who is accountable to the Chief Clinical Officer of the HSE.

Key performance indicators

In order to ensure that the BowelScreen programme is effective and adheres to the highest international standards, each step of the screening process is quality assured, monitored and assessed. BowelScreen has published Guidelines for Quality Assurance in Colorectal Screening, which are pivotal to the management of a high-quality screening programme.[7] All targets are continually reviewed in light of experience and revised accordingly with respect to results achieved and best clinical practices. Targets given refer to people aged 60–69 years participating in the BowelScreen programme. Some standards will not be measured for some time, as data are collected over a period of years. Each element of the programme and screening pathway is quality assured, from population coverage and participation rates through to colonoscopy, surgery, and other treatments (Table 4). The quality standards of colonoscopy practice include key performance indicators such as caecal intubation rate (CIR), adenoma detection rate (ADR) and post-colonoscopy colorectal cancer (PCCRC) rate.

Adequate access to high-quality colonoscopy is pivotal for a successful colorectal screening. The FIT's threshold of haemoglobin per gram of faeces and the background prevalence of colorectal cancer in the population determine the rate of referral to colonoscopy. The FIT is more sensitive at a lower threshold, hence more cancers will be detected, but this lower threshold also increases the demand for colonoscopies. Threshold levels internationally range from 20 µg /g of faeces to 150 µg /g of faeces, and this determines both the number of cancers detected and the number of interval cancers. BowelScreen is working closely with the HSE's National Endoscopy Working Group, the HSE's Acute Hospitals Division, the Department of Health, and the National Treatment Purchase Fund to develop a national strategy for endoscopy services. BowelScreen is committed to working in partnership with the National Endoscopy Working Group to promote and drive service improvements across all Hospital Groups. The work streams identified by the group will include developing support plans for capacity and demand, standardised referral pathways, validation and scheduling, quality assurance, and training.

Table 4. Summary of Quality Assurance Standards

Quality standard	Minimum standard	Achievable standard
Completeness of population register	Within 95% of census figures	
Coverage by invitation: Proportion of eligible population on register invited for screening every 2 years	≥95%	100%
Coverage by screening: Proportion of eligible individuals screened in the period (screening round) every 2 years	≥45%	≥55%
Uptake: Proportion of invited individuals who returned a satisfactory FIT kit	≥50%	≥60%
Proportion of invited population who do not respond to invitations within 8 weeks who are sent one reminder	≥95%	100%
Proportion of FIT kits and instructions dispatched within 5 working days to clients who request them	≥95%	100%
Proportion of clients who request and are sent test kits who are sent a reminder if test kit is not received at laboratory within 4 weeks	≥95%	100%
Proportion of FIT samples tested within 2 working days of receipt in laboratory	100%	
Proportion of results of FIT samples tested by the laboratory made available to the National Screening Service (NSS) within 3 working days of receipt of samples in laboratory	100%	
Proportion of positive FIT results notified to screening colonoscopy unit by NSS within 7 working days of receipt of result from laboratory	≥95%	100%
Proportion of FIT result letters to clients dispatched to clients within 5 working days of receipt of result from laboratory	≥95%	100%
Proportion of FIT result letters to general practitioners dispatched within 5 working days of receipt of result from laboratory	≥95%	100%
Proportion of unacceptable tests received by laboratory for measurement	≤3%	≤1%
Proportion of repeat test kits dispatched to clients within 10 working days following receipt of unacceptable test kits by laboratory above)3.5.6	≥95%	100%
Proportion of clients offered a colonoscopy appointment date that occurs within 20 working days from when the client was deemed clinically suitable following pre-assessment	≥90%	100%
Minimum number of colonoscopies (symptomatic and screening) undertaken annually by each screening colonoscopies5.2.2	>300	
Bowel cleanliness at colonoscopy: bowel preparation described as excellent or adequate5.2.3	≥90%	≥95%
Acceptance rate for colonoscopy after positive FIT.	≥85%	>90%
Colonoscopy comfort is recorded	80% should have a comfort score of 1 or 2 on the Gloucester Scale	
Medication used for comfort during lower gastrointestinal (GI) endoscopy is recorded	Auditable outcome	
Use of reversal agents is recorded	<1%	
CIR with photographic evidence (adjusted only for obstructing lesions)	≥90%	≥95%
Perforation rate of colonoscopy	<1 per 1,000 colonoscopies	
Post-polypectomy perforation rate	<2 per 1,000 colonoscopies where polypectomy is performed	

Quality standard	Minimum standard	Achievable standard
Post-polypectomy bleeding requiring transfusion	<1% of colonoscopies where polypectomy is performed	
Percentage of individuals scheduled for surveillance colonoscopy who undergo that procedure within 3 months of scheduled date	≥85%	>90%
ADR, measured in terms of both individual endoscopist and screening colonoscopy unit	≥45% of colonoscopies	≥50% of colonoscopies
Following colonoscopy, the proportion of "no abnormality detected" result letters dispatched to clients within 10 working days of colonoscopy date	≥95%	100%
Following colonoscopy, the proportion of result letters to general practitioners dispatched within 10 working days of receipt of result from screening colonoscopy unit	≥95%	100%
Referral rates for computed tomography (CT) colonography of all clients referred for colonoscopy following a positive FIT	≤10%	
Minimum number of CT colonography cases read per consultant radiologist per year	≥100	
Proportion of CT colonography clients offered a CT colonography appointment date that occurs within 30 working days of receipt of referral	≥95%	100%
Proportion of CT colonography procedures that are complete/adequate	≥90%	
Perforation rate of CT colonography	<1 per 3,000 CT colonography examinations	
Other major complications of CT colonography recorded	Auditable outcome	
CT colonography radiation dose recorded	Auditable outcome	
Large polyps (≥10 mm) visualised and recorded during CT colonography	Auditable outcome	
Cancers visualised and recorded on CT colonography	Auditable outcome	
Prevalence of extracolonic lesions that warrant additional investigation recorded	Auditable outcome	
Turnaround time for report being issued to the programme after CT colonography examination is performed	≤15 working days	≤10 working days
Clients in receipt of abnormal CT colonography report with a CRADS classification of C4 (or other equivalent classification) will have follow-up colonoscopy within 15 working days or be referred to multidisciplinary team (MDT) for a date that occurs within 15 working days	≥95%	≥98%
Clients in receipt of abnormal CT colonography report with a CRADS classification of C3 (or other equivalent classification) will have follow-up colonoscopy within 30 working days or be referred to MDT for a date that occurs within 30 working days	≥95%	≥98%
Proportion of patients with C3 or C4 CT colonography findings who subsequently have biopsy or lesion removed at colonoscopy who were discussed at MDT meetings	≥95%	≥98%
Proportion of histopathology reporting consistent with Faculty of Pathology, Royal College of Physicians of Ireland (RCPI) guidelines and including a clear indication of main diagnosis	≥95%	100%
Proportion of pathologists participating in a national external quality assurance scheme for colorectal screening pathology	100%	
Proportion of histopathology laboratories holding CPA/INAB accreditation or equivalent	100%	

Quality standard	Minimum standard	Achievable standard
Proportion of histopathology laboratories participating in RCPI national histopathology quality assurance scheme	100%	
Proportion of histopathology screening results validated by a named screening pathologist	100%	
Proportion of polyp cancers with double reporting	100%	
Median number of lymph nodes retrieved in non-neoadjuvant treated cases	>12	
Proportion of lesions reported as high-grade dysplasia	≤10%	
Proportion of polyp pT1 cancer (removed by polypectomy or local excision) identified as poor differentiation	≤20%	
Proportion of histopathological biopsy reports authorised and relayed to referrer within 5 working days of receipt of specimen in laboratory	≥90%	100%
Proportion of colon cancer referrals to a surgeon at a designated cancer centre taking place within 10 working days of histological diagnosis	≥90%	100%
Proportion of colon cancer patients offered an admission date for surgery that occurs within 20 working days of histological diagnosis. This will not apply to the small number of patients who require pre-operative chemoradiotherapy.	≥90%	100%
Minimum number of colon cancer resections per surgeon per annum	≥20	
Proportion of rectal cancer referrals to a surgeon at a designated cancer centre taking place within 10 working days of histological diagnosis	≥90%	100%
Proportion of rectal cancer patients offered admission date for surgery on a date that occurs within 20 working days of histological diagnosis where surgery is to be the primary treatment	≥90%	100%
Minimum number of rectal cancer resections per surgeon per annum	≥20	
Proportion of rectal cancer patients whose neoadjuvant therapy is initiated within 30 working days of histological diagnosis where surgery is not the initial treatment	≥90%	100%
Overall proportion of resectable rectal cancer treated by abdominoperineal excision	<30%	<25%
Symptomatic anastomotic leakage rate for each surgeon	<8%	<5%
Crude length of stay (date of admission to date of discharge)	Auditable outcome	
Unadjusted operative and procedural 30-day mortality from date of patient's operation or stent	Auditable outcome	
Return to theatre rate during hospital stay (for any reason)	Auditable outcome	
Neoadjuvant and adjuvant radiotherapy/chemotherapy use (% neoadjuvant, % adjuvant)	Auditable outcome	
Readmission rate within 30 days of operation (for any reason apart from planned readmissions for chemotherapy or radiotherapy)	Auditable outcome	
The followings recorded for all surgeries: Radiologic stage of cancer at time of presentation based on CT and/or magnetic resonance imaging scans American Society of Anesthesiologists grade Position of tumour at rigid sigmoidoscopy (0–5 cm, 6–10 cm, 11–15 cm) (rectal cancer only)	Auditable outcome	
Post-colonoscopy colorectal cancers (PCCRCs)	≤8.6%	≤2.5%

Gastrointestinal Endoscopy National Quality Improvement Programme

The Conjoint Board of the Royal College of Physicians of Ireland (RCPI) and the Royal College of Surgeons in Ireland (RCSI) launched the Gastrointestinal Endoscopy National Quality Improvement Programme (EQI Programme) in October 2011. The programme operates in collaboration with the National Cancer Control Programme and is funded by the HSE Quality Improvement Division. The core tenet of the programme is to provide non-judgmental and encouraging support to participating endoscopy units in collecting and uploading their data and conducting quality improvement activities. The programme gathers performance data on a dedicated information technology-based reporting tool, NQAIS-Endoscopy; 41 units across the public and private sectors are now live on the system. It indicates the quality of endoscopy in Ireland each year and is intended to influence decisions regarding the future of the endoscopy service. Where applicable, the EQI Programme report "minimum" and "achievable" targets that reflect the amalgamation of symptomatic and screening guidelines. National data reports created by the EQI Programme should be used to inform health policies surrounding the endoscopy service in Ireland and to help identify variation in practices between each hospital. Where statistics suggest that there may be an area in need of improvement in a hospital, findings should be confirmed locally using local hospital data. Although data have matured in this third year of analysis, this local confirmation of significant findings remains essential. The Acute Operations Endoscopy Programme has been working to strengthen the role of EQI Programme data in individual unit, Hospital Group and national governance structures for endoscopy. The appointment of Hospital Group Clinical Leads for Endoscopy has been an important development for endoscopy services. The importance of individual users and clinicians accessing their own performance data is also included in updated accreditation standards for endoscopy services published by the UK's Joint Advisory Group on GI Endoscopy (JAG). This is another important development in strengthening and embedding quality improvement in endoscopy.

Management of interval cancers

Calculation of the interval cancer rate

The BowelScreen *Guidelines for Quality Assurance in Colorectal Screening*[7] define both the FIT and post-colonoscopy interval cancers:

- "An interval colorectal cancer (CRC) is one diagnosed following a negative FIT and before the next screening FIT or within three years of the client going over the eligible age.
- A post-colonoscopy colorectal cancer (PCCRC) is the diagnosis of a CRC within three years of a negative screening colonoscopy. Likewise, a CRC diagnosed at the next screening colonoscopy is considered to be a PCCRC if it occurs within three years of the most recent colonoscopy."

The guidelines cite the PCCRC rate as a key quality measure of colonoscopy but acknowledge that "it will be a number of years before the PCCRC rate can be calculated".[7]

Notification of PCCRC

BowelScreen receives notification of PCCRCs from screening units, symptomatic units and the NCRI. BowelScreen documents all PCCRCs at a programmatic level. BowelScreen reviews all PCCRCs in accordance with a standard operating procedure (Appendix 5). The review involves confirmation of the interval cancer and notification to the screening colonoscopy unit. The screening colonoscopy unit is then required to manage the notification under its own clinical governance and risk management structures. This includes review of the screening colonoscopy endoscopy record, any histopathology, and the clinical management decision in order to determine if there are potential explanatory variables, correctible factors or quality issues of concern. The screening colonoscopy unit refers any performance or quality issues to the relevant Hospital Group CEO and to the HSE Acute Hospitals Division.

Currently the BowelScreen programme also reviews the notification, the clinical details of the case and the colonoscopy record and cross references this with the each clinician's adenoma detection rate (objective data) and Caecal Intubation Rate unit audit data.

Independently of this process BowelScreen also reviews the screening colonoscopy units twice yearly Global Rating Scale census returns to JAG. The local endoscopy clinical lead reports on quality control measures and escalates issues arising to BowelScreen.

Faecal immunochemical test

Currently, the threshold for haemoglobin detection is set at 45 µg of haemoglobin per gram of faeces. This target was set based on international experience and endoscopy capacity in Ireland. The threshold was increased in 2017, having been set at 20 µg of haemoglobin per gram of faeces at programme commencement. This FIT threshold resulted in more than 8% of participants being referred for colonoscopy and was undeliverable with current resources. Consequently, the FIT threshold was revised to 45 µg of haemoglobin per gram of faeces. While the threshold lies within the internationally accepted range, there is scope to lower the threshold and increase detection rates when sufficient endoscopy capacity is available.

Open disclosure practice in BowelScreen

The *Scoping Inquiry into the CervicalCheck Screening Programme,* by Dr Gabriel Scally, has recommended that the "NSS should consider, with external assistance, the relevance of the HSE policy on 'Open Disclosure' as it develops in light of this Scoping Inquiry, for all of its screening programmes".[9]

In 2013, the HSE implemented an Open Disclosure Policy across all health sectors. The most recent version of this policy defines open disclosure as "an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident".[30]

The HSE Open Disclosure Policy has been in operation for BowelScreen since 2013, and it is fully endorsed and implemented for patient safety clinical incidents or harms which are "unintended or unanticipated".[8] In keeping with the majority of international screening programmes, BowelScreen has not considered interval cancers as unintended or unanticipated incidents, as they are an accepted, unavoidable occurrence in population screening programmes. As such, a universal disclosure policy has not been implemented for interval cancers by BowelScreen except where harm has been attributed to programme failings. This was most notable following a patient safety incident in one of the programme's endoscopy units in 2014. The management of that incident and the quality assurance measures in place within the BowelScreen programme were reviewed by an external expert following the incident. The BowelScreen programme was found to have implemented open disclosure in an appropriate manner, and this was also cited in the 2018 Scoping Inquiry into the CervicalCheck Screening Programme: "There is evidence that disclosure can be done well from another cancer screening issue in Ireland involving the BowelScreen programme".[9] The report goes on to quote the review of the management of BowelScreen incidents in Wexford, which concluded that "disclosure was handled in an appropriate and timely manner".[10]

Consent processes

All those who participate in the BowelScreen programme do so voluntarily. They receive an invitation letter requesting that they use a Freephone number to contact the BowelScreen programme in order to join the programme. Having contacted and verbally consented to take part in the BowelScreen programme, they are sent an explanatory letter, an information sheet, the home test kit with instructions, and a Freepost envelope in order to return the completed test to the laboratory. Accessible information is also available on the BowelScreen website. Currently, all participants are informed that BowelScreen does not detect all colorectal cancers, and are given information on the signs and symptoms of bowel cancer as well as advice on how to reduce their risk. On return of their completed first test kit to the programme, the participant will receive all subsequent test kits automatically; no additional consent is required.

If the participant receives an abnormal result, they will be offered a colonoscopy appointment. Consent for the colonoscopy procedure is obtained using the screening colonoscopy unit's consent form. A standardised colonoscopy consent form should be employed throughout all endoscopy units participating in the BowelScreen programme. The BowelScreen Working Group has developed a revised consent form incorporating these features (Appendix 6a) to accompany a revised information leaflet (Appendix 6b).

Section Four: International Practice

In order to define international best practices, the Expert Reference Group established contact with international screening service leaders to discuss the approaches to interval cancer measurement, clinical audit and open disclosure in established national, provincial or state cancer screening programmes. A formal survey was undertaken along with a systematic review of the peer-reviewed research literature.

Peer-reviewed literature search

Colorectal cancer screening update

Colorectal cancer is the third most common cancer worldwide and the second most common cause of cancer-related death. In developed countries, 1 in 20 people will develop the disease. Given this major burden on healthcare systems, establishing screening programmes has been a global public health priority.[31] People at average risk are generally offered screening from age 50 onwards, but this varies, as does the screening test used and screening interval (Table 5). Recent studies of screening strategies provide evidence on screening effectiveness for up to 15 years all screening modalities; FIT testing, colonoscopy and sigmoidoscopy.[32]

Taxonomy for reporting interval colorectal cancers

Interval colorectal cancer (CRC) rates are an important indicator of the quality and effectiveness of screening programmes. The Expert Working Group on Right-Sided Lesions and Interval Cancers of the Colorectal Cancer Screening Committee of the World Endoscopy Organization has proposed a standardised nomenclature for defining and reporting on interval CRCs in order to facilitate benchmarking and comparison of interval CRC rates across programmes and regions. The group defined an interval CRC as a “colorectal cancer diagnosed after a colorectal screening examination or test in which no cancer is detected, and before the date of the next recommended exam”.[13] This definition was derived from the International Agency for Research on Cancer (IARC) definition of interval cervical cancer, which is defined as an “invasive cancer diagnosed in an attender after a negative screening; and before the next invitation to screening was due”. [33]

In order to apply the definition of an interval CRC in an organised, reproducible manner, an IARC Consensus Panel recommended the following principles regarding classification:

1. Designation of the test/examination that preceded the diagnosis of cancer

   Interval CRC rates should be reported with the designation of the test that preceded the subsequent diagnosis of cancer.

   For example, within a FIT screening programme, a CRC after a negative FIT screening but before the next FIT is due would be designated a 'FIT interval CRC'. Likewise, within a colonoscopy screening (CS) screening programme, a CRC after a negative screening CS but before the next recommended procedure would be designated a 'CS interval CRC'.

2. Designation of the test/examination to which an interval CRC should be attributed

   The screening test to which an interval CRC is attributed should refer to the most recent, most comprehensive examination performed prior to cancer diagnosis. For example, a cancer after a positive FIT screening and a subsequent negative colonoscopy (but before the interval for the next FIT is due) would be considered a CS interval CRC and not a FIT interval CRC.

3. Designation of the context in which the interval cancer arose

   Screen-detected and non-screen-detected cancers can be reported in the context of the programme which led to the diagnosis, for example, FIT biennial screening, primary colonoscopy (CS) or flexible sigmoidoscopy (FS) screening. In the case described in Principle 2, although this was designated a CS interval cancer, the context was that of a programme of FIT screening, so this cancer can be designated a 'CS interval CRC (within a FIT screening programme)'. In the case of a CS interval CRC, the context can be further described, such as an interval CRC within a screening programme or following opportunistic screening.

4. Numeric calculation and reporting of interval CRC rates

   Ideally, screen-detected and non-screen-detected cancers should be reported as numbers per 100,000 person-years of observation.[44] This measure reflects the observed person time at risk and accounts for loss to follow-up. In contrast, reporting rates per 1,000 persons invited to participate (intention to screen) may preclude accurate comparisons because of variability in participation. The *European guidelines for quality assurance in CRC screening and diagnosis* recently recommended a comprehensive approach to interval CRC rate calculation, adjusting for the CRC incidence in the background population, as well as age-specific and sex-specific variations.[34]

5. Minimum dataset

   The Consensus Panel recommends inclusion of the following data for the documentation of interval CRCs: demographic features (age, sex) of the affected subject and the overall population; the indication for the procedure (e.g. screening, surveillance exam, symptoms); the initial test employed (e.g. guaiac faecal occult blood test (gFOBT), FIT, FS, CS); the context in which the test was performed (e.g. organised screening programme versus opportunistic screening); the recommended surveillance interval (where applicable); the upper age limit for screening (where applicable); the time elapsed from the screening test to CRC diagnosis; and the location, the histopathology and the cancer stage at diagnosis of the CRC. In the case of FIT screening, the test characteristics should be included, in particular the type of test (including type of buffer) and the analytic measurement device. If referring to a quantitative FIT device, the cut-off concentration for a positive test in micrograms of haemoglobin/gram of faeces should be included.[35]

Faecal immunochemical test

The faecal immunochemical test (FIT) analyses stool samples for the presence of blood using a mono- or polyclonal antibody to human haemoglobin. When haemoglobin is present, it forms a complex with the antibody, which can be quantified.[36] The FIT is both more sensitive[37] and specific than the gFOBT. It is specific for human haemoglobin and is therefore less affected than the gFOBT by false positive results from food.[38] Meta-analysis of FIT accuracy has shown an overall pooled sensitivity of 0.79 (95% confidence interval (CI): 0.69–0.86) and specificity of 0.94 (95% CI: 0.92–0.95) for CRC.[19]

The FIT analysis process is automated and allows quantitative analysis of stool blood content, although it is generally reported as a positive or negative result, as the cut-off level at which a positive test is reported is specified and set by the NSS. The higher the threshold, the lower the positivity rate and the higher the specificity and positive predictive value for CRC and advanced adenomas.[37]

The participation rate for FIT is higher than for gFOBT.(39) It is thought that the single sample test and simplicity of the FIT method affects the likelihood of completing the screening process.[40]

Post-FIT/gFOBT interval cancer rate

While population-based screening using the gFOBT is known to be effective in reducing colorectal cancer-specific mortality, it is also known that interval cancer rates are substantial and that they increase as screening programmes mature. In the Scottish demonstration pilot of colorectal cancer screening, the percentage of cancers diagnosed in the screened population that were true interval cancers rose from 31.2% in the first round to 58.9% in the third round.[41] A number of countries have converted from the gFOBT to the FIT in recent years. The level at which FIT thresholds are set determine the sensitivity and specificity of the test: “Increased cancer detection at lower positivity thresholds is counterbalanced by substantial increases in positive tests, and hence, increased pressure on endoscopy services”.[42] The ability to vary the ‘positive test’ cut-off allows screening programmes to adjust the level to provide an acceptable threshold for further investigations without exceeding the capacity of the endoscopy service which will deliver those investigations.[40] Lower thresholds increase the sensitivity but lower the specificity of the screening test. This increases demand for endoscopy services and threshold levels are titrated in accordance with available capacity.[43]

Threshold levels vary internationally, as illustrated in a recent international survey of colorectal screening programmes (Table 5).[44]

Table 5. International screening programme approaches to FIT screening

	Started screening	Started FIT screening	Positivity threshold (µg haemoglobin / g faeces)	Age range
Australia	_	_	20	50–74
Canada (Ontario)	2008	2019	30	50–74
Cyprus	_	_	20	_
Denmark	2014	2014	20	50–74
England	2006	2019	120	60–74
Finland	?	2019	?	60–74
France	2002	2015	20	50–75
Guernsey	_	2018	40	60–70
Hong Kong	2018	2018	?	?
Italy (Piedmont)	2004	2004	20	58–69
Malta	_	2012	20	60–64
Netherlands	2014	2014	47	55–75
New Zealand	2017	2017	40	60–74
Norway	_	2020	15	55–65
Republic of Irl	_	_	40	_
Scotland	2007	2017	80	50–74
Slovenia	2009	2009	20	50–74
Spain (Basque)	2009	2009	20	50–69
Sweden	?	2012	?	?
Taiwan	2004	2004	20	50–74
Wales	2008	2019	150	60–74

Post-colonoscopy colorectal cancer rates

The development of interval CRCs has been shown to be multifactorial: factors can be technical (such as the quality standard of the endoscopy unit, the experience of the endoscopist, and the quality of the procedure), or biological (such as the age of the patient, hereditary cancer syndromes, and missed or incompletely excised lesions).[35] Post-colonoscopy colorectal cancers (PCCRCs) are associated with tumour location, being more commonly found on the right (proximal) side.[45] They are also associated with the characteristics of the tumour, e.g. originating in sessile serrated adenomas, which are difficult to detect.[46] Finally, they are increasingly associated with endoscopist technique.[29, 47]

The PCCRC rate is a key quality indicator of colonoscopy quality. PCCRC rates have been shown to vary depending on the methodology applied to their calculation.[48] The BowelScreen Working Group conducted a review of 3-year PCCRC rates in the published literature to inform BowelScreen standards with regard to PCCRC.

Review of 3-year Post-Colonoscopy Colorectal Cancer Rates in the Published Literature

The implementation of population-based screening has led to a reduction in colorectal cancer-related mortality. Although colonoscopy remains the cornerstone of CRC screening, a small proportion of patients who undergo a negative evaluation will subsequently be diagnosed with CRC – a post-colonoscopy colorectal cancer (PCCRC). The majority of PCCRCs occur as a result of a pre-existing lesion being incompletely excised or missed by the endoscopist.[49, 50] Therefore, the PCCRC rate is a surrogate marker of endoscopic quality assurance.[29, 51]

PCCRC rates quoted in the literature vary considerably, from 1.2% to 10.6%. [48, 52] Although this may be partially due to differences in service quality, it also reflects different methods of defining and calculating PCCRC rates. A variety of interval time cut-off points are reported, with studies using a range of 3-year, 5-year and 10-year screening intervals. The World Endoscopy Organization's consensus statement defines 'PCCRC rate' as the number of PCCRCs divided by the total number of PCCRCs plus the number of detected cancers, expressed as a percentage.[53] PCCRCs are more likely to occur in older comorbid females, arise in the proximal colon and have favourable histopathologic features.[26] The aim of this review was to determine the 3-year PCCRC rate of published studies and to analyse the reported secondary quality assessment indicators.

A systematic literature search of the PubMed and Scopus electronic databases was performed using the Medical Subject Headings (MeSH) terms "colorectal cancer" AND "colonoscopy" AND ("interval cancer" OR "post-colonoscopy cancer"). The search was limited to original articles published in the English language since 2009. In order to determine an accurate PCCRC rate in a westernised population with a colorectal cancer screening programme, only studies from Europe and North America were included. Data extracted from selected studies included: year of publication; location; study design; number of patients and their baseline demographics; method of identification; definition of PCCRC; rate of PCCRC; stage, grade and location of CRCs; caecal intubation rate; withdrawal time; and quality of bowel preparation. Statistical analyses were performed only on the extracted data from selected studies. Basic descriptive statistics were used to summarise the patient, study and outcome data. The PCCRC rate was expressed as a percentage of the total number of detected cancers plus PCCRCs.

For this review, PCCRCs were defined as interval CRCs diagnosed between 6 and 36 months following a colonoscopy (i.e. false negative colonoscopy), and detected CRCs defined as those diagnosed within 6 months of colonoscopy (i.e. true positive colonoscopy). Proximal colon refers to the caecum, ascending and transverse colon up to the splenic flexure, while distal colon refers to the splenic flexure, descending colon, sigmoid and rectum. A specialist endoscopist refers to a clinician who has completed specialist training in either gastroenterology or general surgery and is practising at attending/consultant level.

Six studies [45, 47, 48, 54-56] met the inclusion criteria for this review. The majority of the studies (n=4) were conducted in Canada and the USA [45, 47, 54, 56], with two European studies also included.[48, 55] The six studies included a total of 191,971 CRCs with a colonoscopy in the preceding 36 months, of which 14,492 were PCCRCs, giving a 3-year PCCRC rate of 7.6% (median: 7.69%; interquartile range: 6.42% to 8.2%). The individuals in the PCCRC cohort tended to be older than those in the detected CRC group (mean age 72.7 years versus 71.5 years), were more likely to be female (49% versus 45%), and had a higher incidence of comorbidities (Charlson Comorbidity Index score ≥2: 19.2% versus 13.7%). The majority of studies used population-based registries to collect data, and as a result, they did not have access to the indications for colonoscopy in the study cohorts. One study [56] conducted a retrospective chart review of PCCRC cases and reported that 62.5% of the PCCRC cohort was in a screening programme, with the remainder being symptomatic.

PCCRCs were more likely to be detected at an earlier pathological stage, with 66% reported as Tumour, Nodes, Metastases (TNM) stage I or II, compared with just 53.5% of the detected CRCs at stage I or II. In addition, PCCRCs were more likely to be proximally located (51.4% versus 39.6%). Secondary quality assessment indicators were generally poorly reported across the included studies. None of the studies recorded the withdrawal time or the caecal intubation rate of the PCCRC cohort.

This review showed a PCCRC rate of 7.6% over a 3-year time period, which is in keeping with previous published reports.[48, 57] However, it can be difficult to ascertain an accurate PCCRC rate, as the definition of PCCRC varies between institutions, as do the methods used to calculate PCCRC rates. For this review, the interval time period was defined as 6–36 months following index colonoscopy. Some studies define PCCRCs as those occurring within 6–36 months of colonoscopy but preclude any endoscopic diagnoses from being labelled PCCRCs, thus focusing on other diagnostic methods (e.g. radiological),[58] while others necessitate an endoscopic diagnosis.[45, 54]

Quality assessment measures recommended by the British Society of Gastroenterology and the Association of Coloproctology of Great Britain and Ireland advise that endoscopic units have a target PCCRC rate of <5% at 3 years.[51] Only one of the six studies in this review met this target, and the overall rate of 7.6% is significantly higher than recommended. At present, a lack of standardisation hampers accurate assessment of PCCRC rates, emphasising the need for a collaborative approach in order to improve cancer prevention strategies.[59]

The term ‘post-colonoscopy colorectal cancer rate’ can be misleading, as it refers not to the rate of CRC diagnosis following colonoscopy, but rather to the percentage of endoscopically diagnosed cancers that had a negative colonoscopy in the preceding 3 years. It is calculated as follows:

$$\frac{\text{no.of PCCRCs (false negative colonoscopies)}}{\text{no.of PCCRCs (false negatives) + detected CRCs (true positives)}} \times \frac{100}{1}$$

This terminology can be confusing to patients, and care must be taken to ensure accurate use of these statistics during the consent process. Morris et al. note that a more patient-centric denominator might be the total number of colonoscopies, including true negatives, over a 3-year period.[48] Assuming a colonoscopy cancer detection rate of 1%, the risk of PCCRC would be in the order of 0.076% for all colonoscopies performed in a unit. Adherence to the recommended methods [53] of calculating and reporting PCCRC rates among endoscopy units will enable comparability between services and ultimately maximise the benefit of screening programmes.

International survey

A formal survey was undertaken by the Programme Evaluation Unit within the National Screening Service in order to gather information from international population-based bowel screening programmes on their processes for the audit and review of interval bowel cancers. The survey was circulated to 20 screening programmes in May 2019, 65% of which responded. The survey covered areas such as whether interval cancers were audited and how, and whether open disclosure was applied to the findings of interval cancer audits. The questionnaire and detailed findings can be found in Appendix 7a and 7b.

The main findings of the survey are outlined below:

- Seven responding programmes have an audit process in place for interval colorectal cancers, while six countries/regions do not have an audit process in place for interval bowel cancers.
- All seven programmes that carry out audits monitor the post-gFOBT/FIT interval cancer rate, while six of those programmes also monitor post-colonoscopy colorectal cancers (PCCRCs).
- Only one programme conducted individual case reviews of interval cancers.
- None of the seven programmes that carry out audits offered patients a choice with regard to participation in the audit, but three programmes captured consent to audit in the routine consent procedure for screening.
- Of the seven countries/regions that carry out audits of interval cancers, four have an open disclosure policy for medical incidents.
- Of the four countries/regions that have an open disclosure policy for medical incidents, one answered 'yes' to having an open disclosure policy that applies to interval cancers in screening.
- Three countries/regions provided information regarding the type of information provided to patients. The communication pathway is under development in one region, it is non-standardised in one region, and in the third country/region, the patient is only informed of a PCCRC. Patients are not informed following a negative gFOBT.

The Expert Reference Group's response to the recommendations in *Cervical screening in cases of cervical cancer in Ireland between 2008-2018: RCOG Independent Expert Panel Review*

In December 2019, following the publication of the Royal College of Obstetricians and Gynaecologists' (RCOG's) Independent Clinical Expert Panel Review of CervicalCheck, the Minister for Health requested that the Expert Reference Groups incorporate consideration "of the Expert Panel's recommendations on interval cancer audit and disclosure in their ongoing deliberations, along with international best practice and consideration of the wider environment including any other expert input the groups deem necessary".[60]

The Expert Reference Group considered these recommendations (Appendix 4). They were helpful in our deliberations, but do not change any of the recommendations in our report.

Section Five: Proposals for the Management of Interval Cancers in the BowelScreen Screened Population

Consent and informational material in the BowelScreen screening programme

All those who participate in the BowelScreen programme do so voluntarily. They receive an invitation letter requesting that they contact the BowelScreen programme in order to join the programme. Having contacted and consented to be part of the BowelScreen programme, they are sent an explanatory letter, an information sheet and a home test kit. Accessible information is also available on the BowelScreen website. Currently, all participants are informed that BowelScreen does not detect all colorectal cancers. Existing informational material does not describe the conduct of case reviews or any information for patients on how they might request a review of their case should they experience a PCCRC.

Recommendation 1: Participants should continue to be provided with all the information they require in order to make an informed choice to consent to participate in the BowelScreen programme. Informational materials should be revised to strengthen the information on the benefits and limitations of screening. These materials should include explicit information on the occurrence of interval cancers and information on the opportunity to discuss their case should a patient develops a PCCRC. Expanded content on data sharing arrangements between BowelScreen and the National Cancer Registry Ireland (NCRI) should be included. A standardised colonoscopy consent form should be employed throughout all endoscopy units participating in the BowelScreen programme. The revised consent form developed by the BowelScreen Working Group should be piloted for this purpose (Appendix 6a).

Interval cancer rates

The international survey and peer review literature search have shown that while many colorectal cancer screening programmes do not monitor interval cancer rates, those that do so calculate post-gFOBT/FIT rates and PCCRC interval cancer rates. Neither rate has been calculated by the BowelScreen programme to date. Because of the age of the programme, sufficient data have not yet been collated with which to calculate either interval cancer rate. The process of recording and reporting the interval cancer rate for the BreastCheck screening programme has already been established.

The threshold at which FIT sensitivity is set varies between programmes. Upon its establishment in 2012, the BowelScreen programme set the threshold at 20 µg of haemoglobin per gram of faeces. It was subsequently increased in 2017 to 45 µg of haemoglobin per gram of faeces. Internationally, the approach to developing screening programmes differs and is primarily driven by cost and resource constraints, such as endoscopy unit capacity. Increasing the sensitivity of the FIT by changing the threshold at which it is deemed positive will lead to more cancers being diagnosed and to more polyps/adenomas, which could develop into cancer, being detected and removed. Workforce, including colonoscopy capacity, is the rate-limiting factor in implementing these changes.

The age group screened remains set at those aged 60–69 years, with plans to extend eligibility to the full 55–74 age group from 2021 onwards. Furthermore, the most recent published data (2016–2017) show a 41.4% uptake in the current 60–69 target population. This falls short of the BowelScreen target of 50% uptake and the European Guideline target of 65% uptake. However, endoscopy capacity is insufficient to meet current demand, and expansion is required in order to extend the eligibility criteria as originally planned.

Recommendation 2: Implementation of the recommendations of the Scally Report should ensure that communication with NCRI is strengthened to enable a more timely validation of interval cancers and the calculation of the interval cancers rate in the BowelScreen programme.

- Processes should be put in place to calculate the PCCRC rate in BowelScreen. The rate should be calculated as follows:

$$\frac{\text{no.of PCCRCs (false negative colonoscopies)}}{\text{no.of PCCRCs (false negatives) + detected Colorectal Cancers (true positives)}} \times \frac{100}{1}$$

- The maximum rate should be set at 8% and an achievable rate of 5%.
- Notwithstanding capacity concerns, the BowelScreen Working Group recommends calculation of the post-FIT interval cancer rate to inform the determination of the FIT threshold, and to inform international scientific opinion on the sensitivity/specificity of FIT screening. Because of the known limitations of FIT as a screening test, the BowelScreen Working Group does not recommend individual case review or open disclosure of post-FIT interval cancers.

Notification of PCCRC

BowelScreen receives notification of PCCRCs from screening units, symptomatic units and the NCRI. BowelScreen documents all PCCRCs at a programmatic level. This is in keeping with most international programmes.

The current practice whereby BowelScreen also reviews the notification, the clinical details of the case and the colonoscopy record and cross references this with each clinician's adenoma detection rate (objective data) and Caecal Intubation Rate unit audit data is not in compliance with GDPR.

This activity is more appropriately undertaken by the Clinical Director/Endoscopy Lead at the local screening unit. In the absence of any cytological or radiological material to review, it is acknowledged that it is not possible to definitively determine, on review, whether or not a lesion is an interval cancer that was missed on colonoscopy. However, the local endoscopy clinical lead remains responsible for reporting on quality control measures and escalation of concerns including those pertaining to PCCRC.

Recommendation 3: BowelScreen will record PCCRCs from multiple sources; screening units, symptomatic units and the NCRI to allow calculation of the PCCRC rate and monitoring of PCCRC. In compliance with GDPR, BowelScreen will no longer process or review any other patient identifiable information following notification of a PCCRC. Rather, the local Clinical Director/Endoscopy Lead will be responsible for the conduct and disclosure of reviews. The local Clinical Director/Endoscopy lead will be responsible for the escalation of any concerns arising following a review of PCCRC. The programme will continue to monitor KPIs independently of PCCRC notification.

Patient-Requested Review

This refers to the written request of the patient to review their screening colonoscopy. In routine practice, the record of the screening colonoscopy is reviewed once a PCCRC is diagnosed. In most cases, the patient will be diagnosed with a PCCRC in the same unit where the initial screening colonoscopy performed. Under the BowelScreen MOU with local screening units, the local unit is required to openly discuss the diagnosis, treatment plan and review of the screening colonoscopy with the patient following diagnosis of a PCCRC. If this doesn't take place as a matter of routine the patient may request a review. GDPR precludes the disclosure of individual endoscopist's NIQAS data as part of patient-requested case review. In circumstances where the location of the PCCRC diagnosis differs from the Screening Unit, the Screening Unit is obliged to communicate openly with the treating unit and provide all relevant clinical information.

Recommendation 4: In accordance with the BowelScreen MOU with local screening units, the local unit will continue to openly discuss the diagnosis, treatment plan and review of the screening colonoscopy with the patient following diagnosis of a PCCRC. The Screening Unit will respond to any request from the patient to conduct a review of their screening colonoscopy and to meet for full disclosure of the findings of that review.

Rebuilding trust and understanding

Interval cancers, including false negative cases, are an inevitable and unavoidable part of all screening programmes, and measures to implement an open disclosure policy for interval cancers in BowelScreen will help to communicate, but not eliminate, their occurrence. Implementation of open disclosure practices will require appropriate support that considers many factors.

Recommendation 5: The HSE should continue to build and promote understanding of, and public trust in, BowelScreen and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Participants should be made aware that they may, separately from any review process, request access to their records at any time.

Implementation and monitoring

The HSE should establish an implementation team to immediately progress and ensure implementation of these recommendations. The team should include representatives from the BowelScreen programme, external endoscopy experts, patient representatives, and support from both an administrative and a quality and safety perspective. Processes should be continually monitored in the context of updates to the Patient Safety Bill 2018, the GDPR and emerging international practice. The team should provide quarterly implementation progress reports to the Chief Executive Officer of the National Screening Service.

Recommendation 6: The necessary resources should be provided to BowelScreen in order to implement these recommendations. An implementation team should be established in order to ensure continued implementation of disclosure according to the outlined recommendations. Processes should be continually monitored in the context of updates to the Patient Safety Bill 2018, GDPR, and emerging international practice.

Consideration of implications of recommendations

- This document provides the “operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population”, as required by its Terms of Reference with specific reference to the assessment of overall programme performance, the conduct of patient-requested case reviews of interval cancers, consent, and open disclosure (Appendix 1).
- As noted in the recommendations above, the HSE should proceed with the establishment of an implementation team to immediately progress these recommendations. The implementation team should also monitor the effects of the recommendations on all aspects of the functioning of BowelScreen, including the ongoing delivery of the programme, public trust, patient safety, efficacy and cost-effectiveness.
- The recommendations of this report provide for immediate and ongoing access to patient-requested case reviews of interval cancers with disclosure under a BowelScreen MOU following notification of a PCCRC. However, there is no standardised, reproducible review methodology and it involves communication with symptomatic units, treating clinicians, pathologists and other members of the multidisciplinary team. GDPR precludes the disclosure of individual endoscopist’s NIQAS data as part of patient-requested case review and further discussion with the National Endoscopy Programme will be required in this regard under the implementation plan.
- The Expert Reference Group wishes to highlight that the implementation of these recommendations will have significant resource implications if BowelScreen is to meet the needs of patients, their families, and clinicians as outlined in the main report.

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Appendices: Appendix 1

Terms of Reference

Clinical Audit of Interval Cancer in the Screened Population

TERMS OF REFERENCE

11 September 2019

Background

Population screening is a public health tool designed to reduce population mortality and/ or morbidity by early detection. Each screening test is therefore aimed at identifying people who are asymptomatic but who are at higher risk of having or developing the condition screened. All programmes aim to maximise the benefits of early detection while minimising potential harms. Screening tests are not perfect and while such programmes have contributed to a significant reduction in deaths and disease morbidity, not all people diagnosed with the disease will have been detected by screening. Given the limitations of screening, false negative and false positive cases are unfortunately an inevitable and expected outcome. There are international and national guidelines describing anticipated false negative and false positive rates in a screening programme that is working even to the highest standards.

A cancer diagnosed in the period of time after a negative screening test and before the next screening episode is referred to as an interval cancer. Interval cancers are an inevitable, anticipated and unavoidable component of every screening programme. Indeed, there are published reports and guidelines detailing the expected rate of interval cancers in a population screening programme.

Quality Assurance (QA) is a central component of population based screening programmes. A robust QA programme ensures that each programme is functioning to a satisfactory level. All quality measurements are bench marked, collated and complied with National and International standards. The monitoring of the rate of interval cancer is one of many programme performance indicators which together allow those delivering the programme to reassure health authorities and patients about the quality of the service offered.

Audit and feedback are used in all health care settings, involving all health professionals, either as individual professions or in multi-professional teams. Clinical audit is an essential element in quality improvement and patient safety.

In Ireland, the three cancer screening programmes have different timelines and technologies.

This review will identify the key principles and processes upon which the future practice of audit of interval cancers will be based.

Purpose

To define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice.

Objectives

Having regard to the findings of the Scally Review, international best practice and any other evidence deemed appropriate, the Expert Reference Group (ERG) is asked to

1. Establish the current audit practices of the three cancer screening programmes and compare to international best practice.
2. Establish any review practices, in relation to interval cancers, of the three cancer screening programmes, and compare to international best practice.
3. Determine best internationally accepted practice for addressing interval cancers.
4. Develop, in line with National Standards for Clinical Practice Guidance Development, operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population. This guideline should:
   - 4.1. Review standardised informed consent processes
   - 4.2. Outline the potential role of audit in such situations in Ireland, such that cancer screening programmes may be assessed with regard to their operation within agreed standards. This will take into account feasibility, safety, practicality, cost-effectiveness, legality and risk. Appraise the various options available and outline the future method of clinical audit and review in Ireland.
   - 4.3. Outline the future methodology for individual case review in such situations in Ireland including any data protection requirements.
   - 4.4. Establish a process for open disclosure and communication as it pertains to both interval cancer audit and to individual case review for a service user. This will take into account the HSE open disclosure policy, legislative requirements and best practice guidelines. This will also take account of patient's needs, ethical responsibilities, the impact on healthcare professionals and programme sustainability.
5. Outline the benefits and challenges for the National Cancer Screening Programmes regarding implementation of the proposed systems of audit of interval cancer.
6. Recommend the commencement date for the newly proposed system of audit of interval cancer.

Patient Engagement

The Expert Groups will ensure that there is patient engagement as a key input to the design of the new audit and review process. The Expert Groups will include two patients and / or public representatives. In addition, the design process will include consultation with the relevant Public & Patient Involvement (PPI) forums and research will be undertaken on the approach to the audit and review process in other EU countries, which will also indicate the approach taken with the public and patients.

Scope

The Screening Programmes covered by the clinical audit of interval cancers will be:

- CervicalCheck (the National Cervical Cancer Screening Programme)
- BreastCheck (the National Breast Cancer Screening Programme)
- BowelScreen (the National Colorectal Cancer Screening Programme)

Deliverables

A document for each of the three cancer screening programmes will be developed and will detail recommended processes based on agreed principles and guided by best practice.

These three documents will form part of an overarching operational policy document for cancer screening.

Governance

There will be an overarching Steering Group with two Expert Reference Groups. The Steering Group will comprise the two commissioners and the two Expert Reference Group chairs. There will be a shared project secretariat to ensure alignment between the two Expert Reference Groups.

The two Expert Reference Groups will be:

- Cervical and Bowel Screening
- Breast Screening

There will be three working groups which will support each respective screening programme.

The Steering Group will bring the report to the HSE Leadership Team for final approval.

Membership

The Project Steering Group has oversight of the entire project. The steering group will agree principles and approve recommendations from the Expert Reference Groups. It will comprise the two HSE review commissioners and the two chairpersons, supported by the Office of the Chief Clinical Officer.

All screening programmes will adhere to overarching principles. The expert group membership will comprise of:

- External Chairperson
- Patient Advocates
- Patient Representatives
- Screening Clinicians
- International Screening Experts
- Academic and research expertise
- National Clinical Programme leads
- Clinical Audit expertise
- Public Health

Project Secretariat

A project secretariat will be formed with a project manager appointed and support provided by the NSS Programme Evaluation Unit (PEU), Library services, Legal Services, Public Health and the National Cancer Control Programme.

Project Process

The project will be approached in four stages:

Stage 1: An international literature search and communications with other international and regional cancer screening programmes

Stage 2: Development and design of the draft audit cycle, tools and methodologies

Stage 3: Consultation with key stakeholders (i.e. Patient Representatives, HIQA, DoH, SCA) re draft proposals

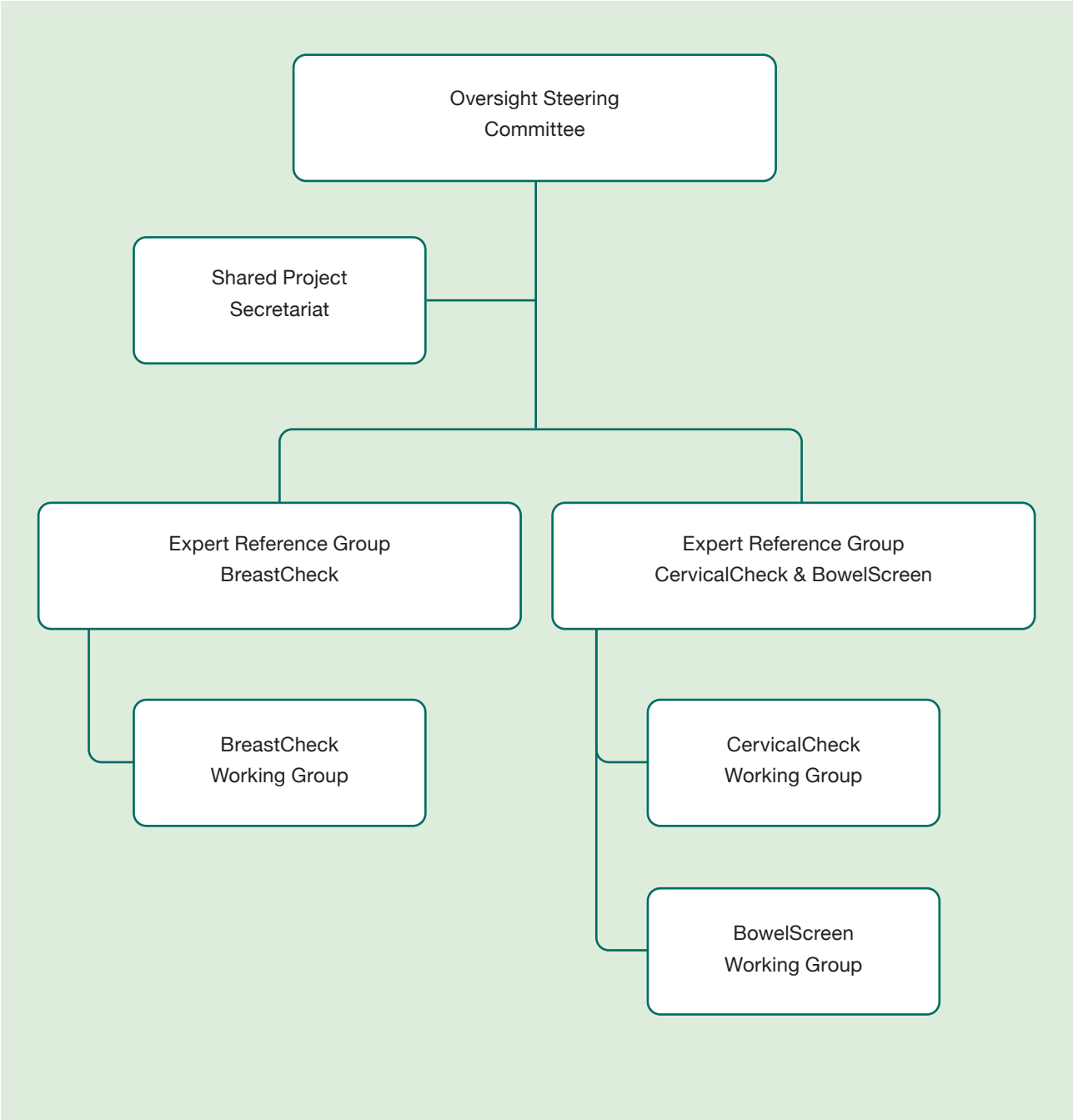
Stage 4: Review and final report

Timeframe

To report within four-six months from its first meeting.

Appendices

Clinical Audit of Interval Cancer in the Screened Population



Clinical Audit of Interval Cancer in the Screened Population

Members List

Project Oversight Steering Group

Project Commissioner - Chief Clinical Officer, HSE	Dr Colm Henry
Project Commissioner - National Screening Service, National Director	Damien McCallion
Chair - CervicalCheck & BowelScreen Expert Reference Group	Professor Susan O'Reilly
Chair - BreastCheck Expert Reference Group	Professor Risteárd Ó Laoide
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy
Chief Clinical Office, General Manager	Deirdre McNamara

CervicalCheck & BowelScreen Expert Reference Group

Chair	Professor Susan O'Reilly
Clinical Director CervicalCheck, NSS/CervicalCheck Working Group Co-Chair	Dr Lorraine Doherty
National Clinical Director, National Women and Infants Health Programme/CervicalCheck Working Group Co-Chair	Dr Peter McKenna
Interim Clinical Director BowelScreen / BowelScreen Working Group – Co Chair	Professor Pádraic MacMathuna
Professor of Public Health, UCC/BowelScreen Working Group – Co Chair	Professor Orla Healy
National Cancer Registry Ireland, Director	Professor Kerri Clough
Director of Public Health, NSS	Dr Caroline Mason Mohan
National Cancer Control Programme, National Director	Dr Jerome Coffey
Consultant Epidemiologist/Director of Evaluation, NSS	Professor Patricia Fitzpatrick*
National Office of Clinical Audit	Professor Conor O'Keane
Associate Professor of Healthcare Ethics, RCSI	Professor David Smith
BreastCheck Nurse Specialist, NSS	Ruth Conboy
International External Expert on Screening	Dr Ameli Trope
Public and Patient Representative	Marie Meaney
Public and Patient Representative	Bridget Doherty
Public and Patient Representative	Niall Coffey

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence
NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

BreastCheck Expert Reference Group

Chair	Professor Risteárd Ó Laoide
Lead Clinical Director BreastCheck outgoing / Consultant Radiologist, NSS	Professor Ann O'Doherty
Lead Clinical Director BreastCheck incoming / Consultant Radiologist, NSS	Professor Fidelma Flanagan
Consultant Surgeon, BreastCheck, NSS	Mr Martin O'Sullivan
Head of School of Medicine / Professor of Surgery, RCSI	Professor Arnold Hill
Director, National Cancer Control Programme	Dr Jerome Coffey
Public Health, National Cancer Control Programme	Dr Deirdre Murray
Consultant Epidemiologist / Director of Programme Evaluation Unit (PEU), NSS	Professor Patricia Fitzpatrick*
Director of Public Health, NSS	Dr Caroline Mason Mohan
National Office of Clinical Audit	Professor Conor O'Keane
Associate Professor of Healthcare Ethics, RCSI	Professor David Smith
National Cancer Registry Ireland, Director	Professor Kerri Clough
Head of Services and Advocacy, Irish Cancer Society	Donal Buggy
General Practice MD	Dr David Hanlon
Psychologist	Dr Marie Ward
Dean, Faculty of Radiology, RCSI	Dr Niall Sheehy
Faculty of Radiology Representative	Dr Patricia Cunningham
Health Economist, UCC	Dr Brian Turner
International External Expert on Screening	Solveig Hofvind (Norway)
International External Expert on Screening	Kristina Lang (Switzerland)
Patient and Public Representative	Clara Clark
Public and Patient Representative	Eileen Woods
Public and Patient Representative	Brigid Doherty
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence
HSE: Health Service Executive; NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

CervicalCheck Working Group

CervicalCheck Clinical Director (Co-Chair)	Dr Lorraine Doherty
National Clinical Director, National Women and Infants Health Programme (Co-Chair)	Dr Peter McKenna
Gynaecologist/Colposcopy Consultant	Dr Francois Gardeil
Gynaecologist/Colposcopy Consultant	Dr Gunther Von Bunau
Gynaecological Oncologist Consultant	Professor Donal Brennan
General Practice MD	Dr David Hanlon
CervicalCheck Laboratory Coordinator, NSS	Maeve Waldron
Nurse Colposcopist	Anne Redmond
CervicalCheck National Laboratory Quality Assurance Lead, NSS	Dr Dave Nuttall
Medical Virologist, Director, National Virus Reference Laboratory	Dr Cillian F. De Gascun
Head of Programme Evaluation Unit, NSS	Dr Therese Mooney
CervicalCheck Programme Manager	Gráinne Gleeson
Primary Care Representative	Anne Marie Ellwood
Patient and Public Representative	Sheera Harmon
Patient and Public Representative	Moira Dillon
CervicalCheck Report Writer	James McGrath
Lead Project Report Writer	Professor Orla Healy

BowelScreen Working Group

Interim Clinical Director BowelScreen / BowelScreen Working Group Co Chair	Professor Pádraic MacMathuna
BowelScreen Working Group Co Chair / Professor in Public Health, UCC	Professor Orla Healy
Colorectal Surgeon	Professor Des Winter
Consultant Gastroenterologist, UHG	Dr Eoin Slattery
ANP / CNM Nurse Endoscopist	Ann Cooney
BowelScreen Programme Manager, NSS	Hilary Coffey
Public and Patient Representative	Tom O'Keefe
Public and Patient Representative	Celia Hogan

UCC: University College Cork. UHG: University Hospitals Galway. NSS: National Screening Service

BreastCheck Working Group

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Lead Clinical Director BreastCheck incoming / Consultant Radiologist, NSS	Professor Fidelma Flanagan
Lead Clinical Director BreastCheck outgoing / Consultant Radiologist, NSS	Professor Ann O'Doherty
Clinical Director, BreastCheck Western Unit / Lead Consultant Radiologist, NSS	Dr Aideen Larke
Clinical Director, BreastCheck Southern Unit, / Lead Consultant Radiologist, NSS	Dr Alissa Connors
Consultant Surgeon, BreastCheck, NSS	Mr Martin O'Sullivan
Consultant Histopathologist, NSS	Professor Cecily Quinn
National Radiography Service Manager, NSS	Suzanne Lynch
Consultant Epidemiologist / Director of Programme Evaluation Unit (PEU), NSS	Professor Patricia Fitzpatrick*
Director of Public Health, NSS	Dr Caroline Mason Mohan
BreastCheck Nurse Specialist, NSS	Ruth Conboy
Head, Programme Evaluation Unit, NSS	Dr Therese Mooney
BreastCheck Report Writer / Research Fellow RCSI	Dr Maeve Mullooly
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence
HSE: Health Service Executive; NSS: National Screening Service; PEU: Programme Evaluation Unit; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

Project Secretariat

Project Manager, NSS	Antoinette Morley
Executive Assistant, NSS	Administrative Team
Head of Programme Evaluation Unit, NSS	Dr Therese Mooney
Clinical Librarian	Gethin Smith
HSE Legal Advisor	Philip Lee

NSS: National Screening Service

Appendix 2: Wilson and Jungner

The criteria of Wilson and Jungner classic screening criteria as outlined according to the World Health Organisation are outlined below[1]

The condition sought should be an important health problem.

There should be an accepted treatment for patients with recognized disease.

Facilities for diagnosis and treatment should be available.

There should be a recognizable latent or early symptomatic stage.

There should be a suitable test or examination.

The test should be acceptable to the population.

The natural history of the condition, including development from latent to declared disease, should be adequately understood.

There should be an agreed policy on whom to treat as patients.

The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.

Case-finding should be a continuing process and not a 'once and for all' project.

These criteria continue to be monitored and updated and a synthesis of emerging screening criteria proposed over the past 40 years as outlined by the World Health Organisation are outlined below:

The screening programme should respond to a recognized need.

The objectives of screening should be defined at the outset.

There should be a defined target population.

There should be scientific evidence of screening programme effectiveness.

The programme should integrate education, testing, clinical services and programme management.

There should be quality assurance, with mechanisms to minimize potential risks of screening.

The programme should ensure informed choice, confidentiality and respect for autonomy.

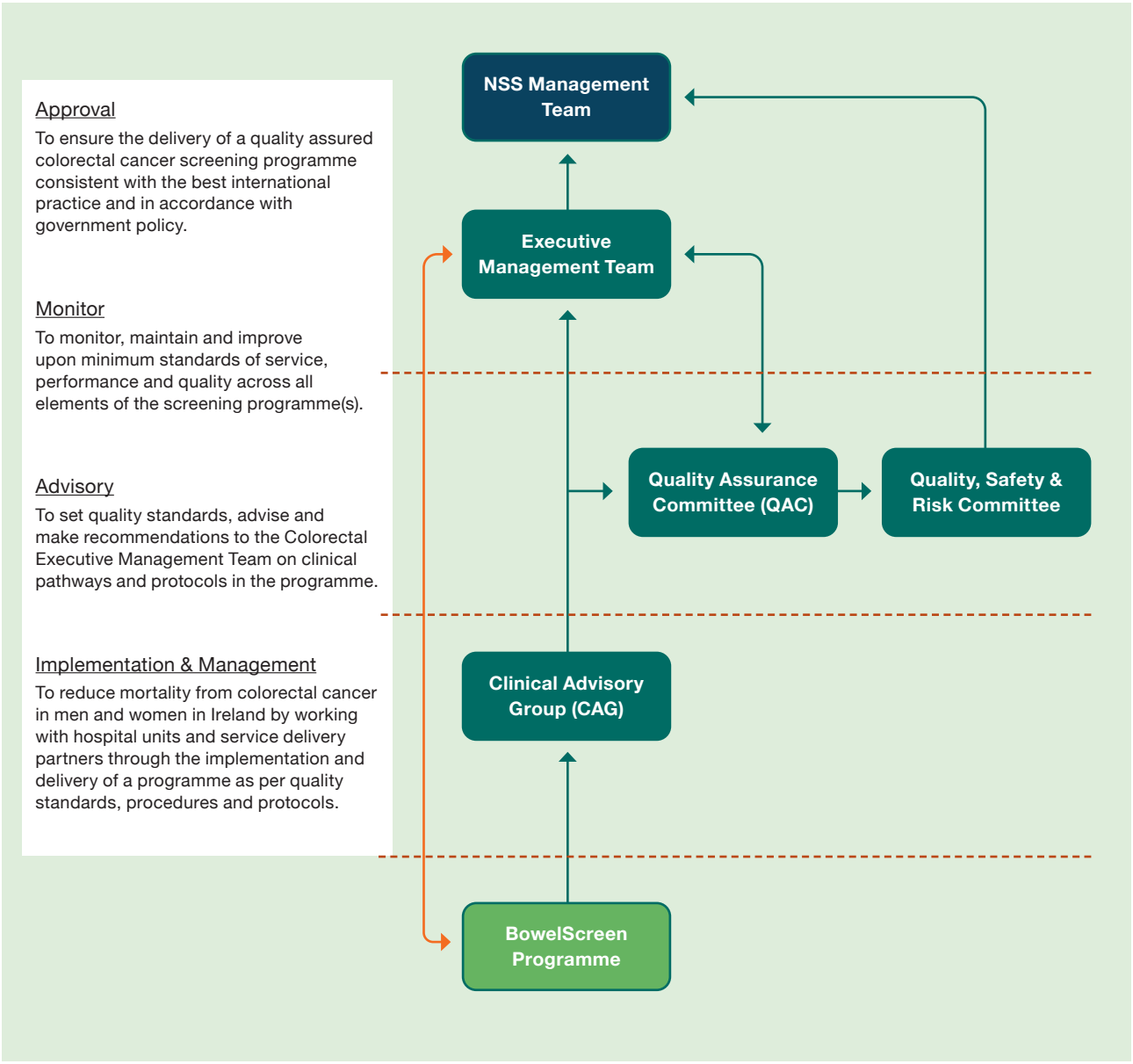
The programme should promote equity and access to screening for the entire target population.

Programme evaluation should be planned from the outset.

The overall benefits of screening should outweigh the harm.

Appendix 3

BowelScreen Governance Structure



Appendix 4

Letter to Expert Reference Group post RCOG

Feidhmeannacht na Seirbhise Sláinte
Health Service Executive

Office of the Chief Clinical Officer
Dr Steevens' Hospital
Steevens' Lane, D08 W2A8
email: cco@hse.ie

Oifig an Príohoifigeach
Cliniciúil Eatromhach Ospidéal
Dr. Steeven, Baile Átha Cliath 8, D08 W2A8

By Email Only

11th December 2019

Prof. Susan O'Reilly

RE: Interval Cancer Audit & Review - BreastCheck Expert Reference Group

Dear Susan,

The aggregate report of the Independent Clinical Expert Panel Review of Cervical Check, completed by the Royal College of Obstetrics & Gynaecology was published on the 3rd December 2019. The report makes ten recommendations overall and recommendation four; five and six specifically refer to clinical audit of cancers in the screening programme.

The Minister is requesting that the Expert Reference Group for Bowel and Cervical Screening would consider these recommendations in relation to international best practice and the functioning of the screening programme.

I wish to acknowledge the significant work, which has been completed to date by the Expert Reference Group and welcome your feedback regarding these recommendation before the end of January 2020.

Dr Colm Henry
Chief Clinical Officer

Damien McCallion
HSE National Director
Emergency Management &
Director General CAWT

Appendix 5: SOP post notification of a post colonoscopy colorectal cancer (PCCRC) (interval cancer)

Response to the notification of a post colonoscopy colorectal cancer (PCCRC) (interval cancer)

Written /Revised By (Title)	Name	Signature	Date
Interim Clinical Director	Prof Pádraic MacMathuna		
Approved By (Title)	**Name**	**Signature**	**Date**
Programme Manager BowelScreen	Ms Hilary Coffey		
Interim Clinical Director & Chair of CR Clinical Advisory Group	Prof Pádraic MacMathuna		

Document Revision History

Rev	Change Details	Revised By	Date
1	Initial Release	N/A	8/6/15
1.1	Add “if applicable” to point 2 on appendix	CAG	18/6/18
2	Reviewed and remained unchanged CAG 24/9/18. No need to circulate Rev2 1/4/19 Update to Rev2.1 to remove Prof O’Donoghue from “Appendix BowelScreen PCCRC Case Report Format”	CAG	24/9/18
3	• Add explanation of PCCRC • Remove reference to interval cancer. • Remove requirement for reviewing 50 sequential photos of the caecum. • Delete questions from the SOP that are on appendix. • Add question re verifying the event is reported on NIMS by the screening colonscopy unit. • Add section re case review, including photography, bowel prep quality and polypectomy.		
4			

1. Purpose & Scope (including Quality Standards)

1.1. To outline the actions following the notification of a post colonoscopy colorectal cancer.

1.2. A post-colonoscopy colorectal cancer (PCCRC) is the diagnosis of a CRC within three years of a negative screening colonoscopy.

1.3. Likewise, a CRC diagnosed at the next screening colonoscopy is considered to be a PCCRC if it occurs within three years of the most recent colonoscopy

2. Responsibility

2.1. Responsibility for Implementation of document: Programme Manager and Clinical Director.

2.2. Responsibility for Upkeep of document: Clinical Director

3. References

3.1. HSE Open Disclosure Policy

3.2. National Cancer Screening Service Guidelines for Quality Assurance in Colorectal Screening

3.3. CR-QP-002 Appendix BowelScreen PCCRC Case Report

4. Method

4.1. BowelScreen CAG follow the checks a in CR-QP-002 Appendix BowelScreen PCCRC Case Report.

4.2. BowelScreen CAG to review case documentation and to classify case notification as either (1) PCCRC (non-surveillance) or (2) surveillance PCCRC

4.3. BowelScreen CAG to make recommendation of either (1) 'PCCRC – no further investigation required' or (2) 'PCCRC – further investigation required'.

4.4. Complete case notification report (Appendix)

4.5. BowelScreen Executive Management Team to review and approve case notification report

4.6. BowelScreen to send a copy of the case notification report to the relevant screening colonoscopy unit

4.7. In the event of "PCCRC – further investigation required" the NSS Head of Screening or CEO to notify National Director.

4.8. Based on the findings of any such investigation the NSS will act on the further recommendations of CAG

5. Quality Control & Audit

Nov 2021

Appendix 6a

Revised Colonoscopy Consent

What is a colonoscopy? A colonoscopy is a procedure in which the endoscopist passes a thin flexible tube through the anus (back passage) to examine the large bowel (colon).This allows the endoscopist to check for a number of conditions such as inflammation, hemorrhoids (piles), polyps and cancer. During the test biopsies (small pieces of tissue) may be taken and polyps can be removed.

What will happen during the procedure? You will be checked in by an administrator on arrival and then a nurse will call you and complete a medical questionnaire. **Please bring a list of all medications with you.** You will be shown to a room/cubicle where you will be given a gown to wear for the test. An IV (intravenous) line will be inserted into your arm.

In the endoscopy room the nurse will go through a safety check and your blood pressure, pulse and oxygen levels will be monitored throughout the procedure. You will be instructed to lie on your left side. Sedation can be given at this stage if required. Being relaxed and comfortable is the desired effect of the sedative. The endoscopist will then commence the test by performing a digital (finger) examination of the rectum. This allows lubrication of the area and examination for hemorrhoids. The scope is then passed through the anus and advanced up through the colon. The endoscopist will inflate your colon with either water or air to get a good view of the colon. You will be encouraged to pass air during the test. You will also be asked to move from side to side or over onto you back during the test. The nurse may also press on your tummy during the test as this can help reduce pain and ease the passage of the scope along the colon. When the scope is complete you will be transferred to the recovery room and monitored until you are fully awake. Once you have eaten your escort can take you home. A nurse will give you results and a copy of your test will be sent to your GP.The sedation will impair your ability to perform a number of tasks for 24 hours (driving).It is possible to have your colonoscopy without sedation. You will experience abdominal discomfort and bloating during and after the test. However you will not require a lift home if you choose this option.

Risks of colonoscopy; The risk of a serious complication as a result of a diagnostic colonoscopy is low, estimated to occur in **2 people in every 1000** procedures. Risks increase if therapy is done eg; removing a polyp or if patients are elderly or have significant medical problems

- **Undetected cancers**

As previously stated this test is not perfect and research shows that significant polyps and cancer can remain undetected even in experienced hands. **This can occur in approximately 1 per 2000 colonoscopies.** At present there is no better test for the examination of the large bowel. A good bowel preparation and an experienced careful endoscopist help to reduce this risk.

- **Perforation**

This is a small tear in the lining of the colon and can occur in **1 per 1000** cases. This risk increases when polyps are removed, older age, multiple medical conditions and diverticular disease can be associated with a higher risk of perforation. Emergency surgery may be required to deal with perforation.

- **Bleeding**

Bleeding risk is usually associated with removal of a polyp **(1/200 cases).**This risk is increased if you have a bleeding condition or if you are taking any blood thinners. You may be asked to stop taking blood thinners prior to having your scope and your preassessment nurse will advise you about this prior to your test.

- **Medication**

Injected sedatives can cause problems with the heart and breathing. For this reason we sedate slowly and observe your response. We must be careful to avoid "oversedation" We use the term "conscious sedation" which is defined as a technique in which the use of drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation.

Bowel preparation can cause fluid disturbances. Rarely a life threatening allergic reaction known as anaphylaxis can occur in response to drugs given for this procedure.

- **Infection**

This is a rare occurrence following colonoscopy. The risk of aspiration (overflow of stomach contents in to lungs) is small and this is why we ask you to fast before your procedure. Over sedation can also be related to aspiration pneumonia.

- **Failure to complete**.

The endoscopist will complete this test in >90% of cases. Failure to complete can be due to many factors. A poor bowel preparation can impede the advancement of the scope in the bowel and a poor view is not acceptable or is it safe to continue. Please follow bowel preparation instructions very carefully. If your test is incomplete another test maybe required and this will be discussed with you after the colonoscopy.

Alternatives to colonoscopy. A CT COLON is an alternative to colonoscopy and is performed in the X-ray Department. Please be aware that if polyps or cancer are seen on CT Colonoscopy you will then require a full colonoscopy to remove or biopsy these. If you decide **not** to go ahead with colonoscopy or alternative test it is important to know the risk attached to leaving a potential bowel problem undiagnosed or untreated.

Please note;

Only Bowelscreen Certified endoscopists will carry out your procedure. This may be an Advanced Nurse practitioner who has achieved the level of expertise required to safely perform your scope. This person will also be under the supervision of a consultant.

During the procedure, video footage and photographs and data will be collected as these will form part of the medical record. This data may also be used for audit and/or research but will be anonymous.

Your consent;

I,.....

Have read the information provided outlining the procedure, the associated risks and complications, the benefits and alternatives to a full colonoscopy. I have been given the opportunity to ask questions and they have been answered to my satisfaction.

I understand that I can withdraw my consent at any time even after this form has been signed.

I understand that in the event of an emergency, the medical staff will carry out any medically necessary interventions. This may include but limited to surgery, radiologic procedures, anesthesia and blood transfusion. Every effort will be made to include me in the decision making process.

I consent to undergo the procedure Full Colonoscopy.

Signature of Client/Patient

.....Date;

Signature of Endoscopist

.....Date;

Should you develop a cancer within 36 months of having your colonoscopy, this colonoscopy will be reviewed at the local screening unit and the findings discussed with you by your clinician either at diagnosis or soon afterwards.

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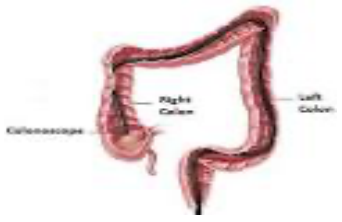
The National Bowel Screening Programme

Consent for a Full **Colonoscopy**



Benefits of a colonoscopy; Removal of polyps (small growths) and detection of cancers before symptoms develop is saving lives.

Please read this leaflet carefully as it provides vital information to enhance your experience and maximize the efficiency of the test. You will be signing this form to confirm you have read this leaflet and understand the procedure. Questions and concerns can be addressed on the day of your procedure with the medical team.

A colonoscopy is the best procedure for examination of the large bowel. However it is not a perfect test. You need to be aware of its limitations and how you can improve its accuracy.

Appendix 6b

Colonoscopy Information Leaflet

When will I get the results?

After the colonoscopy you will be told if any samples were taken or if polyps were removed. You will get the results in two weeks.

If the colonoscopy shows that you need more tests or treatment we will discuss and explain this to you and together decide the best course of action.

It can happen that the doctor could not see all of your bowel. This can happen if your bowel was not completely empty or the tube could not reach the end of your bowel. We may ask you to have another colonoscopy or another test. A copy of your results will be sent to your GP (family doctor).

Are there any risks with a colonoscopy?

For most people, having a colonoscopy is very straightforward. There can be complications but serious problems are rare as you are carefully monitored during the procedure.

While a colonoscopy is the best way to diagnose bowel cancer and other conditions, there is a small chance that a cancer or polyp will not be seen. This can happen because the bowel is not completely empty or, on rare occasions, if the doctor misses it. There is also a small chance that the colonoscope will not go along the entire length of the bowel because of a blockage or other difficulty.

The main risks of a colonoscopy are outlined below.

Bleeding: Usually this is not serious and stops on its own. However in less than one in 150 cases this may need further investigation.

A small tear in the lining of your bowel: If this happens, you may need an operation to repair the tear. This happens in less than one in 500 cases.

Breathing or heart problems: You may have a reaction to the sedative and this may cause temporary problems.

In extremely rare cases (less than one in 11,000) colonoscopy may result in death.

If you have any concerns about attending for your colonoscopy, you should discuss these with the nurse who calls you or contact BowelScreen on Freephone 1800 45 45 55.

Freephone 1800 45 45 55
www.bowelscreen.ie

BSP/COM-004 Rev 05

Plain English Approved by NALA

BowelScreen
An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme

Colonoscopy

What is a colonoscopy?

A colonoscopy is an examination of your bowel using a small camera on the end of a thin flexible tube. The test looks for any polyps or signs of disease in the lining of your bowel. Polyps are small growths that are not cancer but, if not removed, might turn into cancer over time. If polyps are found they are usually removed during the colonoscopy to reduce the risk of cancer developing. This is painless.

A small sample of the lining of your bowel may be taken to look at more closely. This is called a biopsy.

Why do I need a colonoscopy?

We offer a colonoscopy to everyone who has a BowelScreen home test result showing traces of blood not visible to the eye.

A colonoscopy is the best way to diagnose bowel cancer and other conditions. If bowel cancer is found at an early stage, it is easier to treat.

A colonoscopy is carried out in a screening colonoscopy unit in a hospital organised by BowelScreen. The hospital is obliged to levy a statutory charge for all (except medical card holders) day care procedures of €80.

What should I do to prepare for my colonoscopy?

Before your colonoscopy, a nurse will phone you and explain what will happen at the colonoscopy. You should tell the nurse if you are taking any medications, in particular any blood thinning tablets such as aspirin or warfarin. The nurse will ask you about your health and you can ask any questions you may have about the colonoscopy.

The day before your colonoscopy you will have to empty your bowel completely so that the doctor doing the colonoscopy can see the lining of your bowel clearly. You will receive a bowel preparation (a strong laxative) to take at home. It is very important that you follow the instructions that come with this to fully empty your bowel.

What happens during the colonoscopy?

When you arrive at the screening colonoscopy unit in the hospital, a nurse will meet you and answer any questions you may have. You will be asked to sign a consent form, giving your permission for the colonoscopy.

The colonoscopy is a day procedure (not requiring you to stay overnight). You may be given a sedative to help you relax. This will make you drowsy and you may not remember anything about the colonoscopy afterwards. While you are sedated, your heart and breathing will be carefully monitored.

You will be asked to lie on your side. A thin flexible tube called a colonoscope is passed into your back passage (rectum) and guided around your bowel. At the end of the tube there is a small camera with a light that shows the doctor the inside of your bowel on a screen.

During the colonoscopy your bowel will be gently filled with air to help show the lining of your bowel more clearly. The air can give you a bloated or cramping feeling in your abdomen (tummy).

Sometimes small samples of the lining of your bowel are taken to look at more closely. This is called a biopsy. The samples will be tested in a laboratory. If any polyps are found, they may be removed and tested.

Once you have recovered from the colonoscopy (after about 30 minutes), you will be able to sit up. You will need to arrange to have someone to take you home from the screening colonoscopy unit as the sedative may leave you drowsy.

Appendix 7a

International Bowel Screening Survey

Colorectal screening: Clinical Audit of Interval Cancers in the Screened Population

1. Respondent information

1. Please provide us with the following information *

Your name	
Your organisation	
Region or Country	
Contact email address	
Contact telephone number	
Screening programme web address	

2. About your colorectal screening programme

2. What year did your colorectal screening programme commence?*

3. What age groups do you screen? *

4. What is your current primary screening test?

- ☐ FIT
- ☐ FOBT
- ☐ Sigmoidoscopy
- ☐ Other (please give details below)

Other details:

5. What year did you implement this?

6. What is your screening interval? *

7. How many clients did your programme screen in 2017? *

8. Does your colorectal screening programme undertake an audit of invasive colorectal cancers in the screened population? *

- [ ] Yes
- [ ] No

3. Interval cancers audit

9. What is your definition of an invasive interval cancer?

10. Please tick one appropriate answer that best describes how your colorectal screening programme undertakes an audit of invasive interval colorectal cancers in the screened population?

- [ ] Post colonoscopy colorectal cancers (PCCRC)
- [ ] Post FIT or FOBT
- [ ] Both PCCRC and FIT or FOBT
- [ ] Post CT colonography
- [ ] Other (please give details below)

Other details:

4. Post colonoscopy colorectal cancer (PCCRC)

11. Which of the following best describes how you audit Post-colonoscopy Colorectal Cancers (PCCRC) (please tick all relevant) *

- [ ] Routine programme wide review only, with calculation of interval cancer detection rates
- [ ] Routine individual patient cancer review
- [ ] Only on patient/treating physician request
- [ ] Routine sample of screened population
- [ ] Other (Please give details in comment box below)

Other details:

12. If your programme audits a routine sample of the screened population for PCCRC, please give details of sample size below

5. Post FIT or FOBT

13. Which of the following best describes how you audit Post FIT or FOBT cancers

- [ ] Routine programme wide review only, with calculation of interval cancer detection rates
- [ ] Routine individual patient cancer review
- [ ] Only on patient/treating physician request
- [ ] Routine sample of screened population
- [ ] Other

Other details:

14. If your programme audits a routine sample of the screened population for post FIT/FOBT cancers, please give details of sample size below

6. Colorectal cancer notification

15. How is your programme notified of invasive colorectal cancers arising in clients screened (post FIT or PCCRC)? *

16. How do you confirm/validate notifications of invasive colorectal cancer in screened clients? *

7. Interval cancers audit process

17. Is the interval cancer audit procedure different for cases requested for review by an individual patient versus overall programme audit?

- [ ] Yes
- [ ] No

8. Interval cancers audit process

18. Please explain how the procedure of interval cancers audit is different for cases requested for review versus overall programme audit

9. Informing patients

19. Are patients informed that a colorectal cancer audit is taking place?

- [ ] Yes
- [ ] No

10. Informing patients

20. Who contacts the patient in respect of telling them that the audit is taking place?

21. What processes are in place to facilitate informing the patients that a colorectal cancer audit is taking place?

11. Patient choice

22. Do patients have a choice to be part of the audit?

- [ ] Yes
- [ ] No

12. Information for patients who are part of an interval cancer audit

23. What information do you give patients who are participating in an interval cancer audit?

24. How do you inform them that they will be part of an audit?

25. Please upload relevant documentation about how you inform patients that they are part of an audit

Choose File

Comments

13. Consent

26. Do you capture consent from clients to take part in a clinical audit?

- [ ] Yes
- [ ] No

27. Where do you capture consent?

At screening event	[ ] Yes
After diagnosis of invasive colorectal cancer	[ ] No

14. Consent

28. Does your routine consent procedure for screening cover the audit process?

- [ ] Yes
- [ ] No

15. Consent

29. Please give weblink to where documents relating to consent can be accessed or attach your consent form and/or policy document(s)

Choose File

Comments

16. Interval cancers audit results

30. Are the results of the clinical audit of colorectal cancers communicated to the affected patients?

- [ ] Yes
- [ ] No

31. Are patients asked if they want to know the outcome of the audit ? i.e. given a choice

- [ ] Yes
- [ ] No

17. Interval cancers audit results

32. Who communicates the audit results to patients (or their next of kin)?

- [ ] GP/ Family doctor
- [ ] Treating oncologist/consultant
- [ ] Screening programme clinical lead
- [ ] Other (please give details below)
- [ ] Not applicable

Other details

33. What is the procedure for communicating results to patients? (e.g. letter, phone call, face to face meeting etc.)

18. Open disclosure/duty of candour

34. In Ireland we have an open disclosure policy for medical incidents. Do you have such policy(s) in your country?

- [ ] Yes
- [ ] No

19. Open disclosure/duty of candour

35. Is this policy mandatory or voluntary?

- [ ] Mandatory
- [ ] Voluntary
- [ ] Other (please give details below)

Other details

20. Open disclosure/duty of candour

36. Does the open disclosure / duty of candour policy extend to the results of audit of invasive interval cancers in your screening programme?

- [ ] Yes
- [ ] No

21. Open disclosure/duty of candour documentation

37. Please upload relevant policy documentation on open disclosure/duty of candour

Choose File

Comments

22. Legal protection for interval cancers

38. Is there any legal protection for the colorectal screening programme in relation to cancers arising post screening?

- [ ] Yes
- [ ] No

23. Legal protection for interval cancers

39. If there is legal protection for interval cancers, please give details below

24. Compensation

40. In your country/programme is there any financial compensation for interval cancers?

- [ ] Yes
- [ ] No
- [ ] Not applicable

25. Compensation

41. What is the procedure for financial compensation?

- [ ] No fault (routine financial compensation)
- [ ] Adversarial (legal route)
- [ ] Programme/state offers support to affected clients
- [ ] Other (please give details below)

Other details:

26. Compensation

42. In what form does the programme/state offer support to clients?

- [ ] Free treatment
- [ ] New cancer drugs
- [ ] Other (please give details below)
- [ ] Not applicable

Other details:

27. Publication of interval cancer rates

43. Do you capture interval cancer rates for an internal report?

- [ ] Yes
- [ ] No

44. Do you publish your interval cancer rates?

- [ ] Yes
- [ ] No

28. Format of publication(s)

45. if yes to above, in what format do you publish results?

- [ ] Annual report
- [ ] Peer-review publication
- [ ] On website
- [ ] Other (please give details below)

Other details:

29. How we will use data from this survey

46. The feedback from this survey will form a key element of the analysis of international best practice to drive improvements in the Irish colorectal screening programme and will be included in a final report to Government. Are you happy for your data to be included in summary tables with references to your documents or website as indicated? *

- [ ] Yes, with programmes identified
- [ ] Yes, with programmes anonymised
- [ ] No

47. We may also publish findings from this survey in an academic journal. Do you agree to your programme data being included in a publication? *

- [ ] Yes, with programmes identified
- [ ] Yes, with programmes anonymised
- [ ] No

30. Further comments

48. Do you have any further comments that you would like to add?

Appendix 7b:

International Bowel Screening Survey Result Findings

Results from an international survey on clinical audit of interval cancers in the screened population are presented in this report.

All comments from respondents are in italics and transcribed verbatim.

Introduction

Thirteen out of twenty invited countries/regions completed the survey giving a response rate of 65% (Figure 1). Of the thirteen countries/regions that completed the survey, seven countries/regions have an audit process in place for interval cancers, while six countries/regions do not (Figure 2). Of the seven countries/regions that have an audit process in place, five are using FIT for primary screening while two are using FOBT.

Figure 1. Flow diagram of main survey results

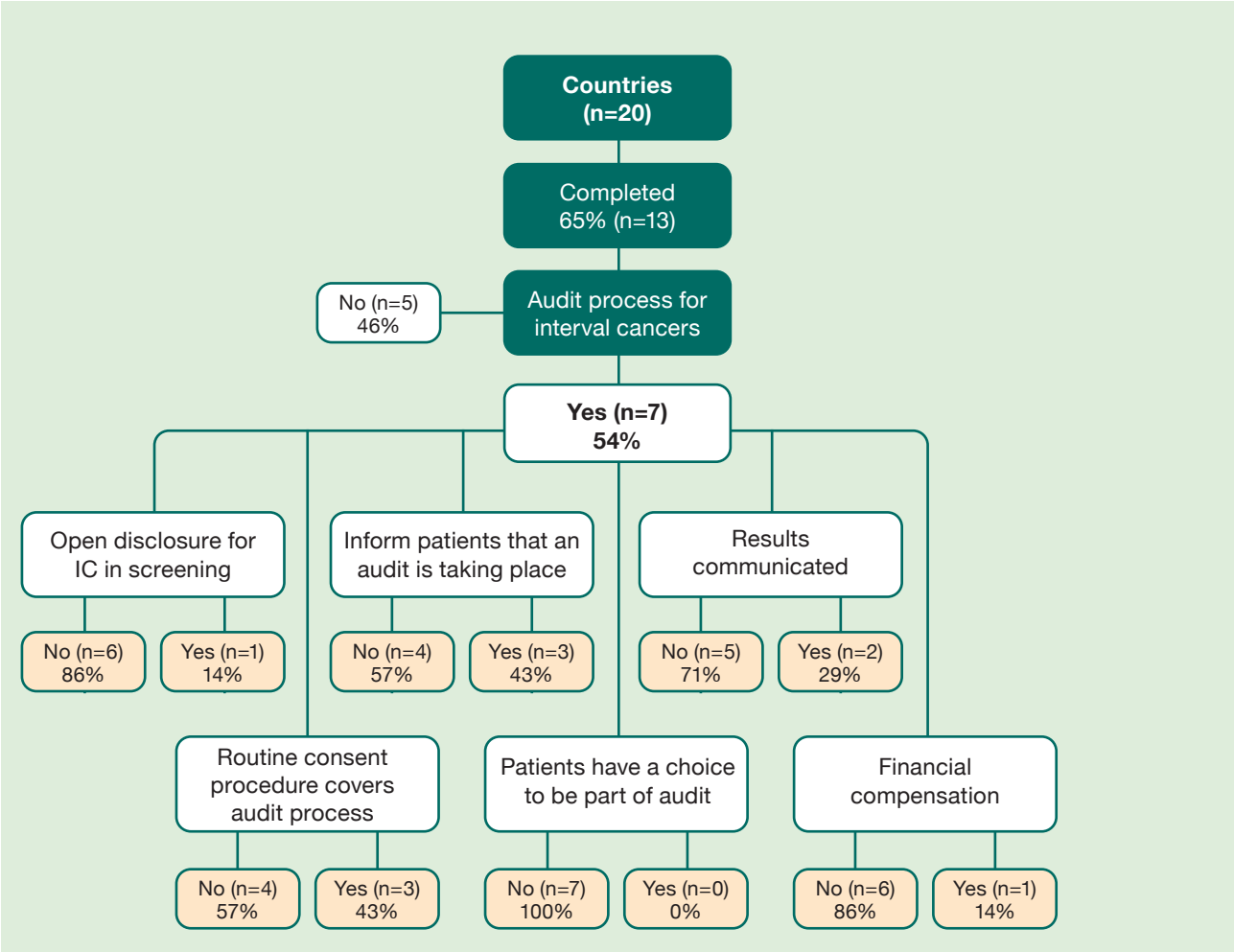
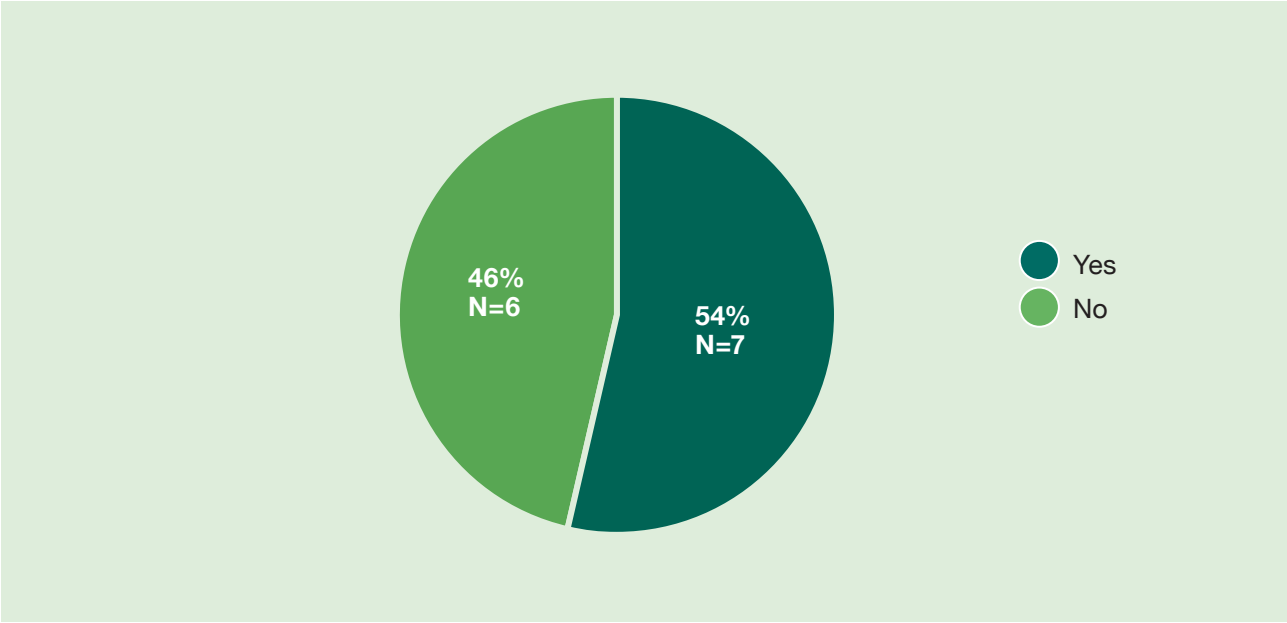


Figure 2. Does your colorectal screening programme undertake an audit of invasive colorectal cancers in the screened population?



How does your colorectal cancer screening programme undertake an audit of interval colorectal cancers in the screened population?

All seven countries/regions carry out audit post FOBT/FIT. Six of these also carry out PCCRC audit; one of these six also carries out audit of post CT cancers.

Which best describes how your audit is undertaken?

FIT or FOBT

All seven countries/regions carry out post FIT/FOBT audit. Of these, four desribe their audit process as routine programme wide review, with calculation of interval cancer detection rates. One country/region carries out routine individual patient cancer review,one country/region carries out audit on a routine sample of screened population and one country/region did not provide information in relation to this process.

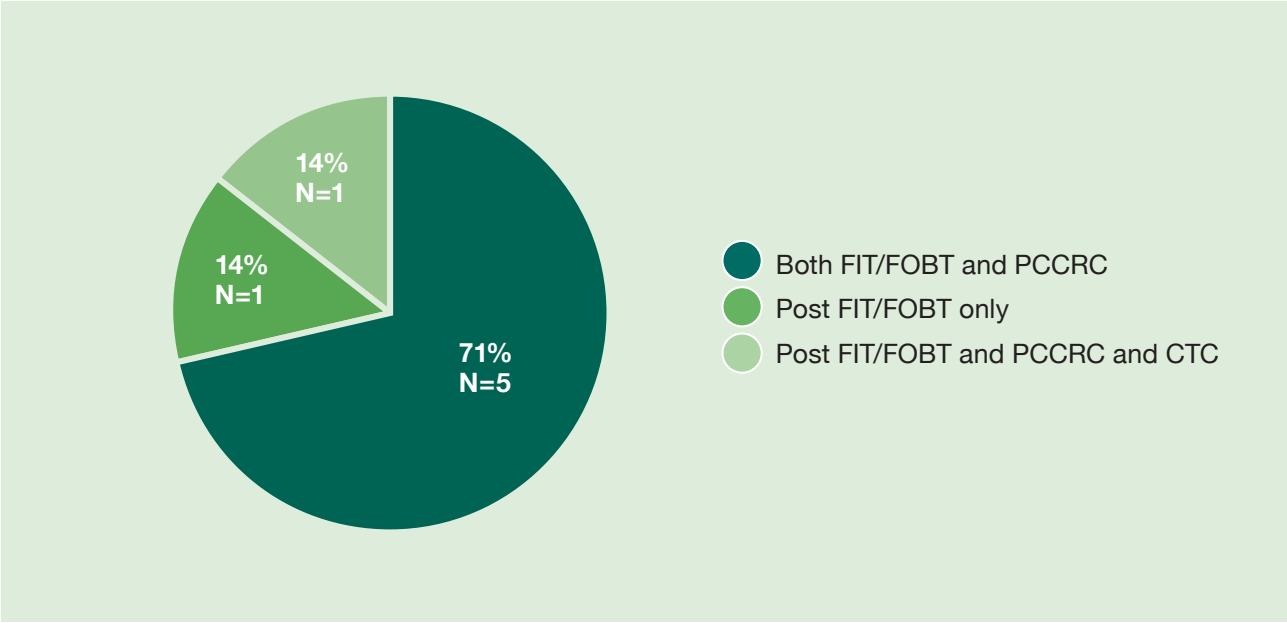
PCCRC

Six countries/regions carry out PCCRC audit. Of these, three countries/regions carry out a routine programme wide review, with calculation of interval cancer detection rates, two countries/regions carry out routine individual patient cancer reviews and one country/region did not provide information in relation to this process.

CTC

One country/region states that audit is carried out post FIT/FOBT, PCCRC and CTC, however no further information in relation to this process was provided.

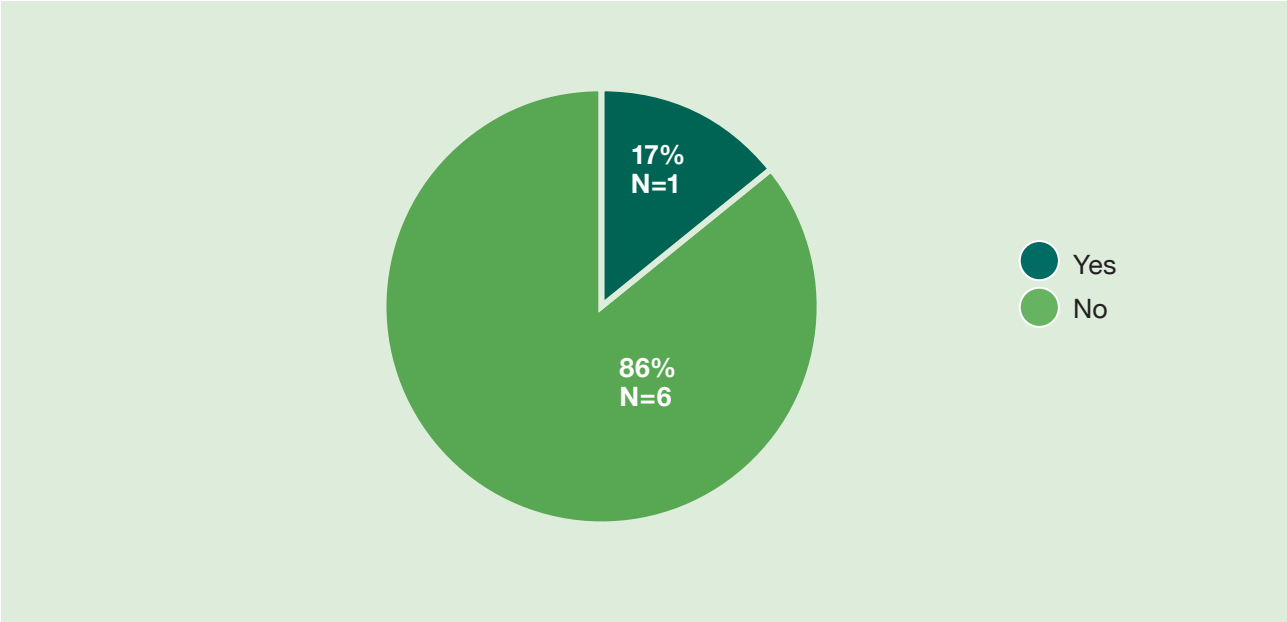
Figure 3. How does your colorectal cancer screening programme undertake an audit of interval colorectal cancers in the screened population?



Is the interval cancer audit procedure different for cases requested for review by an individual patient versus overall programme audit?

One country/region only reported that they have a different audit process in place for cases requested for review by an individual patient compared to the overall programme audit; they state that if a review is requested by a patient, then that patient's medical chart is reviewed. This country/region carries out audit post FIT/FOBT and PCCRC (Figure 4).

Figure 4. Is the interval cancer audit procedure different for cases requested for review by an individual patient versus overall programme audit?



Are patients informed that a colorectal cancer audit is taking place?

Three of the seven countries/regions that perform audit inform patients that an audit is taking place. Of these three, two carry out audit post FIT/FOBT and PCCRC while one country/region carries out audit post FIT/FOBT, PCCRC and CT.

Who contacts the patient in respect of telling them that the audit is taking place?

Of the three countries/regions that inform patients that an audit is taking place, the following information was provided in relation to who contacts the patient:

- *GPs and Programme*
- *Initial information is included in cancer screening patient information leaflets, specific information and a patient communication pathway is under development*
- *Patients receive a participation form with the FIT; they give consent that data is used for evaluation, but not explicitly mentioned that this concerns (interval) cancers.*

What processes are in place to facilitate informing patients that a colorectal cancer audit is taking place?

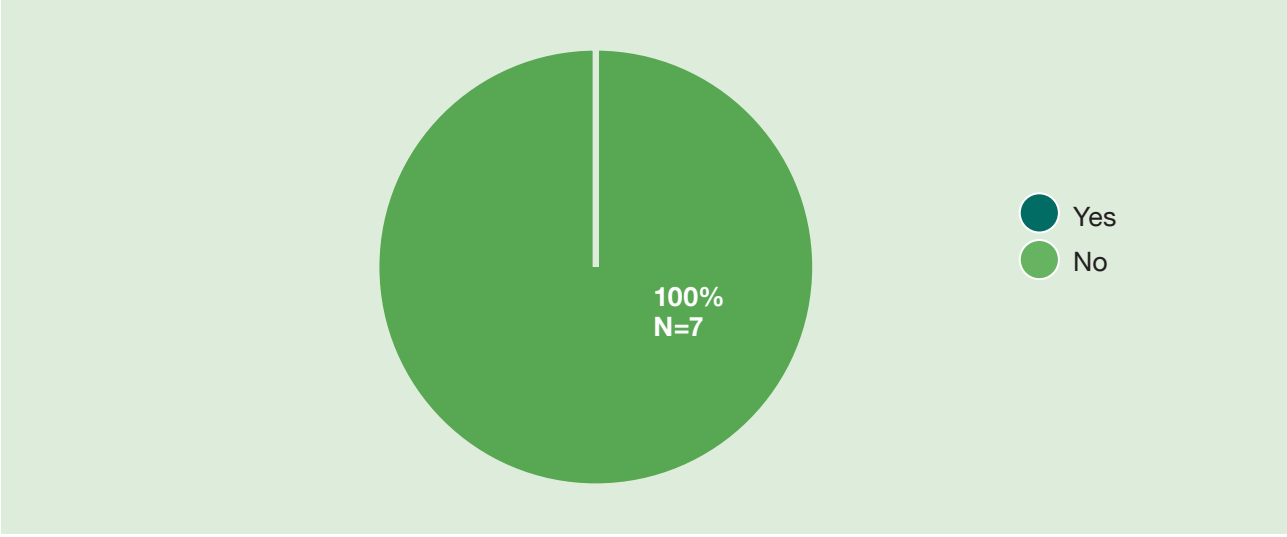
Of the three countries/regions that inform patients that an audit is taking place, the following information was provided in relation to the processes in place to facilitate informing the patients:

- *This is under development*
- *None, however all the information about quality indicators in our yearly monitoring reports are available at our website (on aggregated level)*

Do patients have a choice to be part of the audit?

All seven countries/regions answered no to this question. Patients do not have a choice to be part of the audit in all seven countries/regions.

Figure 5. Do patients have a choice to be part of the audit?



What information do you give to patients who are participating in an interval cancer audit?

Three countries/regions provided information on this question as follows:

- *Communication pathway is under development*
- *Non standard*
- *Patient informed if a post-colonoscopy interval cancer only. Patients not informed if following a negative FOB test*

How do you inform them that they will be part of an audit?

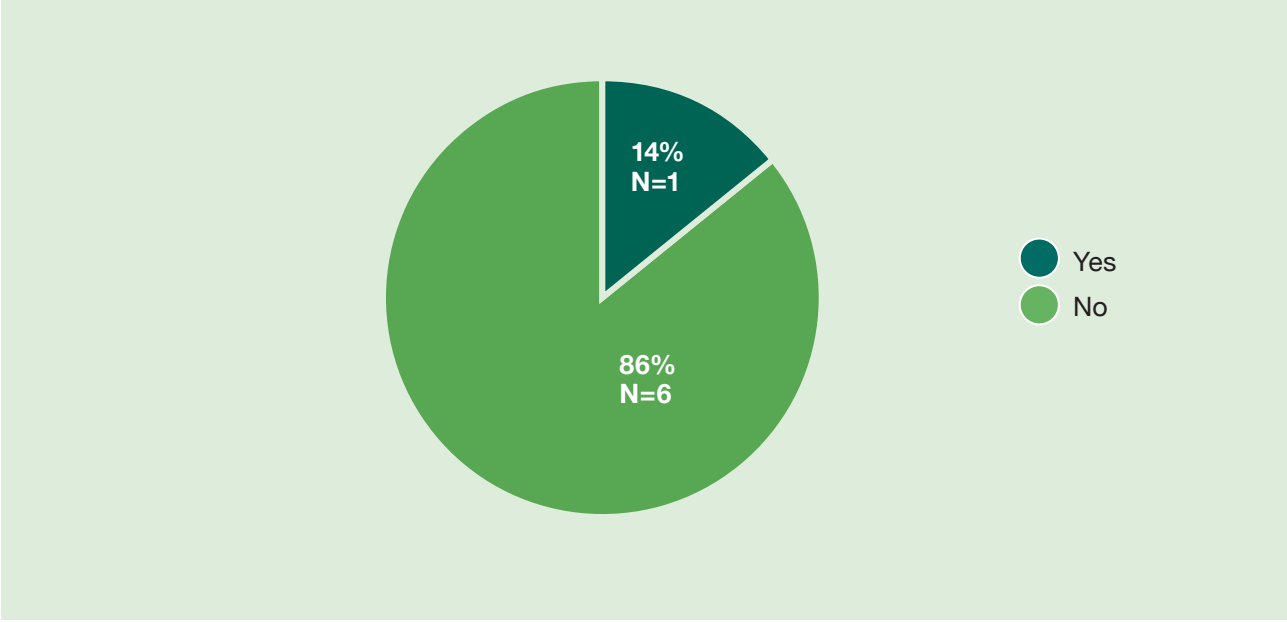
Two countries/regions provided information on this question as follows:

- *Non individual*
- *Letter to participant following the audit*

Do you capture consent from clients to take part in a clinical audit?

One country captures consent from clients to take part in clinical audit. This country/region carries out audit post FIT/FOBT and PCCRC.

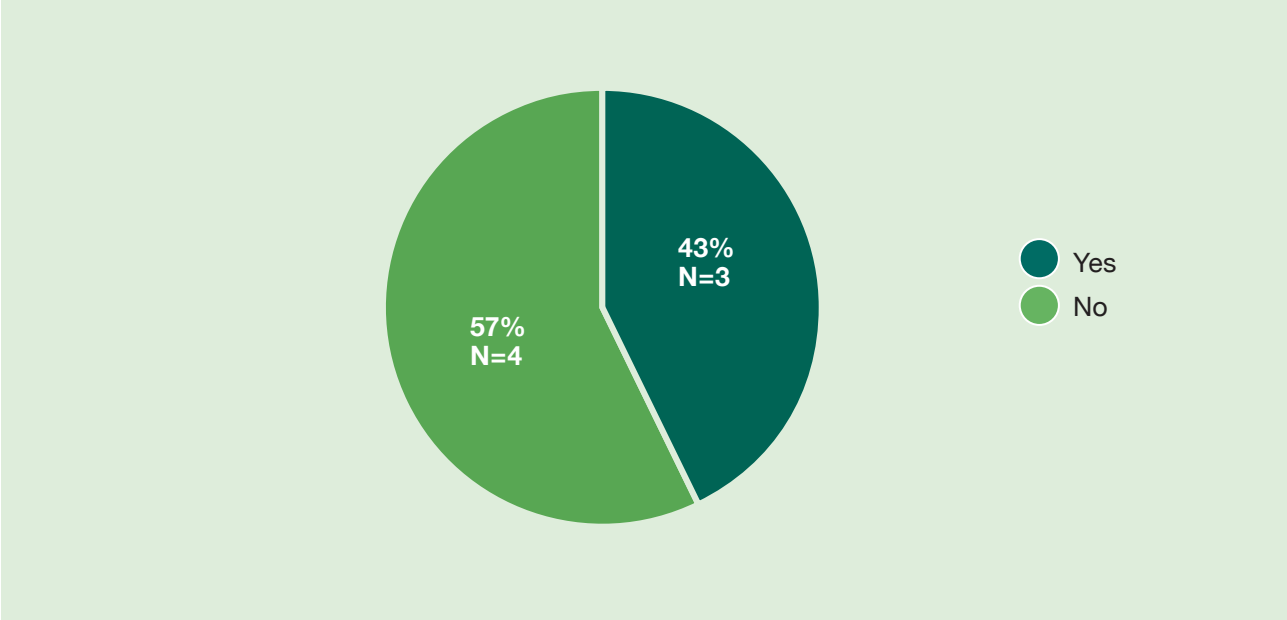
Figure 6. Do you capture consent from clients to take part in a clinical audit?



Does your routine consent procedure for screening cover the audit process?

Three countries/regions capture cosent as part of their routine consent procedure for screening. Two of these countries/regions carry out audit post FIT/FOBT and PCCRC while one country/region carries out audit post FIT/FOBT, PCCRC and CT.

Figure 7. Does your routine consent procedure for screening cover the audit process?



Are the results of clinical audit of colorectal cancers communicated to the affected patients?

Two countries/regions answered yes to this question. One of these countries/regions carries out audit post FIT/FOBT, PCCRC and CT while the other country/region carries out audit post FIT/FOBT and PCCRC.

Who communicates the results to patients?

Two countries/regions provided details on the procedure for communicating results to patients as follows:

- *Local practice - would be expected to be the screening colonoscopist*
- *Screening programme clinical lead*

What is the procedure for communicating results to patients?

Two countries/regions provided details on the procedure for communicating results to patients as follows:

- *Local practice. Regional communication framework being developed*
- *Letter*

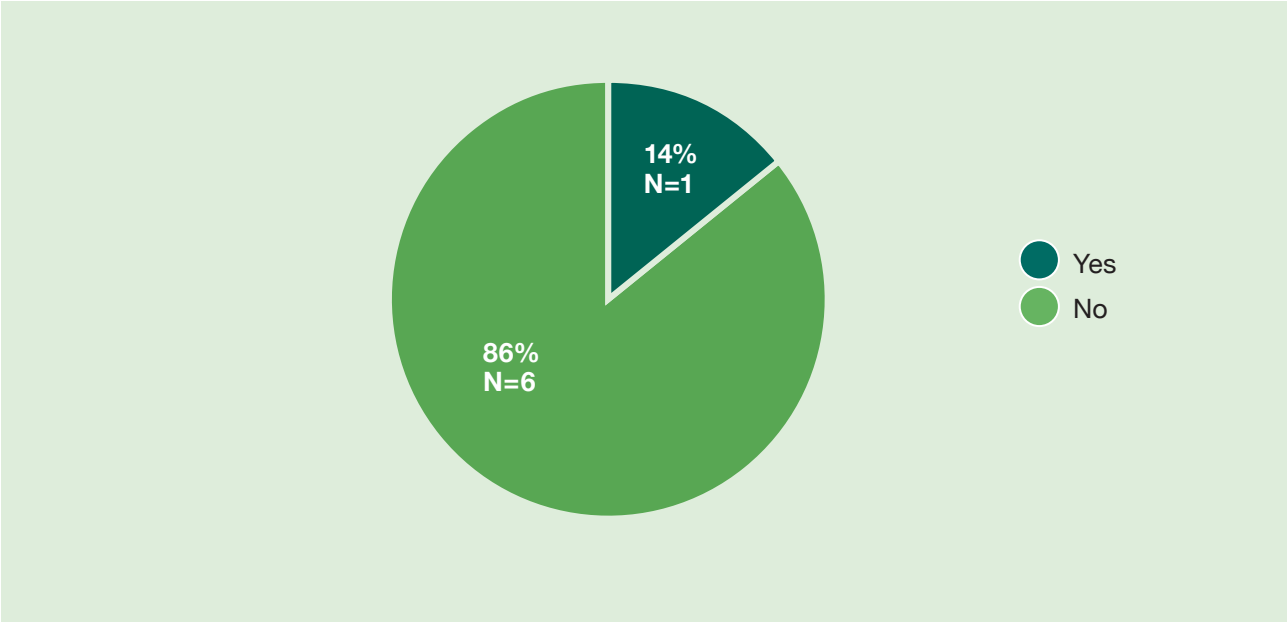
In Ireland we have an open disclosure policy for medical incidents. Do you have such policy(s) in your country?

Of the seven countries/regions that carry out audit of interval cancers, four countries have an open disclosure policy for medical incidents. Of these, two countries/regions have a voluntary open disclosure policy for medical incidents, while one country/region has a mandatory policy and one country/region states that use of the policy is expected.

Does the open disclosure / duty of candour policy extend to the results of audit of invasive interval cancers in your screening programme?

Of the four countries/regions that have an open disclosure policy for medical incidents, one country/region has an open disclosure policy that applies to interval cancers in screening. This country/region carries out audit post FIT/FOBT and PCCRC.

Figure 8. Does the open disclosure / duty of candour policy extend to the results of audit of invasive interval cancers in your screening programme?



Is there any legal protection for the breast screening programme in relation to cancers arising post screening?

Two countries/regions answered “Yes” to this question and provided additional information as follows:

- *Same protection than other health data*
- *If care deemed to have been outside that expected*

In your country/programme is there any financial compensation for interval cancers?

Of the seven countries/regions who conduct audit, six countries/regions do not provide financial compensation for interval cancers. One country/region did not answer this question, however stated that there is a no fault (routine financial compensation) system in place.

Do you capture interval cancer rates for an internal report?

Six countries/regions capture interval cancer rates for internal reporting.

Do you publish your interval cancer rates?

Five of the countries/regions publish their interval cancer rates. Three of these are reported in the form of an annual report, three also report rates in peer reviewed publications and four report the rates on their website.

	Country or region						
	1	2	3	4	5	6	7
Audit invasive colorectal cancers in the screened population	*	*	*	*	*	*	*
Primary screening test	FIT	FOBT	FOBT	FIT	FIT	FIT	FIT
Audit type	Post FIT/ FOBT	Post FIT/ FOBT and PCCRC and CT	Both post FIT/ FOBT and PCCRC	Both post FIT/ FOBT and PCCRC	Both post FIT/ FOBT and PCCRC	Both post FIT/ FOBT and PCCRC	Both post FIT/ FOBT and PCCRC
Inform patients that an audit is taking place		*		*	*		
Patients have a choice to be part of the audit							
Capture consent from clients to take part in a clinical audit						*	
At screening event						*	
After diagnosis of invasive colorectal cancer							
Routine consent procedure for screening covers the audit process		*			*	*	
Results of the clinical audit of colorectal cancers are communicated to the affected patients		*	*				

	Country or region						
	1	2	3	4	5	6	7
Patients are asked if they want to know the outcome of the audit		*	*				
Who communicates results to patients?							
GP/ Family doctor							
Treating oncologist/ consultant						*	
Screening programme clinical lead			*				
Other (please give details below)		*					
Have an open disclosure policy for medical incidents	*		*			*	*
Mandatory policy			*				
Open disclosure policy extends to the results of audit of invasive interval cancers						*	
Legal protection for the screening programme in relation to cancers arising post screening				*		*	
Financial compensation for interval cancers						*	
Capture interval cancer rates for an internal report	*	*	*	*	*		*
Publish your interval cancer rates	*			*	*	*	*
Annual report	*			*	*		
Peer-review publication				*	*	*	*
On website	*			*	*		
Other				*			

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

BowelScreen
An Clár Náisiúnta Scagthástála Putóige
The National Bowel Screening Programme