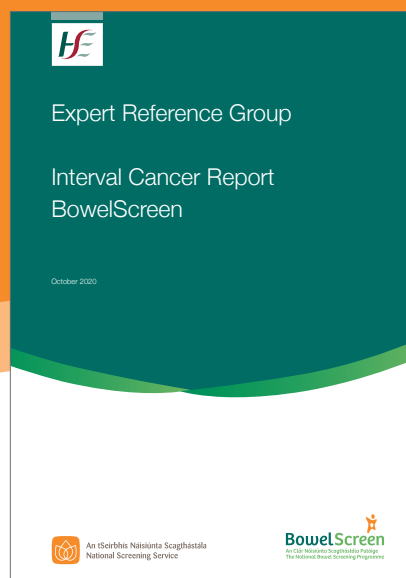
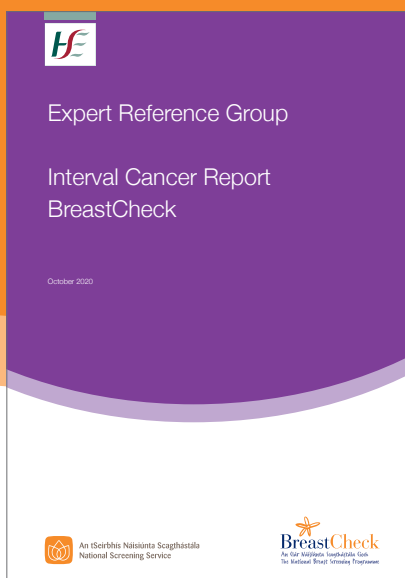
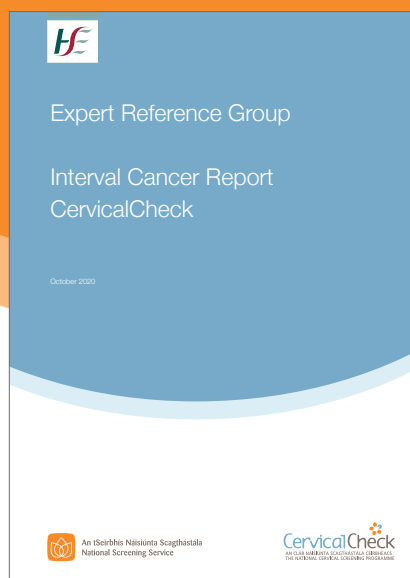




Interval Cancer Project

Implementation of recommendations arising from the Interval Cancer Expert Reference Group Reports

Project closure report
2023



An tSeirbhís Náisiúnta Scagháistála
National Screening Service

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Message from the National Screening Service Chief Executive

The Expert Reference Groups' Interval Cancer Reports, published in October 2020, set out a new and comprehensive approach to reviews of interval cancers in people who have been screened by Ireland's breast, bowel and cervical cancer screening programmes.

The reports acknowledged that Ireland's screening programmes operate to the best international standards and that they reduce deaths from cancer among people in Ireland. These findings have been further endorsed by the [2022 National Cancer Registry Ireland report](#) on national trends for cancers with population-based screening. This reported that incidences of all three cancers showed clear evidence for the benefits of screening. Screen-detected cancer cases were, on average, detected at a substantially earlier stage than other cases. Survival has improved for all three cancers, with the biggest improvements seen in the age-groups targeted by the national screening programmes. Death rates of all three cancers have fallen significantly.

World class screening programmes must balance the benefits and harms that are inherent in population screening programmes. Patient trust, staff recruitment and affordability are all critical. Despite best efforts, interval cancers are a fixed feature of any screening programme.

The 2020 reports' final recommendations had three themes in relation to interval cancers, as follows:

1. Individual case reviews may be requested by a patient to ensure patients have access to their own information if desired.
2. Retrospective programme-wide review of screening results of patients with cancers would be anonymised and blinded or under an agreed legislative framework, to ensure that the key deliverables of quality assurance and professional education are sustained.
3. Programme key performance indicators for cervical and bowel screening would include the annual interval cancer rate as it already does for breast cancer screening.

The National Screening Service (NSS) committed to implementing the recommendations arising from the reports, in partnership with the people we care for, and our professional screening teams around the country. Over the past three years, implementation groups with wide-ranging expertise have been working through the recommendations relevant to their specific area of focus, and designing and executing their implementation. The content of this report outlines the work completed and the next steps. Significant progress has been made and the NSS now offers individual case reviews to patients in all three programmes. We are delighted that the WHO has recently issued best practice statements on an interval cancer rate for cervical cancer and we will work with colleagues internationally to measure and publish this indicator in future. The existence of these two practices, along with enhancement of education resources and strengthened real-time quality assurance measurements, has reduced the need for specific clinical audit of interval cancer which remains hampered by the lack of available technology for anonymisation.

Implementation has not been straightforward and has required considerable deliberation, input and collaboration. All groups agreed that it was crucial that the voice of stakeholders, particularly patients and/or families impacted by interval cancers, were heard. We have co-designed our processes with patients and have engaged extensively with many stakeholders.

We are committed to a full disclosure of interval cancer reviews for all participants in screening. Sadly, we cannot say that interval cancers will not happen to other people. Screening detects or prevents most, but not all cancers and some screened people will still develop disease.

The reports in 2020 recognised the serious concern that the growth in number of legal claims against CervicalCheck would affect its viability and potentially that of other programmes. They warned that the effect of this is two-fold: it could further challenge recruitment and retention of professional staff and the costs of litigation may greatly exceed the screening resources available, risking the continuance of the programme. It has so-far been sustained thanks to the concerted effort of a great many people. However, the legal claims have continued such that the recent WHO report highlighted a concern that uncontrolled litigation poses a serious threat to our screening programmes, and to the establishment of new programmes.

The Legal Framework Group comprised people with a wide range of expertise and experience who came together to review the legal environment for screening and report on their findings.

In conjunction with the WHO's findings, their report concludes that the Irish legal environment is not fit for purpose in the context in which screening programmes operate and calls for alternative approaches to be introduced. It proposes to Ireland to engage in a structured debate on the long-term viability of cancer screening programmes. We look forward to continuing to work with stakeholders on these critical issues.

As chair of the Interval Cancer Steering Group and chief executive of the NSS, I am grateful to those who contributed to the implementation of the reports' recommendations, including patient advocacy representatives, screening clinicians, international screening experts and research experts, as well of course to my NSS colleagues who put a huge amount of work in to lead this initiative.

Fiona Murphy

Chief Executive, National Screening Service

October 2023

Executive Summary

The NSS welcomed the publication of the Expert Reference Groups (ERG) Interval Cancer Reports on the 21 of October 2020. The recommendations of the Expert Reference Groups provide a design for interval cancer review which supports quality assurance within each programme, and which is in line with international best practice for cancer screening programmes.

An Interval Cancer implementation project team with a clear governance structure (see Appendix 1) was established to plan and develop the methodologies, standard operating procedures and resources required for the implementation of these recommendations.

Implementation groups had wide ranging membership and agreed terms of reference along with project implementation plans detailing actions, activities and timelines.

The Interval Cancer Steering Group had its final meeting in June 2023 having agreed that the terms of reference for the group have been completed.

Key achievements of the Interval Cancer Project include:

- Design and implementation of patient-requested reviews for people diagnosed with an invasive cervical cancer.
- Standardisation of the patient-requested review process for BreastCheck and BowelScreen.
- Strengthening of the link between the NSS and the National Cancer Registry of Ireland to enable data sharing and calculation of interval cancer rates.
- Collaboration to further develop information resources to inform choice and build trust and confidence in our screening programmes.
- Research conducted on behalf of the Legal Framework Group on ethical considerations in relation to population screening, the legal environment in which screening operates, how this compares internationally, and the benefits and limitations of population screening with respect to mortality and morbidity.
- Informed contribution to and from the WHO's International Agency for Research on Cancer's (IARC) report on Best Practices in Cervical Screening: Audit of Cancers, Legal and Ethical Frameworks, Communications, and Workforce Competencies.

The ERG recommendations are now either implemented and/or integrated into the National Screening Service business-as-usual activities. The recommendations made by the Legal Framework Group are being progressed by the NSS Executive Management Team.

Introduction

The purpose of this report is to outline the substantive progress made during the implementation of the recommendations arising from the Expert Reference Group Interval Cancer Reports and reflect on the conclusion of the project. The report describes the background to the project, how the recommendations have been addressed and what happens next now that the project is complete.

Background

The NSS welcomed the publication of the Expert Reference Groups (ERG) Interval Cancer Reports on the 21 of October 2020. These reports were commissioned as part of the 2018 [Scoping inquiry into the CervicalCheck screening programme](#). The recommendations of the Expert Reference Groups provided a design for interval cancer review which supports quality assurance within each programme, and which is in line with international best practice for cancer screening programmes (see recommendations in Appendix 2).

An Interval Cancer implementation project team with a clear governance structure (see Appendix 1) was established to plan and develop the methodologies, standard operating procedures and resources required for the implementation of these recommendations.

The implementation structure comprised an interval cancer implementation group for CervicalCheck, BreastCheck and BowelScreen respectively, a legal framework group and a communications group, all overseen by an overarching steering group.

Implementation group membership included representation from patient and public advocacy groups, primary care, cancer screening experts, public health, legal experts, communication specialists, medical ethics, and health economics.

All groups had agreed terms of reference for their work and developed project implementation plans detailing actions, activities, and timelines.

During the project, we published two annual reports: [Year 1](#) and [Year 2](#)

This report is the Year 3 report and concludes the project.

Patient and Public Input

Patient and public input and guidance was embedded in the process of implementing the ERG recommendations. Each implementation group had representation from patient/public advocates so that the needs of screening programme participants were considered during design and implementation. We engaged directly with those who have been impacted by an interval cancer. Additionally, an interval cancer patient/public representative advisory forum was formed. This was a free discussion forum to garner valuable feedback on elements of the Interval Cancer project.

BowelScreen Interval Cancer Implementation Group

This group was established in December 2020 and was chaired by Professor Pádraic Mac Mathúna. The group comprised BowelScreen clinical and administrative personnel alongside clinical colleagues from the wider endoscopy community.

Recommendations relevant to the BowelScreen implementation group included:

- Agree a definition of a post colonoscopy colorectal cancer (PCCRC).
- Support the NCRI/NSS Data Sharing Strategic Planning Group with any required information in the development of processes to calculate the interval cancer rate.
- Collaborate with the Communications Interval Cancer Implementation Group to develop patient information to enable informed choice and consent.
- Recording of PCCRCs from non NCRI sources.
- Management of patient-requested review and disclosure process.
- Building and promoting understanding, confidence and trust in the BowelScreen programme.
- Provision of the necessary resources to implement all BowelScreen recommendations.

The Interval Cancer Steering Group approved the closure of the BowelScreen Interval Cancer Implementation Group in January 2023. The summary of the conclusion of the implementation group is as follows:

ERG recommendation 1: Information resources

- A standardised colonoscopy consent form to be used across all endoscopy screening units was developed and ratified. It is now in operation across all screening endoscopy units.
- Further revision of information resources is being managed by the BowelScreen programme with support as required from the NSS Communication Engagement and Information Development Hub (CEID).

ERG recommendation 2: Interval cancer rate

- The design and implementation of an interval cancer rate for bowel cancer is managed by the National Cancer Registry of Ireland (NCRI) /NSS Data Sharing Strategic Planning Group with support provided by the BowelScreen programme.
- Post Faecal Immunochemical Test (FIT) interval cancer rate – will not be implemented within the lifecycle of this project as no international benchmark exists for same.

Recommendation 3: Recording of post-colonoscopy colorectal cancer (PCCRCs) from non-NCRI sources

- A template to record PCCRCs from non-NCRI sources has been developed, approved and is now operational in all screening endoscopy units.
- The BowelScreen programme continues to monitor KPIs independently of PCCRC notification.

Recommendation 4: Patient Requested Reviews of PCCRCs

- The BowelScreen memorandum of understanding (MOU) with local screening units has been updated to reflect the responsibility of the local screening units in the conduct and disclosure of PCCRS reviews.

Recommendation 5: promote understanding of, and public trust in, the BowelScreen programmes

- The BowelScreen Implementation Group provided expertise as required for the behaviours, attitudes and knowledge research conducted by Communications Interval Cancer Implementation Group.
- Further work will be managed by the BowelScreen Programme who will engage the expertise of the NSS Communications Engagement and Information Development Hub (CEID).

Recommendation 6: Provision of necessary resources in order to implement ERG recommendations

- The BowelScreen Implementation Group implemented the programme-specific recommendations by using existing resources within the group and the BowelScreen programme. A need for further resources was not warranted during the project.



BowelScreen easy read leaflet

BreastCheck Interval Cancer Implementation Group

This group was established in February 2021 and was chaired by Dr Niall Sheehy – consultant radiologist. Membership of this group comprised BreastCheck clinical and administration staff, NSS staff, patient advocates and external symptomatic clinicians.

The key deliverables associated with the BreastCheck Implementation Group were:

- Strengthening the established patient-requested review and associated disclosure processes.
- Collaborating with the NCRI in relation to the timely validation of interval cancers and the calculation of an updated interval cancer rate.
- Determining the feasibility of blinded, anonymised radiological assessment of all interval cancers for educational purposes.

The Interval Cancer Steering Group approved the closure of the BreastCheck Implementation Group in June 2023. Recommendations have been addressed as follows:

Recommendation 1: Development and revision of informational resources

This group supported the development of patient information to enable informed choice and consent by the Communications Interval Cancer Implementation Group. Further work in this area will be by the NSS Information Development Hub as business as usual with support from the BreastCheck programme.

Recommendation 2: Interval cancer rate

Ongoing clinical support was provided to NCRI/NSS Data Sharing Strategic Planning Group in their calculation of an updated interval cancer rate for breast cancer. An interval cancer rate up to 2016 is now available and work will continue to develop the next interval cancer rate. BreastCheck continues to work closely with the NCRI to strengthen links between the two organisations. This recommendation will continue to be managed by the NCRI/NSS and Programme Evaluation Unit (PEU).

Recommendation 3: Educational learning

The group recognises the importance of education and learning from the mammograms of women who have been screened and subsequently go on to develop an interval cancer, as part of accreditation. There is no safe mechanism to review or to fully anonymise interval cancer mammograms. However, there are a number of additional mechanisms radiologists have access to in the programme for continual medical education e.g. DetectedX - leading image-based diagnostic improvement learning platform. This group is working towards accreditation with EUREF in 2024.

Recommendation 4 & 5: Patient-requested review process

Women who develop an interval cancer after their last normal screening mammogram may wish to have their previous screening history reviewed. Procedures are in place to support and accommodate these requests. A BreastCheck Liaison Nurse has been recruited to manage and support this process.

The BreastCheck programme continue to provide individual case reviews as requested. These reviews are conducted as per agreed standard operating procedure (SOP). All findings of patient-requested reviews are communicated in line with the agreed SOP. The patient-requested review process will continue to be implemented by the BreastCheck programme.

Recommendation 6: The necessity to build and promote understanding of and trust in screening programmes

This group supported the Communications Interval Cancer Implementation Group in building and promoting understanding of and trust in the national screening programmes. Further work in this area is being managed by NSS Communications Engagement and Information Development Hub (CEID) as business as usual. The BreastCheck programme will continue a central role in supporting greater understanding of screening and promoting trust and confidence in BreastCheck.

Recommendation 7: Further analysis of the records of educational exercises undertaken prior to and during accreditation is not recommended

The retention and deletion of historic educational materials under GDPR procedures has been completed (January 2022). This recommendation is now closed as all actions were fully implemented.

Recommendation 8: Review of record retention policy

The National Screening Service (NSS) has a local record retention policy in line with the HSE Record Retention Policy. The NSS and BreastCheck programme have contributed to the recent revision of the HSE Record Retention Policy. Effective, efficient, and appropriate record management in the context of the General Data Protection Regulation (GDPR) is supported by the NSS Information Governance Department. This recommendation has been fully implemented as it has moved into business as usual under the NSS Information Governance framework.

Recommendation 9: To ensure the necessary resources to fully implement the BreastCheck ERG recommendations

The BreastCheck Implementation Group identified the resources required to implement the BreastCheck ERG recommendations. This includes the establishment of a BreastCheck Liaison service and identified education and training for all stakeholders involved in the patient-requested review process.



BreastCheck social media campaign developed from 2021 public attitudes survey findings

CervicalCheck Interval Cancer Audit Implementation Group

The CervicalCheck Interval Cancer Audit Implementation Group was established in December 2020 and chaired by Prof Nóirín Russell – Clinical Director of CervicalCheck. Membership of this group comprised CervicalCheck clinical and administration personnel, representation from colposcopy, cyto-histopathology, the Faculty of Pathology, health ethics, patient & public advocacy, primary care and gynae-oncology. Recommendations of focus for this group included:

- Development of patient-requested review and disclosure processes
- Developing processes for blinded and anonymised programmatic review of cytology of all invasive cervical cancers for the purpose of professional education and quality assurance
- Developing a new KPI, the interval cancer rate.

A summary of the recommendations relevant to the CervicalCheck programme is as follows:

Recommendation 1: provision of informational material

The CervicalCheck Interval Cancer Audit Implementation Group collaborated with the Communication Interval Cancer Implementation Group to support the implementation of this recommendation. Further work in this area is being managed by NSS Communications Engagement and Information Development Hub (CEID) as business as usual.

Recommendations 2 & 3: patient-requested reviews

Patient-requested reviews, known as ‘personal cervical screening reviews’ (PCSR), were designed and implemented during the Interval Cancer project. Phase 1 implementation began in Q1 2023.

The design of the review and communication process was informed through engagement with stakeholders, including patient groups.

As the implementation of PCSRs will be an ongoing function, governance of the CervicalCheck personal cervical screening reviews has transferred to the CervicalCheck senior management team.

Recommendations 4: programmatic review of cytology

Representatives from this group joined with the WHO’s International Agency for Research on Cancer IARC@ and the Department of Health to establish a report on Best Practice for the role of Clinical Audit Within Cervical Cancer Screening both in Ireland and internationally. The group concurred with the recommendations of the Legal Framework Group (see below) on the need for a specific legal mechanism to enable anonymised audit before any future retrospective audits could be planned. The group further determined that audit is only one of many important benchmarks that enable screening programmes to maintain and develop quality in real time. These further benchmarks include 1. Interval cancer rate 2. Laboratory quality assurance 3. Published detection rates of low- and high-grade abnormalities 4. Positive predictive value of cytology. Each of these benchmarks are either incorporated or – in the case of the interval cancer rate – being incorporated into CervicalCheck’s QA processes.

This recommendation was specifically addressed by the Legal Framework Group. In summary:

- The Legal Framework Group recommends ceasing the use of the term ‘programmatic audit’ for population screening programmes and that any clinical audit should be given a full descriptive title to ensure clarity of purpose and consistency of understanding.
- The Legal Framework Group recommends that future retrospective audits [of invasive cancer] should only be undertaken on an anonymised basis and published in aggregate format. Audits should be carefully designed by an overarching NSS multidisciplinary Steering Committee (or equivalent) that includes a patient/public representative and international research representative. This is in line with the findings of the [IARC report](#).

Recommendations 5 & 6: interval cancer rate

The CervicalCheck programme collaborates with the National Cancer Registry of Ireland Data Sharing Strategic Planning Group to design a methodology process of calculating an interval cancer rate for cervical screening. This will be used as a performance indicator for the programme.

This work will be informed by the recent report by the WHO’s International Agency for Research on Cancer (IARC) which has provided a definition of interval cervical cancers for cervical. This definition and further collaboration with international colleagues will enable benchmarking to take place.

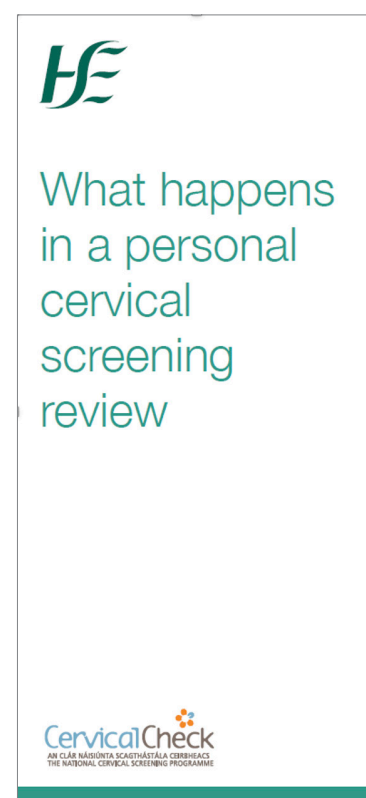
This recommendation will continue to be managed by the NCRI/NSS and NSS Programme Evaluation Unit (PEU).

Recommendation 7: promoting an understanding of, and public trust in, CervicalCheck

The CervicalCheck programme works closely with the NSS Communications Engagement and Information Development team in relation to promoting trust and confidence in the programme. This is an NSS business as usual activity.

Recommendation 8: ensuring the necessary resources to fully implement the CervicalCheck ERG recommendations

The team designing the PCSR process has determined the resources required for phase 1 implementation. Requirements will be monitored in line with uptake. All other recommendations were implemented using existing resources.



Information materials developed with patients and advocacy members for personal cervical screening reviews

Improving the Patient journey

Care, empathy, respect, transparency, clarity and structure must be present in all steps of the journey

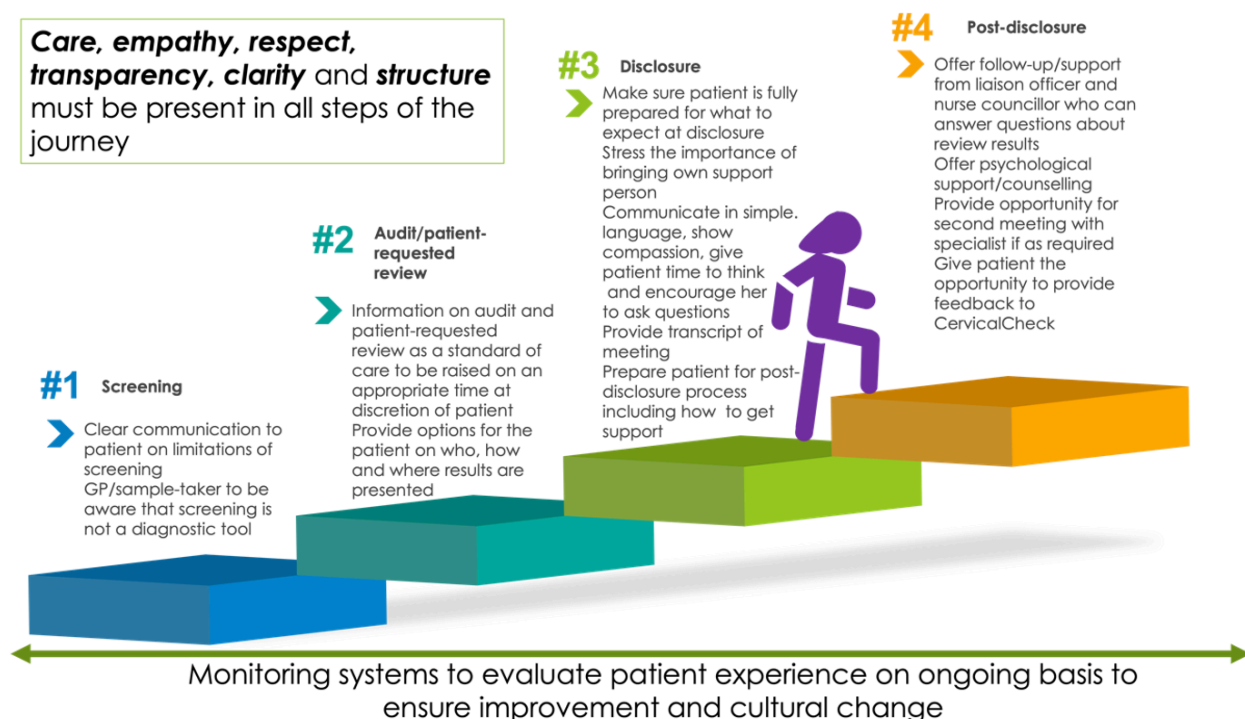


Image taken from research report developed by 221+ group and NSS on audit and disclosure processes

Communications Interval Cancer Implementation Group

This group was established in December 2020 and was chaired by Brenda Ryan (Head of NSS Client Services). This diverse group comprised representatives from all four national screening programmes, NSS Communications, NSS Clients Services, HSE Communications & Campaigns, patient/ public advocates, GP and legal representatives.

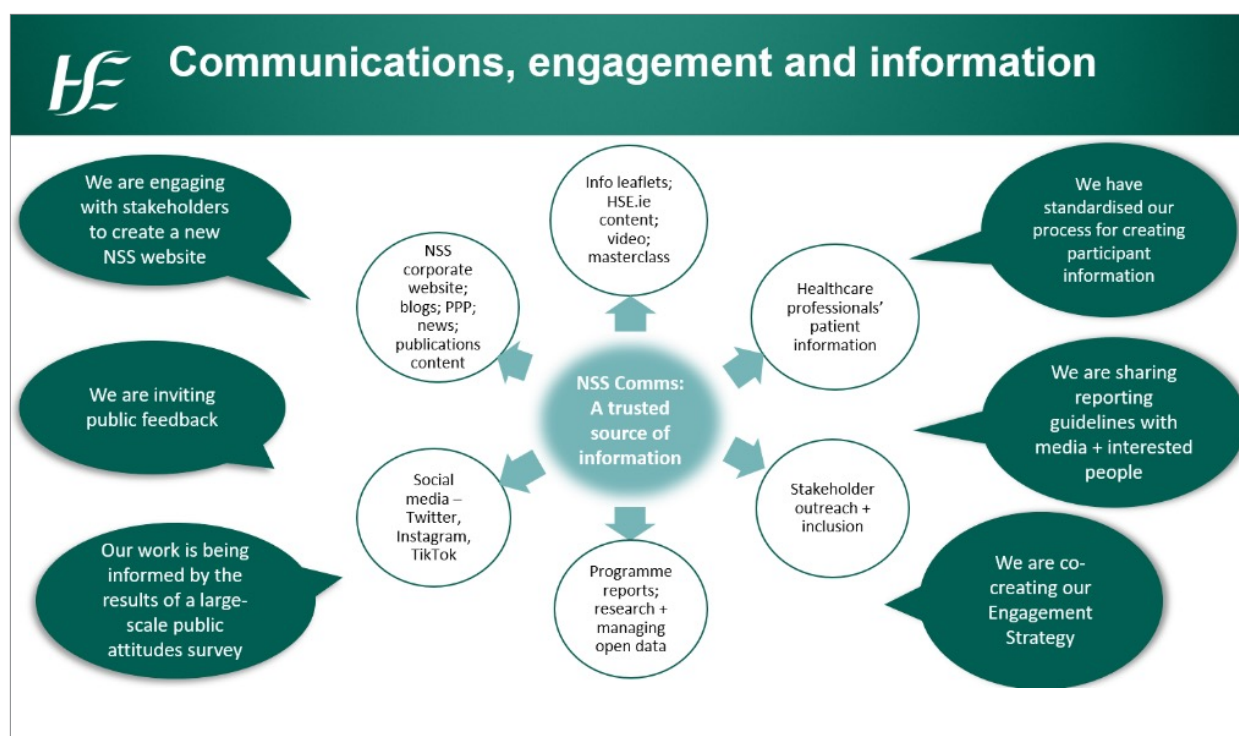
The ERG recommendations addressed by this group included the development and/or revision of information resources and the building of trust and confidence in the public in population cancer screening provided in Ireland.

The Interval Cancer Steering Group approved the closure of the Communications Implementation Group in January 2023.

Project closure update as follows:

- Following the research conducted on determining the behaviours and attitudes of the public towards screening, a specific action plan was developed from the research findings. The implementation of this action plan has transitioned into business as usual for the NSS Communication Engagement and Information Development Hub (CEID). This plan focused on four key areas:
 - Campaigns to address knowledge gaps on screening
 - Trust building (in conjunction with HSE actions)

3. Proactive engagement with stakeholders on messages.
 4. An increased engagement with GPs and other healthcare professionals to support screening participant.
- A process is in place for ongoing development/revision of informational resources using best practice methods combining research, Public Health, Behavioural and Cultural Insights (BCI), programme participants' and communications' expertise.
 - A new NSS corporate website is increasing transparency in our work and processes with the aim of building greater access to our work, and trust and confidence in screening.
 - A BCI research project was undertaken through which the development of decision-making aids for each of the four programmes is under way – these tools have been the communications section of the IARC report. They offer greater opportunities for informed choice for programme participants as part of the consent process for screening.
 - The NSS Communication Engagement and Information Development Hub will continue the activity outlined as business as usual.



Work of the NSS's Communications, Engagement and Information Development hub during report implementation

Legal Framework Group

The Legal Framework Group (LFG) was established in March 2021 and was chaired by Professor David Keegan (Clinical Director, Diabetic RetinaScreen Programme). Membership of this group was broad, including representation from the Department of Health (DOH), legal experts, health ethics, health economics, Public Health, NSS clinical directors and patient advocacy.

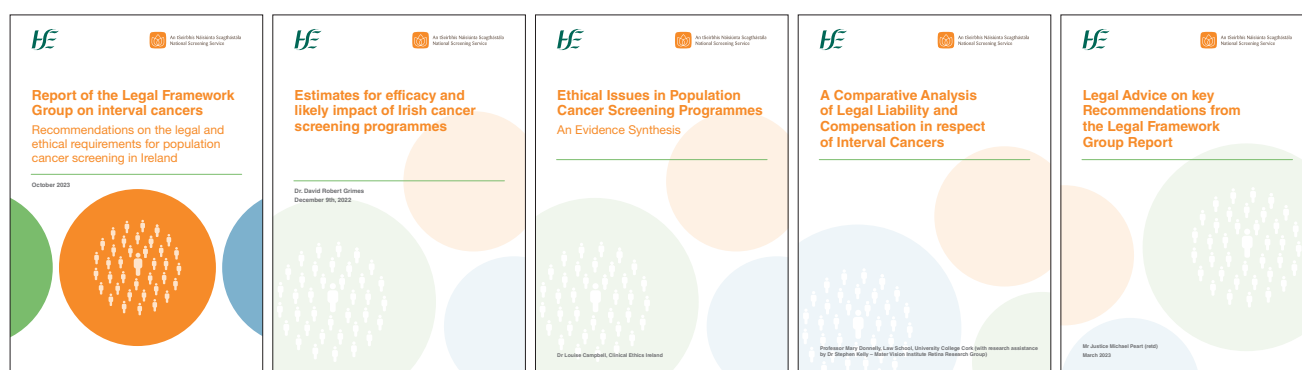
The LFG has developed clear recommendations around the conduct of screening and participation in screening based on current legal instruments such that the public, medical, legal and political interpretation of screening (positives and limitations) are clearly defined and understood.

The approach taken included an analysis of the recommendations arising from the ERG reports, discussion and debate on the ERG recommendations in the context of the current screening and medico-legal environment, the input of a data security and technology expert and four areas of commissioned research and advice consisting of:

- 1) The benefits and limitations of population screening with respect to mortality and morbidity;
- 2) Ethical considerations in relation to population screening with specific attention to the balance between the benefits and harms of screening and the limitations of participation;
- 3) An analysis of the legal environment in Ireland and benchmarking that against the operational environment of other international population screening programmes;
- 4) Advice on the Legal Framework Group Interim Report.

The Legal Framework Group has made 14 recommendations categorised under the following themes: communications; quality assurance and clinical audit; patient requested reviews and hindsight bias; and legal instruments.

The LFG final report was presented to HSE Executive Management Team, Safety and Quality Committee, and noted at the HSE Board. The NSS Executive Management Team has responsibility for progressing the recommendations made by the Legal Framework Group including engaging with stakeholders about the content of the report.

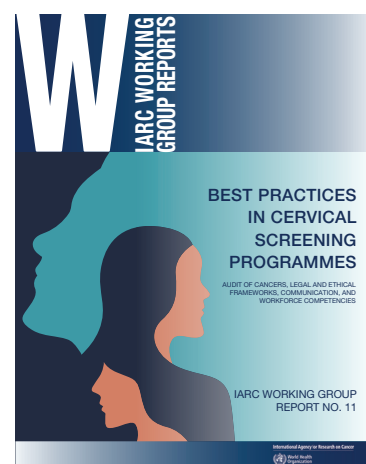


Collaboration with WHO's International Agency for Research on Cancer

During the course of the Interval Cancer project, the National Screening Service collaborated with the World Health Organization's International Agency for Research on Cancer (IARC) and the Department of Health to develop best practice guidance for cervical screening programmes. The output of this work is a new, globally relevant report with recommendations focusing on the audit of cervical cancers, the legal and ethical framework of cervical screening, communication and workforce competencies. The publication is an invaluable addition to the literature and some of its key messages endorse many of the recommendations presented by the Legal Framework Group, and the Interval Cancer project in general.

The report aims to provide global best practices in cancer screening which can be contextualised and implemented at a national level. Some important messages from the report are:

- Effective communication is a crucial element of cervical screening programmes. Communication should be transparent, understandable and culturally appropriate. Workforce competencies should be built to ensure women get the information and support they need to make an informed choice about their health.
- Ethical and legal frameworks have a critical role in obtaining consent, conducting cancer audits, and communicating the audit outcomes to patients and healthcare workers.
- Regular audit of cervical cancers is an important quality improvement measure rather than a tool to investigate perceived lapses in care. There is no legal or ethical consensus internationally on audits; and processes should be put in place – legislative or otherwise – to reflect the inherent limitations in cancer screening.
- Personal cervical screening reviews should be available to women who have had a cancer diagnosis and have come for screening in the past.



The report reinforces the significant progress we have made in Ireland in how and when we communicate, and has supported our consideration of the role of clinical audit, quality improvement and quality assurance in our programmes. Specifically, the report endorses our approach to offering [personal cervical screening reviews](#), a new development launched in 2023.

IARC reports:

1. [Recommendations on Best Practices in Cervical Screening Programmes: Audit of Cancers, Legal and Ethical Frameworks, Communication, and Workforce Competencies](#)
2. [Summary brochure](#)

Conclusion

The Interval Cancer Steering Group met for the last time in June 2023. At this meeting, the Steering Group agreed that the project implementation groups had met the objectives set out in the relevant terms of reference and the Steering Group agreed to close on this basis.

This report summarises how each of the recommendations has been addressed. Some of the recommendations have been completely implemented and others have become part of the ongoing business-as-usual activity of the National Screening Services. The Legal Framework Group has made new recommendations that the NSS Executive Management team has responsibility for progressing.

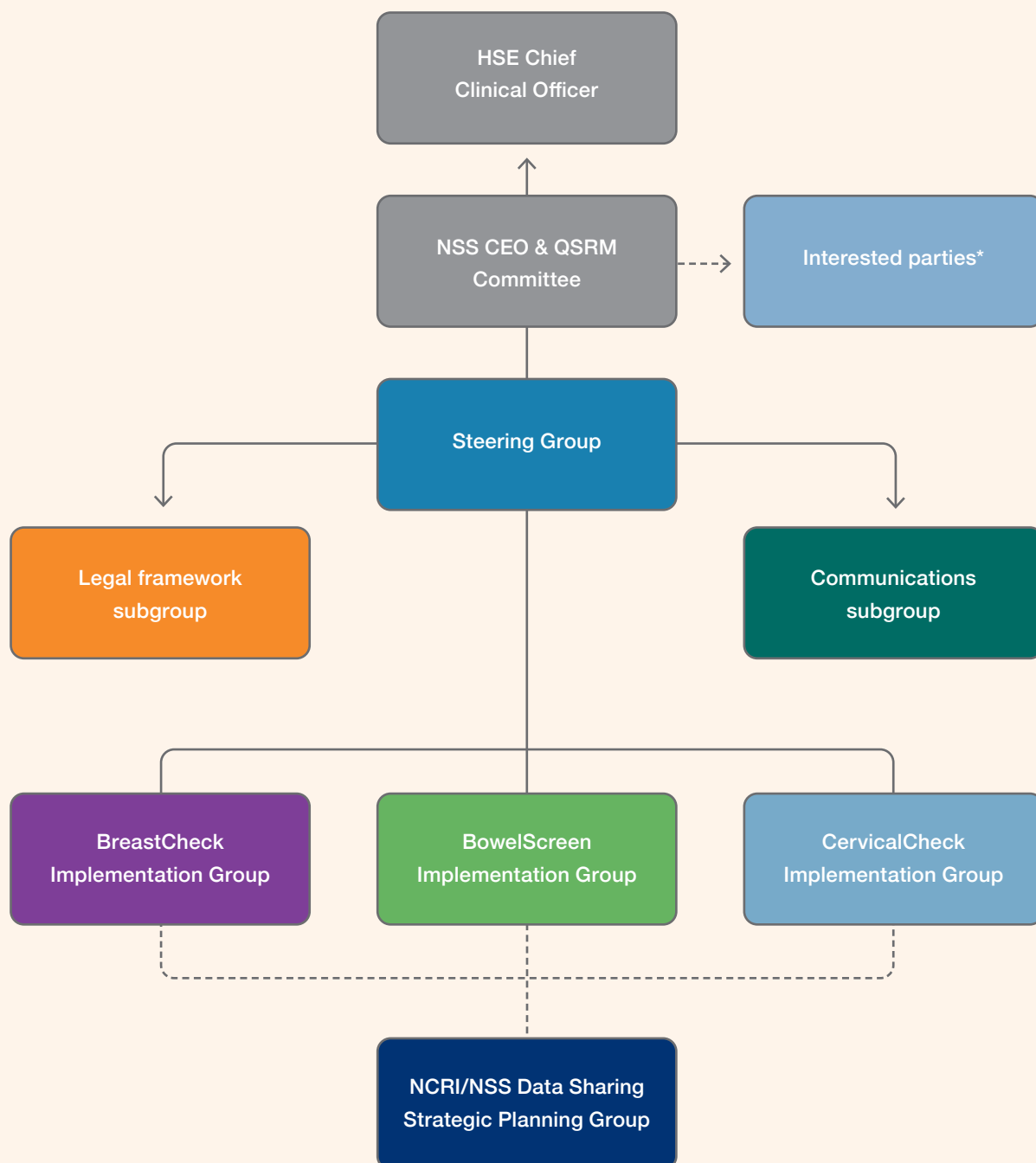
Significant collaboration, expertise and cooperation has resulted in the completion of this project. Notable achievements of the project include the design and implementation of patient requested reviews for cervical cancer; strengthening of the link with the NCRI to enable interval cancer rate measurement; the research, debate and analysis relating to the legal environment in which screening operates; informed contribution to the IARC collaboration and enhanced the communications activities of the NSS.

We are grateful to all implementation group members, HSE colleagues and wider stakeholders who contributed to the design and implementation of the project.

On completion of the project, we acknowledge that screening will not benefit every individual participating in our programmes, but we believe that the implementation of the ERG recommendations makes a positive impact on how we provide our screening services.

APPENDICES

Appendix 1: Implementation Governance Structure



* Interested parties include but are not limited to patient advocacy groups, HSE Quality Assurance and Verification, HSE Quality Improvement Division, HSE/Screening staff, Department of Health, Professional bodies, State Claims Agency.

Appendix 2: Expert Reference Group Report recommendations

ERG BreastCheck Report Recommendations

No	Recommendation	Lead implementation owner
1	<p>Women should continue to be provided with all the information they require in order to help them make an informed choice to consent to participate in the BreastCheck programme. Current informational material should be revised in order to reinforce the information on the benefits and limitations of screening. This material should continue to include explicit information on the occurrence of interval cancers. It should also include information on how women can request a review of their case, if desired. Expanded content on data-sharing arrangements between BreastCheck and the NCRI should be included.</p>	<p>Communications Interval Cancer Implementation group</p>
2	<p>BreastCheck should continue to monitor interval cancers at the programmatic level through the assessment of the interval cancer rate. The Expert Reference Group recommends that the interval cancer rate should continue to be the main programmatic KPI used to monitor BreastCheck performance relating to interval cancers. 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 cancer rate.</p>	<p>NSS/NCRI Strategic Planning Committee</p>
3	<p>The Expert Reference Group recognises the educational value of radiological review and classification of all interval cancers as recommended by EUREF. The Expert Reference Group therefore recommends the development of technology which will allow blinded, anonymised radiological assessment of all interval cancers. In the absence of such technology, legislation that would facilitate this activity is recommended.</p>	<p>BreastCheck Implementation Group</p>
4	<p>BreastCheck should continue to conduct patient-requested case reviews of interval cancers. The Expert Reference Group further recommends that all patients diagnosed with breast cancer in Ireland should be asked if they have had a previous screening mammography performed. All interval cancer patients thus identified should then be offered a review of their previous screening mammography at a time which is appropriate to their care and after they have provided their informed written consent to BreastCheck. The consent should include a request to use the reviews for future educational exercises. The results of these reviews should be communicated to the interval cancer patient.</p> <p>The current (interim) SOP developed by BreastCheck should continue to be used for this purpose, until the programme develops updated operational guidance, as part of the implementation of the recommendations of this report. In updating the SOP, the programme should aim to provide completely blinded reviews. Blinding should be employed for all reviews when the appropriate technology is available in order to ensure that the reviews can be performed efficiently and safely without compromising the service for women attending routine screening. The SOP should be continually monitored with reference to all stages, including interval cancer notification, consent, review, classification and open disclosure.</p>	<p>Implementation Group</p>

No	Recommendation	Lead implementation owner
5	The findings of all patient-requested individual case reviews should continue to be disclosed using the BreastCheck SOP. The BreastCheck SOP is aligned with the current HSE Open Disclosure Policy, and is consistent with the principles of open disclosure and professional ethical responsibilities.	BreastCheck Implementation Group
6	The HSE should continue to build and promote understanding of, and public trust in, BreastCheck and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Women should be made aware that they may, separately from any review process, request access to their imaging records at any time.	Communications Interval Cancer Implementation group
7	The Expert Reference Group does not recommend further analysis of the records of educational exercises undertaken prior to and during accreditation. The records did not employ a standardised, reproducible methodology for classification of interval cancers. Further analysis of these records, or a retrospective review of all historic cases of interval cancer, would not alter the clinical course of a woman diagnosed with and treated for an interval cancer.	BreastCheck Implementation Group
8	In order to ensure effective and efficient record management, the National Screening Service should review the implementation of the HSE record retention policy in the context of the General Data Protection Regulation (GDPR) which was introduced in May 2018.	NSS
9	The Expert Reference Group recommends that the necessary resources should be provided to BreastCheck 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, tort reform and emerging international practice.	Steering Group / Legal Framework subgroup

ERG CervicalCheck Report Recommendations

No	Recommendation	Lead implementation owner
1	<p>Women should continue to be provided with all the information they require in order to help them make an informed choice to consent to participate in the CervicalCheck programme. Current informational materials should be revised in order to reinforce the information on the benefits and limitations of screening. These materials should continue to include explicit information on the occurrence of interval cancers. They should also include information on how women can request a review of their case, if desired. Expanded content on data-sharing arrangements between CervicalCheck and the National Cancer Registry Ireland (NCRI) should be included. The Privacy Notice provided to patients in relation to their participation in the CervicalCheck Programme may need to be updated to explain what personal data the HSE will share with the National Cancer Registry Ireland (NCRI) and any other third parties, including but not limited to the purpose(s) of processing, the legal basis for processing, etc., to ensure compliance with data protection law.</p>	<p>Communications Interval Cancer Implementation group</p>
2	<p>CervicalCheck should establish a process to conduct patient-requested reviews of all invasive cancers (both interval and screen-detected cancers) and establish a standard operating procedure (SOP) for this purpose. Patient-requested reviews should only be undertaken following receipt of written consent from the patient. These reviews should be available to all women diagnosed with invasive cancers, including historic cases of women who did not participate in any other National Screening Service or Royal College of Obstetricians and Gynaecologists cytology review processes. Based on international experience, CervicalCheck should advise that a patient-requested review may take more than 12 months to complete.</p>	<p>CervicalCheck Implementation Group</p>
3	<p>The findings of all patient-requested reviews should be fully disclosed, and arrangements for this will be included in the CervicalCheck SOP. It is further recommended that the responsibility for disclosure of the review outcome rests with the treating clinician, generally the colposcopist or oncologist. This disclosure will be conducted in collaboration with the CervicalCheck programme and the woman's general practitioner (GP). CervicalCheck must notify the disclosing clinician of the outcome of the review, and in turn, the disclosing clinician must confirm with CervicalCheck that disclosure has taken place. Discordance in cytology review is not unexpected or unanticipated. This would not meet the definition of a patient safety incident. If a serious adverse event is identified, HSE policies must be followed.</p>	<p>CervicalCheck Implementation Group</p>
4	<p>The Expert Reference Group recognises the educational value of programmatic review of cytology of all invasive cancers including interval cancers. The Expert Reference Group therefore recommends that Clinical Audits be conducted only where either (1) such Clinical Audits are both blinded and anonymised; or (2) legislation protecting the confidentiality of Clinical Audits is passed by the Oireachtas. If such Clinical Audits are conducted, CervicalCheck will include the outcomes of such Clinical Audits in an annual report. The results of the Clinical Audits will be anonymised and/or confidential under future legislation, and therefore results of the Clinical Audits cannot and will not be disclosed in respect of individual cases reviewed.</p>	<p>CervicalCheck Implementation Group</p>

No	Recommendation	Lead implementation owner
5	The CervicalCheck programme should develop a new KPI, the interval cancer rate. The programme should liaise with other international screening programmes and the International Agency for Research on Cancer (IARC), specifically with regard to: Definition of interval cancers, Methodology to calculate the interval cancer rate, and Benchmarking for participating programmes.	NSS/NCRI Strategic Planning Committee
6	Implementation of the recommendations of the Scally Report should ensure that communication with NCRI is strengthened to enable a more timely validation of invasive cervical cancers. This includes consideration of the development of a population screening registry or equivalent in collaboration with the NCRI. Implementation of the individual health identifier would facilitate this process.	NSS/NCRI Strategic Planning Committee
7	The HSE should continue to build and promote understanding, confidence and trust in CervicalCheck and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Women should be made aware that they may, separately from any review process, request access to their screening records at any time.	Communications Interval Cancer Implementation group
8	The Expert Reference Group recommends that the necessary resources should be provided to CervicalCheck 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 General Data Protection Regulation (GDPR), tort reform and emerging international practice.	Steering Group / Legal Framework subgroup

ERG BowelScreen Report Recommendations

No	Recommendation	Lead implementation owner
1	<p>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).</p>	<p>Communications Interval Cancer Implementation group</p>
2	<p>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 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.</p>	<p>NSS/NCRI Strategic Planning Group</p>
3	<p>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 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.</p>	<p>BowelScreen Implementation Group</p>
4	<p>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.</p>	<p>BowelScreen Implementation Group</p>

No	Recommendation	Lead implementation owner
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.	Communications Interval Cancer Implementation group
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.	Steering Group / Legal Framework subgroup



An tSeirbhís Náisiúnta Scagthástála
National Screening Service