Interval Cancer Project

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

Annual Report 2021/2022 Year 2

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Contents

Message from the National Screening Service Chief Executive

In October 2020, the HSE published the Expert Reference Groups' Interval Cancer Reports, which 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. They affirm that world class screening programmes must balance patient trust, staff recruitment and affordability, and that despite best efforts, interval cancers are an inherent feature of any screening programme. They emphasise the need to sustain our vital public health screening programmes.

The National Screening Service (NSS) continues to be fully 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. Throughout Year 2, the project groups have worked to achieve the objectives, and to overcome the complexities and challenges of this project. Implementation requires considerable deliberation, input and collaboration.

Over the past year, we have fully implemented a number of the Expert Reference Groups' recommendations across the different implementation strands. I am pleased to note that the design of a new end-to-end process for patient-requested reviews in CervicalCheck has been completed. We have taken a restorative, patient-centred approach to communications to enable us to provide information about cervical cancer in a way that we hope minimises the harm felt for everyone. We are extremely grateful for the invaluable insights of our patient and public participants, and to the patients and/or families impacted by interval cancer, who have guided and informed the design of this process. This process has been approved by the Interval Cancer Steering Group and is in an active consultative process with key stakeholders. The primary focus for Year 3 of this project will be the operationalisation of this process.

In addition to other goals reached by the implementation groups, an interim report has been developed by the Legal Framework Group which makes recommendations that look to harmonise the legal and screening environment to ensure sustainability of screening for the people of Ireland. A final report is due in early 2023.

As chair of the Interval Cancer Steering Group and chief executive of the National Screening Service NSS I am indebted to all our stakeholders who have given over their valuable time to the implementation of the reports' recommendations, including patient advocacy representatives, screening clinicians, international screening experts and research experts, as well as my NSS colleagues. I hope this report will serve to recognise how much has been achieved over the past year and provide detail about the next steps required to conclude the implementation of the Expert Reference Groups' recommendations.

Fiona Murphy

Chief Executive, National Screening Service

Executive Summary

In October 2020, the HSE welcomed the publication of the Expert Reference Groups' Interval Cancer Reports (see the News section of *screeningservice.ie*, or click here). The Expert Reference Groups' reports proposed a suite of recommendations across all three cancer screening programmes. An interval cancer project was initiated following the publication of the reports encompassing programme-specific implementation groups, and communications and legal framework groups. The work of all groups is governed by an Interval Cancer Steering Group (see Appendix 1).

A patient and public partnership engagement process is embedded throughout the Interval Cancer project. The programme-specific implementation groups also work closely with a National Cancer Registry of Ireland (NCRI) / NSS Data Sharing Strategic Planning Group. This group was established to develop and implement data sharing protocols between both organisations and ensure efficient and effective delivery of data sharing.

High Level Progress of Groups – Year 2

The CervicalCheck Interval Cancer Implementation Group has continued to focus largely on the design and implementation of patient-requested review processes (now known as personal cervical screening reviews). A standard operating procedure and ancillary documents for patient-requested review process have been developed and approved. A communications and stakeholder engagement strategy has been developed.

The BowelScreen Interval Cancer Implementation Group has developed and implemented a system for recording post-colonoscopy colorectal cancer. A standardised colonoscopy consent form has been operationalised across all local endoscopy screening units. The memorandum of understanding between BowelScreen and the local screening units has been updated to reflect the responsibility of the screening units in conducting and disclosing the outcomes of patient-requested reviews. This group will continue to work closely with NCRI/NSS Data Sharing Strategic Planning group to support the development of processes to calculate an interval cancer rate for post-colonoscopy colorectal cancer.

The BreastCheck Interval Cancer Implementation Group has focused on strengthening existing processes for patient-requested reviews. The BreastCheck programme continued to provide patient-requested reviews in line with the agreed standard operating procedure. The retention and deletion of historic educational materials under GDPR procedures has been completed. Ongoing data retention/deletion and compliance with GDPR policies and procedures is in full operation. An updated interval cancer rate for breast cancer screening was calculated during Year 2 of this project.

The Communications Interval Cancer Implementation Group has concluded its three-stage research project to support future communications work to build the public's trust and confidence in the screening programmes. Findings of this research have informed communications work through the development and implementation of an action plan.

The Legal Framework Group has developed an interim report while awaiting the outcome of the commissioned research to support the work of the parallel Interval Cancer implementation groups, and to provide a progress update to interested stakeholders. This report has received approval by the Interval Cancer Steering Group, and consultation is taking place on the findings of the report. Research in the areas of law, health ethics and efficacy of screening is near completion. Research on the cost effectiveness of screening has commenced. The outcome of these research projects will inform the final report.

Introduction

The purpose of this report is to outline the substantive progress made during the second year of implementing the recommendations arising from the Expert Reference Groups' Interval Cancer Reports. The report describes the background to the project, progress made and next steps. Included in the appendices are the project governance structure and implementation group membership.

Background

The HSE welcomed the publication of the Expert Reference Groups' Interval Cancer Reports on 21 October 2020. These reports were commissioned as part of the Scally Review in 2018. Over the past two years, we have been working diligently towards the implementation of the recommendations.

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 comprises an interval cancer implementation group for CervicalCheck, BreastCheck and BowelScreen respectively; a Legal Framework group; and a Communications group. An overarching steering group has been assembled to provide assurance to the NSS Quality, Safety and Risk Management committee and the HSE on the timely implementation of the recommendations of the Expert Reference Groups' Interval Cancer Reports.

Membership of these groups is diverse and includes representation from patient and public advocacy groups, primary care, cancer screening, public health, medical ethics, and health economics; as well as legal and communication specialists (see Appendix 2).

All groups have agreed terms of reference for their work and have developed project implementation plans detailing actions, activities, and timelines. During Year 2, the project moved from the design phase to the implementation phase, and is within planned scope, timelines, resources, and funding.

In November 2021, we published our Year 1 annual report which can be located via this link: https://www.screeningservice.ie/publications/NSS-Interval-Cancer-Project-Year1-Nov-2021.pdf

Patient and Public Input

Patient and public input and guidance continues to be embedded in the process of implementing the Expert Reference Groups' recommendations. Each implementation group has representation from patient/public advocates so that the needs of screening programme participants are considered during design and implementation. We are also engaging directly with those who have been impacted by an interval cancer. Additionally, an Interval Cancer patient/public representative advisory forum has been formed. This is a free discussion forum to garner valuable feedback on elements of the Interval Cancer project.

CervicalCheck Interval Cancer Audit Implementation Group

The CervicalCheck Interval Cancer Audit Implementation Group was established in December 2020 and is chaired by Clinical Director of CervicalCheck Professor Nóirín Russell. Membership of this group comprises CervicalCheck clinical and administration personnel, representation from colposcopy, cyto-histopathology, the Faculty of Pathology at the Royal College of Physicians of Ireland (RCPI), health ethics, patient and public advocacy, primary care and gynae-oncology. This group continues to work towards the implementation of the following recommendations:

- 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 key performance indicator, the interval cancer rate

The group collaborated with the Communication Interval Cancer Implementation Group to support the implementation of the following Expert Reference Groups' recommendations:

- To continue to strengthen participant information to help them make an informed choice to consent to participate in screening
- To build understanding and trust in screening programmes, and help the public understand the benefits and boundaries of screening

Patient-requested reviews

During Year 2, the governance structure of the design and implementation of the patient-requested review process was revised, four workstreams (design, delivery, communications and resourcing) were established to design and implement the patient-requested review process.

The end-to-end process of patient-requested review has been agreed. Women with a confirmed cervical cancer and have had cervical screening within 10 years of their diagnosis will be eligible to request a review. The review will include call-recall (administrative side of the programme), cytology, histology and colposcopy. Clinical governance of direct patient care lies with the individual practitioner (either GP or hospital consultant) and does not lie with the programme, and hence is not a part of an Interval Cancer review. Review results will be classified as per Public Health England categories:

- Satisfactory
- Satisfactory within known limitations of screening
- Unsatisfactory

A dedicated clinical team will synthesise the result findings with the patient's clinical history to enable a highly personalised discussion. A centralised highly trained team within NSS/CervicalCheck will discuss the review results with the woman or their representative.

A standard operating procedure and ancillary documents for patient-requested reviews have been designed and approved by the Interval Cancer Steering Group. Consultation with key stakeholders on the standard operating procedure document is currently being sought. Independent cytology review provision from the UK has been secured and a service level agreement is being prepared which in turn will inform the data protection impact assessment process.

The design of the review and communication process was informed by the recommendations and core principles distilled from the 221+ consultation research report. Key elements of the restorative communication approach being taken in the review process include:

- a single designated point of contact within the NSS
- an early introductory meeting (prior to independent review) to allow women to tell their stories and acknowledge the upset they feel at developing cancer following participation in screening
- providing some clear information about what a review will find e.g. a cytology review will find abnormal cells in four out of 10 cases on review. Most of these will be classified as “satisfactory within known limitations of screening”, and very few will be classified “unsatisfactory”.
- explanation about why things may be found on review that were not obvious at screening
- a final review results meeting to discuss results findings
- provision of support and signposting post review meeting

Collaboration with the HSE Open Disclosure Office and National Healthcare Communications Programme is ongoing to develop an intensive communication skills training package to support the delivery of introductory and review results meetings with participants. Extensive work is ongoing by the Communications workstream to develop patient requested review resourcing materials for the participants, clinicians and the wider public. Further to this, an appropriate communications and stakeholder engagement strategy has been developed. This is currently being implemented.

Risks identified in planning and executing patient-requested reviews

- Laboratories might not support and engage in the process
- Lack of cytology expertise to conduct reviews
- Colposcopists might not support and engage in the process
- Lack of expertise among doctors for discussion with patients
- Influence on legal claims and increase the cost of providing the programme
- Impact on recruitment and retention of professional staff due to fear of litigation

All risks are being assessed and managed by the CervicalCheck Interval Cancer Audit Implementation Group throughout the project lifecycle.

Programmatic audit

The design of retrospective programmatic audit for the purpose of professional education and learning will be done in line with the findings of the Legal Framework Subgroup which is currently assessing the feasibility of designing programmatic audits.

Interval cancer rate

The group continues to collaborate with the NCRI/NSS 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.

Next steps

1. Implementation of the patient-requested review process in CervicalCheck
    a. Secure legal indemnity for those providing the process across the review pathway
    b. Finalise consultation with key stakeholders
    c. Finalise the service level agreement and data privacy impact assessment
    d. Determine and allocate the resources (e.g., staffing, technology) required for the delivery of patient requested reviews (personal cervical screening reviews)
    e. Continue to develop resource materials necessary for patient-requested reviews and disclosure processes (with input from patient representatives).
    f. It is expected that patient-requested reviews (personal cervical screening reviews) will commence in the first quarter of 2023.
2. Continue collaboration with NCRI in relation to the development of an interval cancer rate.

BowelScreen Interval Cancer Implementation Group

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

This group have been working towards the implementation of the recommendations arising from the BowelScreen Expert Reference Group Report, which include:

- Agree a definition of a post-colonoscopy colorectal cancer
- 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 post-colonoscopy colorectal cancers 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.

During Year 2, significant progress to fully implement many of the BowelScreen Expert Reference Group's recommendations has been made. This progress includes:

Recommendation 1: Revision of information materials and implementation of colonoscopy consent form

- 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.
- This group continues to support the development of patient information to enable informed choice and consent. This will now move to be managed by the BowelScreen programme which will engage the expertise of the NSS information hub.
- As the core components of this recommendation have been completed or are moving to NSS business as usual, this recommendation is now moving to close.

Recommendation 2: Development of interval cancer rate

- Ongoing clinical support was provided to NCRI/NSS Data Sharing Strategic Planning Group in their development of processes to calculate the interval cancer rate for bowel cancer.
- This recommendation is moving to close as the design and implementation of an interval cancer rate for bowel cancer continues to be managed by the NCRI/NSS Data Sharing Strategic Planning Group. Work is progressing and it is projected that an interval cancer rate for bowel cancer will be available in the third quarter of 2023.
- Post-FIT (Faecal Immunochemical Test) 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 cancers from non-NCRI sources

- This recommendation is moving to close as the group has developed a template for the recording of post-colonoscopy colorectal cancers from non-NCRI sources. This template has been approved by the appropriate parties and is now operational in all screening endoscopy units.
- The BowelScreen programme continues to monitor key performance indicators independently of post-colonoscopy colorectal cancer notification.

Recommendation 4: Patient Requested Reviews of post-colonoscopy colorectal cancers

- The BowelScreen memorandum of understanding with local screening units has been updated to reflect the responsibility of the local screening units in the conduct and disclosure of post-colonoscopy colorectal cancer reviews. This recommendation is fully implemented.

Recommendation 5: Build and promote understanding, confidence and trust in the BowelScreen programme

- This group provided expertise on the BowelScreen programme as required in the behaviours, attitudes and knowledge research conducted by Communications Interval Cancer Implementation Group. In conjunction with this, BowelScreen engaged in various awareness campaigns including Bowel Cancer Awareness Month in April.
- This work will now move to be managed by the BowelScreen programme who will engage the expertise of the NSS information hub.

Recommendation 6: Provision of the necessary resources to implement all BowelScreen Expert Reference Group's recommendations

- This group has implemented the programme-specific recommendations by using existing resources within this group and the BowelScreen programme. A need for further resources was not warranted and this recommendation is now closed.

In conclusion, the BowelScreen Interval Cancer Implementation Group has reviewed the terms of reference and implementation project plan for this group and agree that all programme-specific recommendations have been implemented and works concluded. As outlined above, this group propose to transfer the continued implementation of recommendations 1 and 5 to the NSS BowelScreen Programme under business as usual. Recommendation 2 will continue to be designed and implemented by the NCRI/NSS Data Sharing Strategic Planning Group. This was approved by the Interval Cancer Steering Group in January 2023.

BreastCheck Interval Cancer Implementation Group

This group was established in February 2021 and is chaired by Dr Niall Sheehy – consultant radiologist. Membership of this group comprises BreastCheck clinical and administration staff, NSS staff, patient advocates, and external symptomatic clinicians. The key deliverables associated with the BreastCheck Implementation Group are:

- Strengthening the established patient-requested reviews 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.

Recommendation 1: Development and revision of informational resources

This group continued to support the development of patient information to enable informed choice and consent by the Communications Interval Cancer Implementation Group. This recommendation has moved to be managed by the NSS information hub as business as usual. The revision of consent material will be informed by the outcome from the Legal Framework Group.

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 and NSS, including the NSS's 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 currently no safe mechanism to review or to fully anonymise interval cancer mammograms. The group is engaging with the Legal Framework Group to see if a solution may be developed. In the interim, this group recognises that the mammograms of women who request a review are available. There are a number of additional mechanisms that 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 2023.

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. This group recommends and agrees that a BreastCheck liaison service will be established to help to support and develop the current structures that are in place. The recruitment for a BreastCheck liaison nurse to manage this process is in progress.

During the past year, the BreastCheck programme continued to provide individual case reviews as requested. These reviews were conducted in accordance with the agreed standard operating procedure. All findings of patient-requested reviews were communicated in line with the standard operating procedure. Throughout Year 2, the BreastCheck Interval Cancer Implementation Group continued to monitor and strengthen operational guidance for patient-requested reviews. The outcome from the Legal Framework Group will also help inform these recommendations. On conclusion, recommendation four and five will move to close by the BreastCheck implementation group. 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 continued to support the Communications Interval Cancer Implementation Group in building and promoting understanding of and trust in the national screening programmes. This recommendation is now being managed by the NSS's information hub 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:

The 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 policy. Effective, efficient, and appropriate record management in the context of the General Data Protection Regulation (GDPR) is be supported by the new NSS Information Governance Department, and Interval Cancer Steering Group. This recommendation has been fully implemented as it has moved into business as usual under Information Governance framework and can move to close.

Recommendation 9: To ensure the necessary resources to fully implement the BreastCheck Expert Reference Group's recommendations

This group has identified the resources required to implement the BreastCheck Expert Reference Group's 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.

Next steps

1. Progress the establishment of the BreastCheck liaison service
2. Awaiting final conclusions of the Legal Framework Group to determine if radiological assessment of interval cancers is feasible.
3. Continue collaboration with NCRI in relation to the calculation of a new interval cancer rate (post 2016)

Challenges

1. The current lack of legislative protection for programmatic review.
2. Full anonymisation for image review is not currently possible. Ongoing processes are being explored.
3. Workforce shortages - national and international availability of medical personnel is an ongoing challenge. BreastCheck, as a clinically delivered programme, is hugely impacted by this risk.
4. Impact of COVID-19 Is a challenge in relation to the number of delayed invitations outstanding. The programme is at least a year behind inviting women for their screens, and this continues to impact service delivery.

Communications Interval Cancer Implementation Group

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

The primary focus of this group is the implementation of the following Expert Reference Group report recommendations common to all three cancer screening programmes:

1. The provision of information to participants to help them make an informed choice to consent to participate in screening
2. The necessity to build and promote understanding of, and trust in, screening programmes.

In year two of this project, this group concluded the commissioned quantitative and qualitative research to identify and explore peoples' perceptions of screening services in Ireland and what drives and inhibits them to attend screening. The research, which comprised the following three stages, has been completed:

- Stage 1: One-to-one interviews with healthcare professionals were completed and a report on the themes that emerged from the interviews was developed
- Stage 2: a large-scale omnibus questionnaire targeting 2,000 service users across all screening programmes
- Stage 3: 11 focus groups qualitatively explored a deeper understanding of the questionnaire findings.

The outcome of this research has and will continue to inform, support and validate future communications work. A targeted action plan has been developed to implement the outcomes of this research and this is being managed by the NSS information hub. This action plan comprised four key action areas of campaigns, trust building, clarification of problematic terms, and increasing engagement with GPs.

The revision of informational materials has now moved to be managed by the information hub as business as usual. The Communications and Public Health teams will engage the expertise of the specific screening programmes to support the development of respective informational materials. The revision of consent material will be informed by the Legal Framework Group.

The development of decision-making aids to support the consent process has been ongoing throughout Year 2 of the project.

Next steps

1. Decision making aid fieldwork to commence by year end (2022)
2. Behavioural science training will commence by year end (2022)

To conclude, the Communications Interval Cancer Implementation Group will seek to conclude the work of this group as continued management of the recommendations has moved into business as usual under the information hub. This was approved by the Interval Cancer Steering Group in January 2023.

Legal Framework Group

The Legal Framework Group was established in March 2021 and is chaired by Diabetic RetinaScreen clinical director Professor David Keegan. Membership of this group is broad, including representation from the Department of Health (DOH), the National Cancer Control Programme, the NSS (clinical directors and public health department), patient advocates; and experts from legal, health ethics, and health economics backgrounds.

In Year 2, the group continued to work to develop 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 methodology approach taken included an analysis of the recommendations arising from the Expert Reference Groups' reports; discussion and debate on the Expert Reference Groups' recommendations in the context of the current screening and medico-legal environment; and four areas of commissioned research:

- Legal benchmarking
- Ethical analysis of screening
- Efficacy of cancer screening programmes
- Cost-effectiveness of screening post-Scally review

This group also examined the role of screening in the Patient Safety Bill (Notifiable Patient Safety Incidents) 2019 and considered this in its deliberations.

In Year 2, an interim report was developed by the Legal Framework Group to support the work of the parallel interval cancer implementation groups, while awaiting the outcome of the commissioned research and to provide a progress update to interested stakeholders. The Legal Framework Group has made 12 recommendations to date categorised under the following themes: communications; clinical audit; patient requested review; legislative; Patient Safety (notifiable patient safety incidents) Bill 2019; information governance, and cost-effectiveness.

The interim report was approved by the Interval Cancer Steering Group and is currently under review by relevant stakeholders.

Next steps

The final report is due to be completed in the first quarter of 2023. The group will continue to engage the patient advisory forum in all outcomes of this group and incorporate key learnings and outcomes in final report. Feedback is also incorporated into programme-specific implementation groups.

The final report will be informed by the:

- Key learnings and outcomes from the patient advisory forum
- Conclusion of commissioned research in legal benchmarking, an ethical analysis of screening, and the efficacy of cancer screening programmes (due by the end of 2022)
- Conclusion of cost effectiveness of screening (due in the first quarter of, 2023)
- Include the group's final deliberation on the term 'programmatic audit' and potential future audit practice
- The publication of the amendments to the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 in the final report
- The International Agency for Research on Cancer (IARC) collaboration reports

Implementation Challenges

While working towards achieving the recommendations outlined in the Expert Reference Groups' reports over the past two years, the implementation groups are meeting certain challenges. The challenges arising vary depending on the area of focus, however, they are summarised as follows:

Patient-requested review process

A key challenge in implementing the patient-requested review process is the willingness and availability of relevant professionals to be involved in the review process in the context of the current legal environment.

The implementation groups continue to be cognisant that the implementation of reviews should not jeopardise the overall cost-effectiveness of screening programme, as outlined in the Expert Reference Groups' recommendations.

Given the complexity involved in the design and implementation of the review processes, the implementation groups acknowledge the time and resource implications required to ensure all stakeholders collaborate to implement the recommendations successfully.

Communication challenges

Through this project, we are developing methods to aid the public's understanding of screening, with the aim of building a partnership between our participants and the screening services. As we progress through this work, a number of communication challenges continue to exist for the project. These include increasing the public's awareness and understanding about:

- Screening is a risk-reduction tool not a risk-elimination tool
- Limitations of screening on an individual basis in advance of screening participation
- Interval cancers are the unintended but anticipated findings in all international cancer screening programmes
- The balance of risks and benefits of screening:
- Screening may do you good and prevent you from getting cervical cancer
- Screening may do you harm, through stress or overtreatment

Programmatic review

The Expert Reference Groups' recommendation noted that retrospective programmatic review of screening data in patients with invasive cancers should be conducted whereby technology to blind and anonymise screening data is available, or under an agreed legislative framework, to ensure that the key deliverables of quality assurance and professional education are sustained.

The feasibility of conducting retrospective programmatic review continues to be considered by the Legal Framework Group. Key risks and issues identified in implementing this recommendation include:

- Currently, no technology exists, or is available, to facilitate blinding and anonymisation of screening data.
- Legislative protection for programmatic review is also not available.
- In the case of legal challenges, without such technology, blinded reviews cannot be conducted in a manner consistent with the Dunne principles.
- Experts might not engage in programmatic reviews in the absence of protective legislation or suitable technology.
- There is a risk that the benefit of programmatic reviews to the professional education and quality assurance of staff will not be realised if the conditions to enable programmatic review cannot be satisfied (i.e., technology to blind and anonymise, or legal protection).

In the absence of programmatic review, it is imperative to note, that each programme has alternative quality assurance mechanisms to ensure the quality of individual staff (e.g., regular proficiency testing) and of the programme (key quality performance measures published regularly). This is in line with international standards and comparator programmes. Furthermore, each programme has a range of professional training and education activities for all disciplines involved in the programme. The NSS Quality Assurance Framework aims to ensure continuous improvement in approach. With the development of interval cancer rates, which can be benchmarked internationally, these activities may make programmatic audit of interval cancers redundant. However, consideration is being given to alternative audits to support programme improvement goals. The recommendations from the WHO (World Health Organisation)/IARC collaborative project in cervical screening will inform next steps.

Additional challenges identified by Legal Framework Group

The challenges identified by the Legal Framework Group include:

- The emotional burden and trauma experienced by patients and their families during court cases. These adversarial cases are traumatic experiences for all parties involved.
- Cost of litigation arising from cases of interval cancers meaning screening no longer meets cost-effectiveness criteria. Despite the known limitations of screening, Ireland continues to see a growth in legal cases arising from participation in cancer screening programmes.
- Reduced trust leading to reduced participation and, thus, less effective screening programmes.
- Increased costs of mitigation against the risk of litigation (extra staffing, extra processes, further committees, resource re-allocation to investigate claims).
- Staff retention in an increasingly adversarial environment.

Conclusion

The second year of the interval cancer project built on the significant work accomplished across all implementation groups in Year 1. This report outlines the key achievements completed by the project groups which include the design of a new process for patient-requested reviews in CervicalCheck, the calculation of an updated interval cancer rate for breast screening, the development of an interim report encompassing a suite of recommendation by the Legal Framework Group and the conclusion of a comprehensive research project to determine the public's attitudes and knowledge of screening to inform future communications work.

The report outlines that a significant proportion of the project work will conclude in Quarter 1, 2023. The primary focus for Year 3 of this project will be the implementation of the CervicalCheck patient-requested review process through a Phase 1 programme; and then integrating learnings, as required, into the final refined process. We will continue our work to provide an open and transparent patient-requested review process that gives the patient the opportunity to understand a difficult cancer diagnosis despite participating in screening. We hope that supported discussion of review findings will provide some answers for women and will give them a protected and compassionate space to discuss their experience with clinicians.

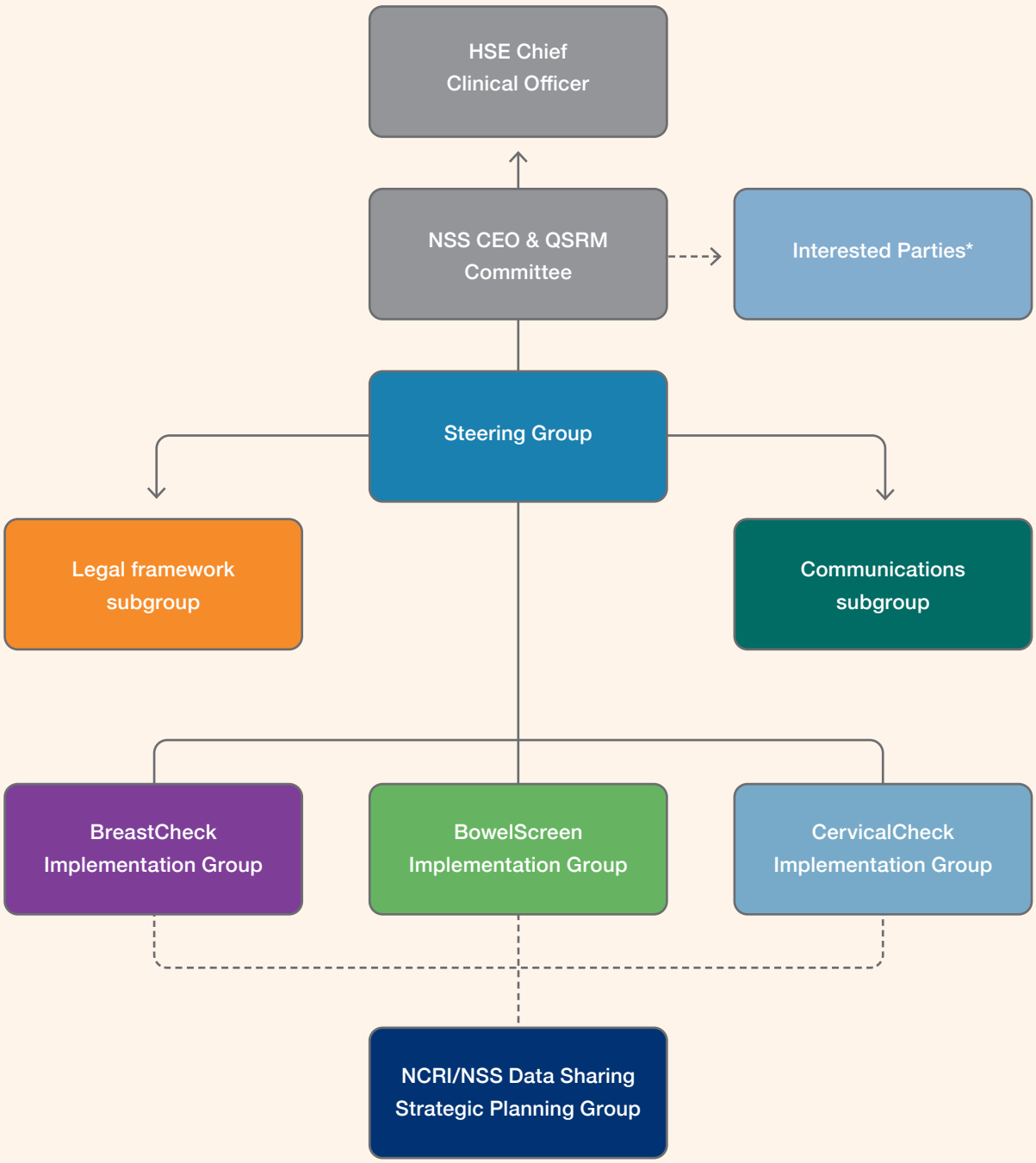
Moreover, we look forward to working closely with the NCRI in Year 3 through the ongoing collaborative work of the NCRI/NSS Data Sharing Strategic Planning Group in strengthening the links between the organisations and developing an interval cancer rate for both the cervical and bowel screening programmes.

We continue to be mindful of the challenges to the successful implementation of the Expert Reference Groups' recommendations. We wholly acknowledge that screening will not benefit every individual in our participating screening population, but we hope that the full implementation of the Expert Reference Groups' recommendations will make positive strides towards restoring screening to its place in healthcare as a service which mainly does good.

As we look forward to moving into Year 3, we will continue to be committed to the implementation of the outstanding Expert Reference Groups' recommendations. We thank the entire project group for their dedicated commitment to this project and to all stakeholders who have supported this work throughout the past two years.

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: Membership

Interval Cancer Steering Group

Chairperson	Ms Fiona Murphy
Head of Quality, Safety and Risk, NSS	Ms Colette Brett
Consultant Obstetrician/Gynaecologist	Prof Tom D'Arcy
Consultant Epidemiologist / Director of the Programme Evaluation Unit, NSS	Prof Patricia Fitzpatrick
BreastCheck Clinical Director	Prof Fidelma Flanagan
Public Health/ Lead Report Writer Expert Reference Group Reports	Prof Orla Healy
National Surgical Oncology Programme Clinical Advisor to the NCCP	Prof Arnold Hill
Diabetic Retinopathy Screening Clinical Director/ Chair of Legal Framework Group	Prof David Keegan
NSS Director of Public Health	Dr Caroline Mason Mohan
Patient Representative	Ms Marie Meaney
BowelScreen Clinical Director/Chair of BowelScreen Interval Cancer Implementation Group	Prof Pádraic Mac Mathúna
Public Advocate	Ms Aoife McNamara
Clinical Director – National Office of Clinical Audit	Mr Kenneth Mealy
CervicalCheck Clinical Director/Chair of CervicalCheck Interval Cancer Audit Implementation Group	Prof Nóirín Russell
Chair of the Cervical/Bowel Expert Reference Group	Prof Susan O'Reilly
Chair of the Communications Interval Cancer Implementation Group	Ms Brenda Ryan
Chair of the BreastCheck Interval Cancer Implementation Group	Dr Niall Sheehy

CervicalCheck Interval Cancer Audit Implementation Group

Chairperson of CervicalCheck Interval Cancer Audit Implementation Group / Clinical Director - CervicalCheck, NSS	Prof Nóirín Russell
Consultant Gynae-oncologist Galway	Dr Katharine Astbury
Patient Representative	Ms Moira Dillon
Public Advocate	Ms Brigid Doherty
Primary Care Representative	Dr Sarah Fitzgibbons
Colposcopist	Dr Myra Fitzpatrick
Nurse Colposcopist	Ms Claire Fry
CervicalCheck Programme Manager, NSS	Ms Gráinne Gleeson
HSE National Open Disclosure Office	Ms Catherine Hand
Faculty of Pathology, RCPI	Prof Conor O'Keane
NSS Director of Public Health	Dr Caroline Mason Mohan
Head of Programme Evaluation Unit	Dr Therese Mooney
Gynaecologist and Colposcopist / Chair of Institute of Obstetricians and Gynaecologists	Dr Cliona Murphy
Communications Manager, NSS	Ms Fiona Ness
CervicalCheck Clinical Laboratory Advisor, NSS	Dr Dave Nuttall
Consultant Histo/Cytopathologist	Prof John O'Leary
Colposcopy Clinical Advisor	Dr John Price
General Practice Nurse Representative	Ms Gillian Redmond
Chair of the Communications Interval Cancer Implementation Group	Ms Brenda Ryan
Health Ethicist, RCSI	Prof David Smith
Health Economist	Dr Brian Turner
HSE National Open Disclosure Office	Ms Angela Tysall
CervicalCheck Coordination Executive Officer, NSS	Ms Maeve Waldron

BowelScreen Interval Cancer Implementation Group

Chairperson of BowelScreen Interval Cancer Implementation Group / Clinical Director - BowelScreen, NSS	Prof Pádraic Mac Mathúna
BowelScreen Programme Manager, NSS	Ms Hilary Coffey Farrell
Gastroenterology ANP	Ms Ann Cooney
BowelScreen Clinical Coordinator, NSS	Ms Lisa Heffernan
Quality Assurance Coordinator, NSS	Ms Niamh McNamara
Head of Programme Evaluation Unit	Dr Therese Mooney
Patient representative	Mr Tom O'Keeffe
Consultant Surgeon	Prof Mícheal O'Ríordáin
BowelScreen Deputy Programme Manager	Ms Mary Sheedy
Endoscopist Representative	Dr Gupta Subhasish Sengupta

BreastCheck Interval Cancer Implementation Group

Chairperson of BreastCheck Interval Cancer Implementation Group / Consultant Radiologist	Dr Niall Sheehy
Project Sponsor/ National Clinical Director - BreastCheck	Prof Fidelma Flanagan
Clinical Director – BreastCheck Southern Unit	Dr Alissa Connors
Clinical Director – BreastCheck Western Unit	Dr Aideen Larke
BreastCheck Programme Manager	Ms Suzanne Lynch
Consultant Surgeon	Prof Malcolm Kell
BreastCheck Nurse	Ms Ruth Conboy
BreastCheck Project Secretariat	Dr Maeve Mullooly
Director - NSS Programme Evaluation Unit	Prof Patricia Fitzpatrick
Head - NSS Programme Evaluation Unit	Dr Therese Mooney
Chair – Communications Interval Cancer Implementation Group	Ms Brenda Ryan
Consultant Radiologist	Dr Rosalind Given-Wilson
Symptomatic Services Surgeon	Prof Arnold Hill
Symptomatic Consultant Radiologist	Dr Sylvia O'Keeffe
Symptomatic Services Breast care Nurse	Ms Yvonne Hanshauser

Communication Interval Cancer Implementation Group

Chairperson of Communications Interval Cancer Implementation Group / Head of Client Services, NSS	Ms Brenda Ryan
Complaints and Compliance Officer, NSS	Ms Susie Black
GP Advisor	Dr Catherine Clifford
Head of CervicalCheck Training and Education Unit, NSS	Ms Rachael Comer
Practice Nurse Representative	Ms Anne Marie Ellwood
CervicalCheck Programme Manager, NSS	Ms Gráinne Gleeson
Cancer Researcher and Science Writer	Dr David Robert Grimes
Patient Representative	Ms Mary Hewson
Deputy Programme Manager - Diabetic Retinopathy Screening , NSS	Ms Helen Kavanagh
Legal Representation	Ms Marie Kinsella
Public Advocate	Ms Laura Larkin
Legal Representation	Mr Philip Lee
BreastCheck Programme Manager, NSS	Ms Suzanne Lynch
Programmes and Campaigns Manager, HSE	Ms Aoibheann Ní Shúilleabháin
Communications Manager, NSS	Ms Fiona Ness
Nurse Colposcopist Representative	Ms Anne Redmond
Quality, Safety and Risk Coordinator, NSS	Ms Nishita Sawant
NSS Public Health Consultant	Dr Alan Smith
BowelScreen Representative, NSS	Ms Caroline Walsh

Legal Framework Group

Chairperson of Legal Framework Group / Clinical Director of DiabeticRetinaScreen	Prof David Keegan
Head of NSS Quality, Safety and Risk	Ms Colette Brett
Health Ethicist **Director of Clinical Ethics Ireland**	Dr Louise Campbell
Legal Academic Representative	Prof Mary Donnelly
BreastCheck Clinical Director (incoming)	Prof Fidelma Flanagan
Cancer Researcher and Science Writer	Dr David Robert Grimes
National Clinical Lead for Patient Safety / Consultant in Public Health Medicine	Prof Orla Healy
Legal Representation	Ms Marie Kinsella
Health Economist (UCC)	Dr Ann Kirby
Public Advocate	Ms Shampa Lahiri
Legal Representation	Mr Philip Lee
BowelScreen Clinical Director	Prof Pádraic Mac Mathúna
BreastCheck Clinical Director – Merrion Unit	Dr Sorcha McNally
Department of Health representative	Ms Kate O'Flaherty
Faculty of Pathology, RCPI	Prof Conor O' Keane
Expert Reference Groups Report Expertise – Clinical Audit of Interval Cancer in the Screened Population / National Director of NCCP	Prof Risteárd Ó Laoide
CervicalCheck Clinical Director	Prof Noirin Russell
NSS Public Health Consultant	Dr Alan Smith

Project Team

Project Sponsor / Head of Strategy, Business and Projects	Ms Grace Turner
Interval Cancer Senior Project Manager - Strategy, Business and Projects	Ms Antoinette Morley
Project Manager - Strategy, Business and Projects (Commenced May 2022)	Ms Lynn Murphy
Patient-Requested Review Project Manager / CervicalCheck (Commenced July 2022)	Ms Sara Kavanagh
Project Support Coordinator - Strategy, Business and Projects	Ms Liz McCarthy

NSS/PUB/PM-4 Rev1

An tSeirbhís Náisiúnta Scagthástála
National Screening Service