



Expert Reference Group

Interval Cancer Report BreastCheck

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An tSeirbhís Náisiúnta Scagthástála
National Screening Service


BreastCheck
An Clár Náisiúnta Scagthástála Gíoch
The National Breast Screening Programme

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Foreword

Evidence from international accreditation, international expert opinion, and review of BreastCheck's (the National Breast Screening Programme) key performance indicators presented to the BreastCheck Expert Reference Group has confirmed that the breast screening programme in Ireland is operating to best international standards. Breast screening reduces the number of deaths from breast cancer in Ireland by approximately 120 per year.

In line with international best practice, this report recommends that BreastCheck continue to monitor and publish the interval cancer rate as the key audit measure for the assessment of interval breast cancers on a programme-wide basis. The report has outlined a new strengthened, more robust model for the performance and disclosure of individual interval cancer case reviews, keeping the provision of information, patient choice and patient consent at the centre of the process. A programme-wide review of historic interval cancer cases for the purpose of disclosure has never been done internationally. The group noted that such a review would have no benefit for individual patient care and could potentially affect the ongoing running of the BreastCheck programme. Such a review is therefore not recommended by the BreastCheck Expert Reference Group; however, all interval cancer patients can request an individual case review at any stage.

The BreastCheck Expert Reference Group, which I was privileged to chair, was set up to address the issue of the management of interval breast cancers in Ireland today. Discussion of this issue is difficult, as it is taking place in a public environment where complex issues are frequently simplified and where individual blame is often sought within diagnostic systems which have a universal inherent error rate. The group was fortunate to have members with a wide variety of skill sets, and in particular, I would like to thank the patients, advocacy representatives and international experts who voluntarily gave so much of their time and insight for the benefit of our deliberations.

Delivery of a sustainable, optimally performing screening programme is influenced by a number of factors, the evaluation of which is outside the scope of this report, but which will require significant consideration in the immediate future. These factors include litigation, the cost-effectiveness of the programme and the sustainable recruitment of radiologists. Addressing these issues in an honest and transparent way will allow breast screening to continue to save the lives of Irish women and nurture the trust which is fundamental and essential to the delivery of any healthcare service.

Professor Risteárd Ó Laoide,
Chairman
10 March 2020

Glossary of terms, definitions and abbreviations

Term	Definition
classification	This refers to classification of interval cancers into categories upon radiological review following diagnosis.
clinical audit	As defined by the Health Service Executive (HSE), “Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements”. ⁽¹⁾ It should be noted that the term is also frequently used for generic quality review processes.
duty of candour	This is a term used by the National Health Service (NHS) screening service which refers to the communication of results of an audit to an interval cancer patient where the results of the interval cancer classification are unsatisfactory and it is deemed that something has gone wrong.
EUREF	The European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services, a pan-European organisation that leads the “development and dissemination of the European Guidelines, Certification of breast services and mammography equipment, Training and will provide support and advice on such issues upon request”. ⁽²⁾
false negative	A false negative breast cancer is defined as follows: “An abnormality on blind review is present on the screening mammogram at the site of the malignancy demonstrated on the mammogram at the time of diagnosis. These signs would normally be considered sufficient to re-call the woman for further assessment”. ⁽³⁾
GDPR	General Data Protection Regulation
GP	general practitioner
HSE	Health Service Executive
interval cancer	An invasive primary breast cancer case occurring within 2 years of a negative screening result.
interval cancer rate	The interval cancer rate “is expressed as a proportion of the underlying (expected) breast cancer incidence rate in the absence of screening”. ⁽³⁾
KPI	A key performance indicator (KPI) within BreastCheck is a predefined parameter by which the performance of a breast screening programme is assessed.
NCRI	National Cancer Registry Ireland
NHS	National Health Service
NHSBSP	NHS Breast Screening Programme
PEU	Programme Evaluation Unit
SOP	standard operating procedure
TOR	terms of reference
UK	United Kingdom

Section One: Executive Summary

Breast cancer in Ireland

Breast cancer is the most common invasive cancer (excluding non-melanoma skin cancer) diagnosed among Irish women, with 1 woman out of every 10 likely to get breast cancer in her lifetime. In Ireland, the latest annual report from the National Cancer Registry Ireland (NCRI) shows that each year, more than 3,300 women are diagnosed with invasive breast cancer,¹ and approximately 720 women will die of breast cancer.⁽⁴⁾

Breast cancer survival rates are improving due to screening, better treatments, and diagnostics, with more than 8 in every 10 women diagnosed with breast cancer in Ireland now likely to be alive 5 years after their initial diagnosis.⁽⁴⁾

Screening increases the survival rates for breast cancer because the cancer is detected and treated at an earlier stage.

Breast cancer screening

Population-based breast cancer screening aims to reduce deaths from breast cancer by 20% among those invited, and by even more among women who are screened.^(5, 6) Data from a study within the United Kingdom (UK) Breast Cancer Screening Programme in England found that 5.7 breast cancer deaths are prevented for every 1,000 women who are screened for 20 years starting at the age of 50, due to the implementation of organised, population-based screening.⁽⁷⁾

Population-based breast cancer screening is most effective among women aged 50–69 years, and each year, BreastCheck detects breast cancer in approximately 1,200 women in Ireland.⁽⁸⁾ In the absence of screening, breast cancer may not have been detected in these women until they developed physical signs or symptoms of more advanced disease.

There is no perfect test for breast screening, and there is a delicate balance between the benefits and limitations of mammographic screening. In spite of its limitations, mammography is the recommended tool for population-based breast screening internationally.^(6, 9)

1 Does not include ductal carcinoma in situ.

Interval cancers

Each year, approximately 300 women who have previously undergone routine screening through BreastCheck will be diagnosed with breast cancer outside of the screening service after a negative screening result and before their next screening appointment. These breast cancers are known as interval cancers.

In the majority of interval cancers, even in retrospect, no sign of cancer will be seen on the previous negative screening mammogram. These cases of interval cancers encompass true negatives, occult cancers, and cases with subtle signs, which are described as follows:

- a) The tumour developed after the screening mammogram was performed (true negative).
- b) The tumour remained undetectable by mammography (occult).
- c) Subtle changes were present, but were not suspected to be cancer or distinguishable from benign breast tissue changes (subtle signs).^(3, 10)

In a minority of interval cancers, a suspicious abnormality will be seen in retrospect on the prior screening mammogram. These interval cancers are known as false negatives. There are many reasons for this, including the limitations associated with mammography as a breast screening tool.^(3, 10)

Since the start of the BreastCheck programme in 2000, women who attend BreastCheck clinics for mammography screening have been informed (via informational BreastCheck literature) of the occurrence of interval cancers and that if they experience breast symptoms following a negative mammogram screening result, they should seek further advice from their general practitioner (GP). This is acknowledged by signing the BreastCheck consent form.

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

While breast screening programmes will not detect all breast cancers, international evidence continues to support mammography for population-based breast screening programmes.

BreastCheck – The National Breast Screening Programme

BreastCheck – The National Breast Screening Programme commenced breast screening nationally in 2008, having been in operation in the east of Ireland since 2000.⁽¹¹⁾ Upon its establishment, BreastCheck developed a *Women's Charter* and *Mission Statement*,^(12, 13) which reflect the women-centred ethos of the programme and have guided the working practice of BreastCheck since it began.

An Irish health service team of doctors, radiographers, nurses and administrators have provided more than 2 million mammograms to approximately 500,000 women in Ireland and have detected more than 13,600 cases of breast cancer since the programme began in 2000.⁽⁸⁾ When the programme commenced, it screened women aged 50–64 years, and has now being expanded to screen women up to age 69 years. The programme is delivered nationally by four static units (two in Dublin, and one each in Cork and Galway) and by more than 21 mobile units.

Every year, the programme performs approximately 170,000 screening examinations and detects approximately 1,200 cases of breast cancer.

BreastCheck Expert Reference Group

The BreastCheck Expert Reference Group was established in 2019. The terms of reference (TOR) set out the requirement to “define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice”. It was also required to provide “an outline of the historic reviews undertaken within breast screening”, “a review of this historical practice in breast screening as it relates to international best practice” and “recommendations in relation to the review and future practice”. In addition, a subgroup of the team was assigned to a BreastCheck Working Group to support the review of the evidence and drafting of the report.

Quality assurance in BreastCheck

Quality assurance in BreastCheck is continually monitored through the assessment of key performance indicators (KPIs).⁽³⁾ BreastCheck publishes an annual programme report describing programme performance, and the programme has received the highest accreditation (Category 4) awarded by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF)⁽²⁾ and is recognised as an exemplar for other European breast screening programmes.

The recording and validation of the interval cancer rate is one of many KPIs and is one measure of quality assurance within BreastCheck.⁽³⁾ Calculation of the interval cancer rate allows measurement against predefined quality standards and comparison with other breast screening programmes internationally. BreastCheck works with the NCRI to measure and validate the interval cancer rate.⁽¹⁴⁾ The most recent BreastCheck interval cancer rate reported aligns with European guidelines.

BreastCheck radiologists have also reviewed prior screening examinations of interval cancer cases after diagnosis in order to maintain and improve their interpretative skills. Classification of interval cancers is one of a number of learning methods used by breast screening radiologists. Review of the individual recall and small cancer detection rates, consensus review of recalled patients, small cancer reviews, and review and classification of patient-requested interval cancer reviews are other valuable learning methods used by BreastCheck radiologists.

EUREF requires programmes that apply for accreditation to review screening mammograms from interval cancers in order to improve radiology interpretative skills and future cancer detection.^(3, 10) In compliance with that requirement, BreastCheck undertook educational exercises prior to and during its accreditation process. A standard operating procedure (SOP) was not employed across BreastCheck units, and therefore findings are not reproducible across units. Records were maintained as evidence of participation. They were not part of the screening process itself or the individual healthcare record. Various classification approaches and systems are recognised by EUREF.

International practice

The management of interval cancers varies between international breast screening programmes. Some international programmes do not examine interval cancers at any level. However, among programmes that do examine interval cancers, most focus on the calculation of the interval cancer rate, and some also conduct individual radiological reviews for quality improvement purposes.

The National Health Service Breast Screening Programme (NHSBSP) in England is the only programme identified that has published guideline documentation describing the open disclosure review processes that take place following individual case reviews for interval cancers in its screening programme. These processes were implemented in 2017⁽¹⁵⁾ and continue to evolve and adapt to the population screening environment in the UK.

There is no international consensus on what constitutes best practice for conducting individual radiological case reviews of interval cancers, and processes vary within and across international breast screening programmes.

EUREF considers radiological reviews of interval cancers important as educational exercises, and as one of the teaching requirements associated with Category 4 accreditation. EUREF does not consider educational exercises disclosable, as they are undertaken for accreditation/quality improvement purposes. This continuous learning and quality improvement ultimately benefits every woman who participates in the BreastCheck programme.

The management of interval cancers within BreastCheck is consistent with international practices.

Open disclosure

From the establishment of the BreastCheck programme, any woman who has participated in the programme and been subsequently diagnosed with an interval cancer has been able to request to have her prior screening mammogram examinations reviewed so that she can better understand her diagnosis. In addition, women can request copies of their screening mammograms and reports from the programme at any stage – for example, in order to have their care transferred or their case reviewed outside the setting of the screening programme.

The Health Service Executive (HSE) Open Disclosure Policy has been in operation within BreastCheck since 2013, and it is fully endorsed and implemented for patient safety incidents which are “unintended or unanticipated”.⁽¹⁶⁾ Disclosure has also taken place following patient-requested case reviews of interval cancers.

In keeping with the majority of international screening programmes, BreastCheck has not considered interval cancers as patient safety incidents, as they are an expected and unavoidable occurrence in population-based screening programmes. As such, BreastCheck has not routinely undertaken disclosure for interval cancers unless it was part of a patient-requested case review of the interval cancer.

Some regions with highly developed screening programmes have enacted legislation to prohibit the disclosure of interval cancer review findings, including false negative diagnoses. This is done in the interest of promoting continual quality assurance and improvement within the screening programme, recognising that interval cancers are an expected part of screening.

In 2018, BreastCheck began to pilot a new SOP for individual case reviews of interval cancers notified to the programme following receipt of patient consent. It involves review by a minimum of two BreastCheck consultant radiologists who did not read the previous negative screening mammogram. The classification system that the NHSBSP in England developed in 2017 is being employed, and the results are disclosed to patients who consent to a review.

BreastCheck Expert Reference Group recommendations

Recommendation 1: 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.

Recommendation 2: 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.

Recommendation 3: 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.

Recommendation 4: 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.

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.

Recommendation 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.

Recommendation 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.

Recommendation 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.

Recommendation 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.

Recommendation 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.

Consideration of implications of recommendations

This document provides the “operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population”, as required by its TOR, with specific reference to the assessment of overall programme performance, the conduct of patient-requested case reviews of interval cancers, consent, and open disclosure.

The recommendations of this report provide for immediate and ongoing access to patient-requested case reviews of interval cancers with disclosure under an interim SOP for women diagnosed with interval cancer. However, the complexity involved in the implementation of a standardised, reproducible review methodology has been highlighted. It involves extensive communication with symptomatic units, treating clinicians and others. Internationally, Public Health England has led the implementation of open disclosure in breast screening. This process took 3 years to implement in England; however, the process is not complete, and individual screening units continue to be carefully monitored.

The HSE should establish an implementation team to immediately progress and ensure implementation of these recommendations. The team should include representatives from BreastCheck, external radiology experts, patient representatives, and support from both an administrative and a quality and safety perspective. The team should provide quarterly implementation progress reports to the Chief Executive Officer of the National Screening Service. The implementation team should monitor the effects of the recommendations on all aspects of the functioning of BreastCheck, including the ongoing delivery of the programme, public trust, patient safety, efficacy and cost-effectiveness.

The Expert Reference Group recommendations do not allow for educational exercises involving classification of all interval cancers in a programmatic manner. The potential impact of this on future applications for accreditation should be considered. EUREF strongly recommends that such a programmatic approach be implemented in order to qualify for future accreditation beyond 2020. Educational exercises should continue to be performed where patient consent has been explicitly obtained for patient-requested case reviews of interval cancers.

The Expert Reference Group wishes to highlight that the implementation of these recommendations will have significant resource implications if BreastCheck is to meet the needs of patients, their families, and clinicians as outlined in the main report.

Section Two: Background

Background and introduction

Breast cancer in Ireland

The latest annual report from the National Cancer Registry Ireland (NCRI) shows that breast cancer is the most commonly diagnosed invasive cancer (excluding non-melanoma skin cancer) and the second leading cause of cancer death among women in Ireland. The report shows that more than 3,300 women are diagnosed with invasive breast cancer,² and approximately 720 women will die of breast cancer, each year in Ireland.⁽⁴⁾ However, survival rates are improving, and breast cancer survivors account for the largest proportion (23%) of cancer survivors. The latest NCRI report states that there are more than 41,000 breast cancer survivors in Ireland. Furthermore, more than 8 in every 10 women in Ireland are likely to be alive 5 years after their initial breast cancer diagnosis, as the current 5-year survival rate for breast cancer is 85%.⁽⁴⁾

Introduction to population-based screening

Cancer screening involves tests that look for early signs of disease before any symptoms have developed in order to enable early intervention and management. Population-based screening programmes offer screening tests to all individuals in a target group deemed to be at higher risk of disease, usually defined by age, as part of an organised programme. The screening test identifies people who may have the disease and who are in need of further investigation and testing, which may lead to a cancer diagnosis.^(17, 18)

Certain criteria must be met before a disease is considered suitable for screening, such as the seriousness of the disease, how common it is, the availability of treatment, and the availability and acceptability of a suitable screening test. These criteria were first defined by the World Health Organization in 1968 and are known as the Wilson and Jungner criteria.⁽¹⁹⁾ A summary of these criteria, outlined by the World Health Organization,⁽²⁰⁾ is provided in Appendix 1.

Population-based screening programmes are complex and should be organised to a high standard according to predefined guidelines, and “target all the population at risk in a given geographical area with high specific cancer burden, with everyone who takes part being offered the same level of screening, diagnosis and treatment service”.⁽²¹⁾ An organised, population-based approach provides an operating model that is “conducive to effective management of performance and continuous improvement of the screening process and outcomes. This is achieved, for example, through linkage of screening registry data with data in population and cancer registries, for optimization of invitation to screening and for evaluation of screening performance and impact”.^(21, 22)

2 Does not include ductal carcinoma in situ.

Limitations of screening

No screening test is 100% accurate, and there is a delicate balance between the benefits and limitations associated with screening.

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

Introduction to breast screening

Breast cancer screening aims to reduce death from breast cancer, and, as highlighted in an independent review conducted by Marmot and colleagues, “Screening is concerned with the detection of disease at an early stage, with the expectation that treatment will be more effective if begun earlier in the disease process. Screening is therefore based on the principle of there being an effective treatment”.⁽⁶⁾ The impact of breast screening on mortality from breast cancer has been debated for many years.⁽⁶⁾ The meta-analysis and systematic review completed by Marmot et al., which included population-based randomised controlled trials, found that mammographic screening reduced breast cancer mortality by 20%.⁽⁶⁾ A further review of observational studies, conducted by the International Agency for Research on Cancer, observed a 40% reduction in mortality.⁽⁵⁾ In addition, data from the UK Breast Screening Programme in England estimates that 5.7 breast cancer deaths are prevented for every 1,000 women who are screened for 20 years starting at the age of 50 due to the implementation of organised population-based screening.⁽⁷⁾ The variation in the effect observed in these studies is attributable to the populations, programmes and time periods studied. However, the “consensus is that well-organised and systematically conducted breast screening, with rigorous internal and external quality control, is effective at the population level”.⁽¹⁴⁾

In order to be effective, a population-based breast screening programme has to be supported by a functioning health system and achieve the appropriate level of population coverage, which is at least 70% participation of the breast screening target population. The necessary infrastructure and resources should be available along with a continuous quality assurance framework.⁽¹⁷⁾

Limitations of mammography as a breast screening test

Mammography is a technical tool that uses low-dose X-rays to produce images of the breast called mammograms. The use of mammography in international population-based screening programmes is an ongoing area of discussion, and the balance between its benefits and limitations continues to be debated.⁽⁶⁾

The benefits of mammography breast cancer screening relate to early detection, less complex treatment and, ultimately, reduced mortality. The limitations include over-investigation, anxiety associated with a false positive result, overdiagnosis (which can lead to overtreatment) and interval cancers.

However, despite its known limitations as a test, mammography is currently the only screening tool recommended for population-based breast cancer screening, as it is the only screening modality that has been shown to reduce deaths from breast cancer.⁽⁹⁾ An additional recent systematic review found that organised mammography screening reduced breast cancer mortality across Europe, with reductions of 12–58% observed for Western Europe.⁽²³⁾ Mammographic screening programmes have been introduced around the world with the aim of reducing breast cancer mortality.⁽²⁴⁾

False positive breast screening results

False positive results are post-assessment results that suggest that a woman has cancer when she does not. One example of a false positive result includes a woman whose mammogram indicated a suspicious lesion and who was recalled for further investigative assessment, but the lesion “turned out at open surgery to be a benign lesion”.⁽³⁾ The collective spectrum of false positive results is an important limitation of a breast cancer screening programme.⁽²⁵⁾ The impact of a false positive diagnosis is an important consideration, and 1 in every 25 women who undergo a mammogram will be called back (recalled) for further tests, which may often include invasive tests such as biopsies.⁽³⁾ This is known to cause anxiety among healthy women, the psychological effect of which has been shown to last up to 3 years.⁽²⁶⁾

Interval cancers

Interval cancers are a feature of all cancer screening programmes. They are defined by the European guidelines as “A primary breast cancer which is diagnosed in a woman who had a screening test, with/ without further assessment, which was negative for malignancy, either: before the next invitation to screening, or within a time period equal to the screening interval in case the woman has reached the upper age limit for screening”.⁽¹⁰⁾ Irrespective of quality assurance measures implemented in order to ensure the most effective and highest-quality screening programme, a proportion of cancers diagnosed each year will include interval cancers.⁽¹⁰⁾ In the majority of interval cancer cases where the last screening mammogram is reviewed, no sign of cancer is seen, even in retrospect. These cases of interval cancers encompass true negatives, occult cancers, and cases with subtle signs, which are described as follows:

- a) The tumour developed after the screening mammogram was performed (true negative).
- b) The tumour remained undetectable by mammography (occult).
- c) Subtle changes were present, but were not suspected to be cancer or distinguishable from benign breast tissue changes (subtle signs).^(3, 10)

In a minority of interval cancer cases reviewed in retrospect, a suspicious abnormality is seen on the last negative screening mammogram that could have been detected at that time. These cancers are known as false negatives. These cases are an expected part of screening, and reflect the significant uncertainty associated with mammography and the inevitable human error associated with the test. Mammography as a screening test is dependent on the perception and interpretation skills of the radiologist reader, which can be subject to intra- and inter-observer variation. All efforts are made to overcome these inherent limitations of mammography as a screening test within screening programmes using quality assurance strategies – for example, double reading, where every mammogram is read by at least two radiologist readers.

Thus, not every woman within the screened population will experience benefits from breast cancer screening, and a minority may experience harm. This potential harm is weighed against the overall benefit to the population of reduced mortality and to the individuals whose cancer is detected early.

In accordance with the Expert Reference Group Terms of Reference (TOR) (Appendix 4), this report will focus on the investigation of interval cancers that include false negative breast cancers within BreastCheck. It is notable that European guidelines highlight that the need for the review and audit of interval cancers is “an essential part of routine radiological audit, and plays a key role in the continuing medical education of radiologists involved in the programme”.⁽¹⁰⁾

BreastCheck – The National Breast Screening Programme

Following a successful pilot screening programme, BreastCheck commenced mammography screening in the east of Ireland in 2000. Further national expansion commenced across Ireland in 2008.⁽¹¹⁾

Upon BreastCheck's establishment, the programme developed the *BreastCheck Mission Statement* and the *BreastCheck Women's Charter*, which reflect the women-centred ethos of the programme and have guided the working practice of BreastCheck since it began.^(12, 13)

The *BreastCheck Women's Charter* outlines BreastCheck's commitment to screening and provides an overview of what women can expect upon participation in the programme.⁽¹³⁾ It places access to screening and the appropriate follow-up care, and effective communication with women, at the fore of this programme. The *BreastCheck Mission Statement* outlines that the goal of the programme is to "reduce the number of deaths from breast cancer in Ireland amongst eligible women".⁽¹²⁾ It states that BreastCheck aims to "provide an effective screening service to the highest quality, so that the maximum number of breast cancers can be detected at the earliest possible stage"⁽¹²⁾ so that women can have the most conservative treatment options available and, ultimately, the most benefit.

Initially, women aged 50–64 years were invited every 2 years to participate in mammography screening at a local mobile or static unit. An ongoing age extension implementation plan, due to be completed in 2021, is currently expanding screening to women up to the age of 69 years.⁽¹¹⁾ BreastCheck operates four static screening units (two in Dublin, and one each in Cork and Galway) and more than 21 mobile units across Ireland for breast screening.

As outlined in the most recent annual *BreastCheck Programme Report 2017–2018*, published in 2019, the screening programme has now provided more than 1.7 million mammograms to approximately 500,000 women in Ireland, and has detected approximately 11,000 cases of breast cancer.⁽⁸⁾ Participation within the programme has reached 73.8% of all eligible invited women, with 63.9% of eligible women undergoing initial screening and 87.7% of eligible women returning for a subsequent screening.⁽⁸⁾ Every year, an Irish health service team of doctors, radiographers, nurses and administrators provides approximately 170,000 screening examinations and detects approximately 1,200 cases of breast cancer.

Women are invited by BreastCheck to participate in breast screening by a notification letter. Informed consent is obtained from each woman prior to participation in the programme. This consent form states that "the mammogram (breast X-ray) does not detect every breast cancer; a small number of cancers may be missed by screening" (Appendix 2). Following mammography, screening results are communicated through a follow-up letter to each woman and her general practitioner (GP) within 3 weeks of her screening appointment. If the mammogram results are negative, women receive a letter communicating the negative result and are informed that they will be called back to the programme in 2 years for their next screening appointment. This letter also states that mammography does not detect all breast cancers. It includes a note to remind each woman to contact her doctor if she notices anything unusual about her breasts (Appendix 3). If a mammogram shows a positive result, women are recalled via a letter for further investigative assessment.⁽¹¹⁾

Establishment of the Expert Reference Group

In Ireland, each of the three cancer screening programmes (BreastCheck, CervicalCheck and BowelScreen) operates independently within the National Screening Service. Each programme has different timelines and technologies specific to the cancer being screened for, and therefore has different strategies for managing interval cancers. Clinical audit in CervicalCheck comprises the programmatic review of cervical cytology in women with invasive cervical cancers. BreastCheck publishes interval cancer rates benchmarked against European guidelines and facilitates patient-requested case reviews of interval cancers (outlined in detail in Section Three). BowelScreen is the most recently established programme and has not yet collated sufficient data to publish interval cancer rates, but it does conduct case reviews of notified interval cancers.

In January 2019, the HSE commissioned two Expert Reference Groups to “define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice” (Appendix 4). The governance and membership of the Expert Reference Groups, along with the TOR, are provided in Appendix 4.

Given that the BreastCheck programme is the longest-running of Ireland’s three cancer screening programmes, the Expert Reference Group was also required to provide the following information (Appendix 5):

- a) “An outline of the historic reviews undertaken within Breast Screening.
- b) A review of this historical practice in Breast Screening as it relates to international best practice.
- c) Recommendations in relation to the review and future practice” (Appendix 5).

In addition, a specific BreastCheck Working Group was established to support the review of the evidence and drafting of the report. The membership of the BreastCheck Working Group is detailed in the Expert Reference Group Terms of Reference (Appendix 4).

In December 2019, following the publication of the report of the Independent Clinical Expert Panel Review of CervicalCheck, the Minister for Health requested that the Expert Reference Groups “incorporate consideration of the Expert Panel’s recommendations on interval cancer audit and disclosure in their ongoing deliberations along with international best practice, consideration of the wider environment including the ongoing process of tort reform and any other expert input the groups deem necessary” (Appendix 6, 6b, 6c). The Expert Reference Group considered this matter in agreeing its final recommendations.

Section Three:

Current Practice in the Breastcheck Screening Programme

Quality assurance in the BreastCheck Screening Programme

Quality assurance is a central component of BreastCheck. The *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition* outlines BreastCheck's "quality assurance requirements and includes detailed guidance for the medical, diagnostic and technical aspects of breast screening".⁽³⁾ The document specifies the standard guidelines that allow for a centralised system of assessment. "It sets out the objectives, policies and organisational procedures that ensure that quality requirements are achieved".⁽³⁾ These "guidelines fully document the quality management system for assuring quality in mammography screening".⁽³⁾

Key performance indicators

The quality assurance of BreastCheck is continually monitored through the assessment of key performance indicators (KPIs). These programme standards, against which performance is measured, are aligned to the *European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth Edition*,⁽¹⁰⁾ the *BreastCheck Guidelines for Quality Assurance in Mammography Screening, Fourth Edition*⁽³⁾ and the *BreastCheck Women's Charter*.⁽¹³⁾ KPIs are reviewed in several levels of detail at a number of forums³ and published annually.^(3, 8) As shown in Table 1, the KPIs relate to guidance for screening standards and show minimum and achievable standards to guide screening performance. The most recent detailed KPIs are outlined in the *BreastCheck Programme Report 2017–2018*.⁽⁸⁾ The monitoring of interval cancers, which is the focus of this report, is just one element of the overall quality monitoring process in the BreastCheck programme.

3 Including the Quality Assurance Multidisciplinary Consultants Group (annual meeting), the Quality Assurance Committee review (approximately three times per year), and through regular multidisciplinary team meetings.

Table 1. Overview of KPIs and their minimum and achievable standards for BreastCheck.⁽³⁾

Stage of process	Minimum standard	Achievable standard
Percentage of invited women attending for screening	≥70%	80%
Invasive cancer detection rate: Initial screen 50-51 yrs. Initial screen 52-64 yrs. Subsequent screen	>2.9/1,000 >5.2/1,000 >2.4/1,000	
DCIS as proportion of all breast cancers detected	10%	10-20%
Proportion of invasive cancers detected at initial screening ≤10mm	≥20%	≥25%
Proportion of invasive cancers detected at subsequent screening ≤10mm	≥25%	≥30%
Invasive cancers <15mm detected at both initial and subsequent screens	≥40%	≥50%
Percentage of women sent their screening mammogram results within three weeks of screening	≥90%	100%
Percentage of women sent their triple assessment results within one week of assessment	≥90%	100%
Re-call for assessment rate in women at initial examination	<7%	<5%
Re-call for assessment rate in women at subsequent examination	<5%	<3%
TR plus TC rate	<3%	<1%
Benign open biopsy rate per 1,000 women screened: Initial screen Subsequent screen	<3.6 <2.0	<1.8 <1.0
Proportion of screen-detected breast cancer with a pre-operative diagnosis of malignancy (core biopsy reported as definitely malignant) ^{5,4, 6.2.1}	≥90%	≥95%
Proportion of screened women subjected to early re-call following diagnostic assessment	<1%	0%
Interval cancer rate per 1,000 women screened in the two years following a normal screening episode: Year 1 Year 2	<0.75/1,000 <1.25/1,000	≤0.5/1,000 ≤0.75/1,000
Percentage of eligible women whose re-invite offered appointment is within 24 months of the previous screen	≥90%	100%
Time interval between first assessment appointment and surgical assessment (patient requiring surgical opinion)	One week	Same day assessment
Percentage of women offered an admission date within three weeks of the decision to operate for diagnostic purposes	≥90%	100%
Percentage of women admitted within three weeks of being informed that they need surgical treatment	≥90%	100%
Number of visits required to make a diagnosis of malignancy	No more than 10% require >3 visits	0% require >3 visits
Proportion of localised impalpable radiographic lesions excised (completely or incompletely) at the first operation	95%	>95%

Source: Reproduced from the BreastCheck Guidelines for Quality Assurance in Mammography Screening, Fourth Edition.⁽³⁾

International accreditation

BreastCheck also periodically undergoes independent review and assessment of performance through accreditation by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF). The most recent accreditation was awarded to BreastCheck in 2015, when EUREF, the principal accreditation body for breast screening in Europe, awarded BreastCheck the highest accreditation (Category 4) status. This status indicates that EUREF regards BreastCheck as an exemplar for other European breast screening programmes. The accreditation will remain in place until 2020. This most recent accreditation designated BreastCheck as a Reference Centre, making it one of two breast cancer screening programmes in Europe to achieve this quality mark, the other being the German Mammography Screening Programme, *Kooperationsgemeinschaft Mammographie*, which received Category 4 accreditation in November 2017. Previous international reviews of BreastCheck included a EUREF pre-certification visit in 2002 and a performance assessment review by NHS Quality Improvement Scotland in 2005.

Management of interval cancers

Within BreastCheck, interval cancers are defined “as breast cancers that arise after a negative screening episode (which may include assessment) and before the next scheduled screening round”.⁽³⁾ For validating the diagnosis within BreastCheck, interval cancers must be an invasive and primary breast cancer case occurring within 2 years of a negative screen.

Since the initiation of BreastCheck in 2000, women have been informed that breast cancer may develop despite a negative screening mammogram result. This limitation is included in information provided by the programme to women who participate in screening. In addition, the notification sent to women about a negative screening result outlines that mammography does not detect all cancers, and women are encouraged to seek advice from their doctors should they notice anything unusual about their breasts, even if their mammogram has detected no abnormality (Appendix 3).

It is expected that each year, the number of interval cancers that will be diagnosed outside of the BreastCheck programme following a negative screening result is 2 per 1,000 women screened.⁽³⁾ This corresponds to approximately 300 interval cancers per year.

Every element of screening is set up to minimise the occurrence of interval cancers, particularly false negative cancers. For example, double reading is standard practice across BreastCheck. Within the programme, two consultant radiologists with specialist breast radiology training read every mammogram at all screening rounds, including mammograms from women who are both undergoing their first mammography screening round and women who are returning for a subsequent screening round. Women are recalled for further investigative assessment if one of the two readers recalls them, in order to gain the maximum possible increase in sensitivity of the screening. Alternatively, a third screening radiologist may also be involved in managing cases of discordant double reading through arbitration and consensus.

To date, BreastCheck has used two main methods to assess interval cancers that occur following a negative BreastCheck screening mammogram. These include the assessment of the interval cancer rate and radiological reviews of interval cancers.

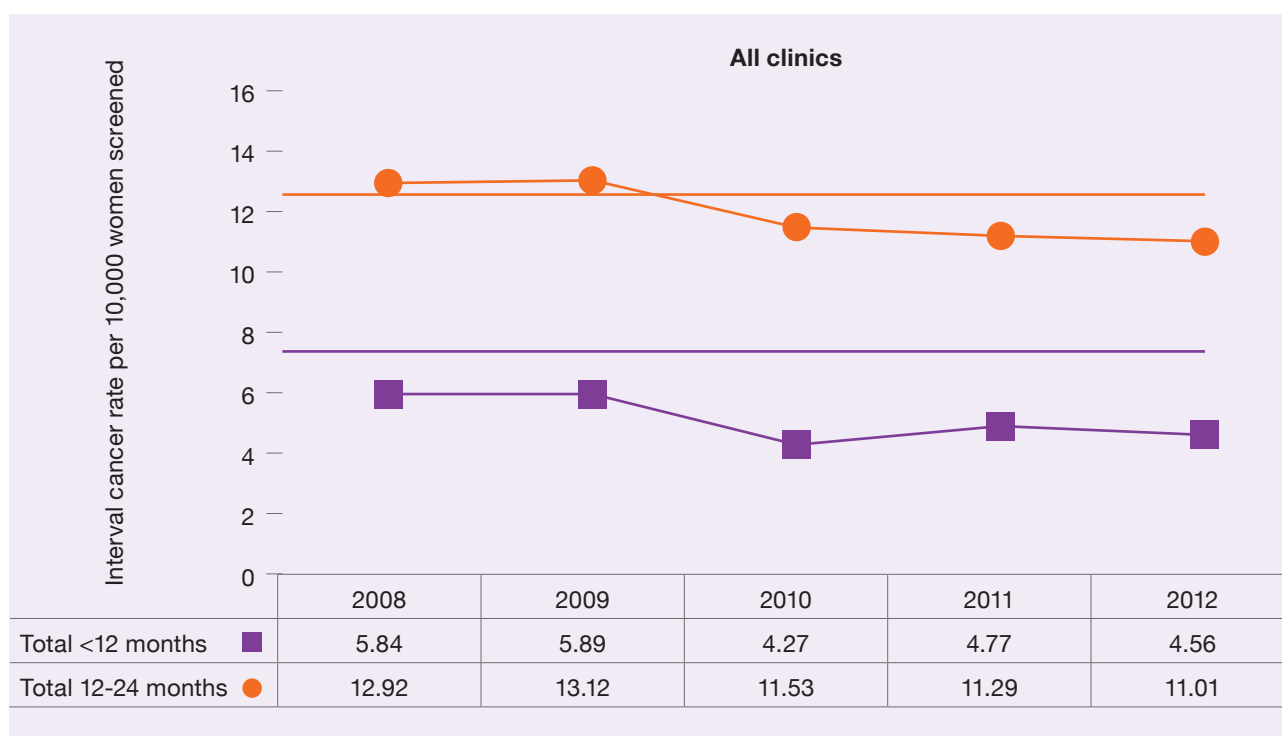
BreastCheck and the interval cancer rate

The recording and validation of the interval cancer rate is a KPI, and one of many measures of quality assurance within BreastCheck (Table 1).

The interval cancer rate, derived from a validated process, is a quality measure that provides critical information about the performance of the screening programme.⁽³⁾ Finding that the interval cancer rate is within the expected rates provides reassurance that the programme is on target to achieve its predefined KPIs outlined by the BreastCheck and European breast screening guidelines.^(3, 10, 14)

BreastCheck's most recent interval cancer rate is shown in Figure 1. In 2012, BreastCheck's interval cancer rate was 4.56 per 10,000 persons screened at 12 months following screening, and 11.01 per 10,000 persons screened at 12–24 months following screening, which is within the minimum standards outlined in BreastCheck's guidelines shown in Table 1.⁽³⁾ It is notable that the most recent data refer to 2012. This is attributable to the time lag in collating and validating data from the NCRI. In recent communications with BreastCheck, EUREF has noted that there is a system in place to calculate the interval cancer rate^(27, 28). However, the rate must be validated with the NCRI before it is published in order to ensure accuracy. During the EUREF accreditation process, it was noted that BreastCheck's interval cancer rates are within European guidelines. It was also noted that EUREF accredited the programme overall, as well as each unit within the programme.

Figure 1. Interval cancer rate per 10,000 women screened, among women who received a normal breast screening result within BreastCheck between 2008 and 2012



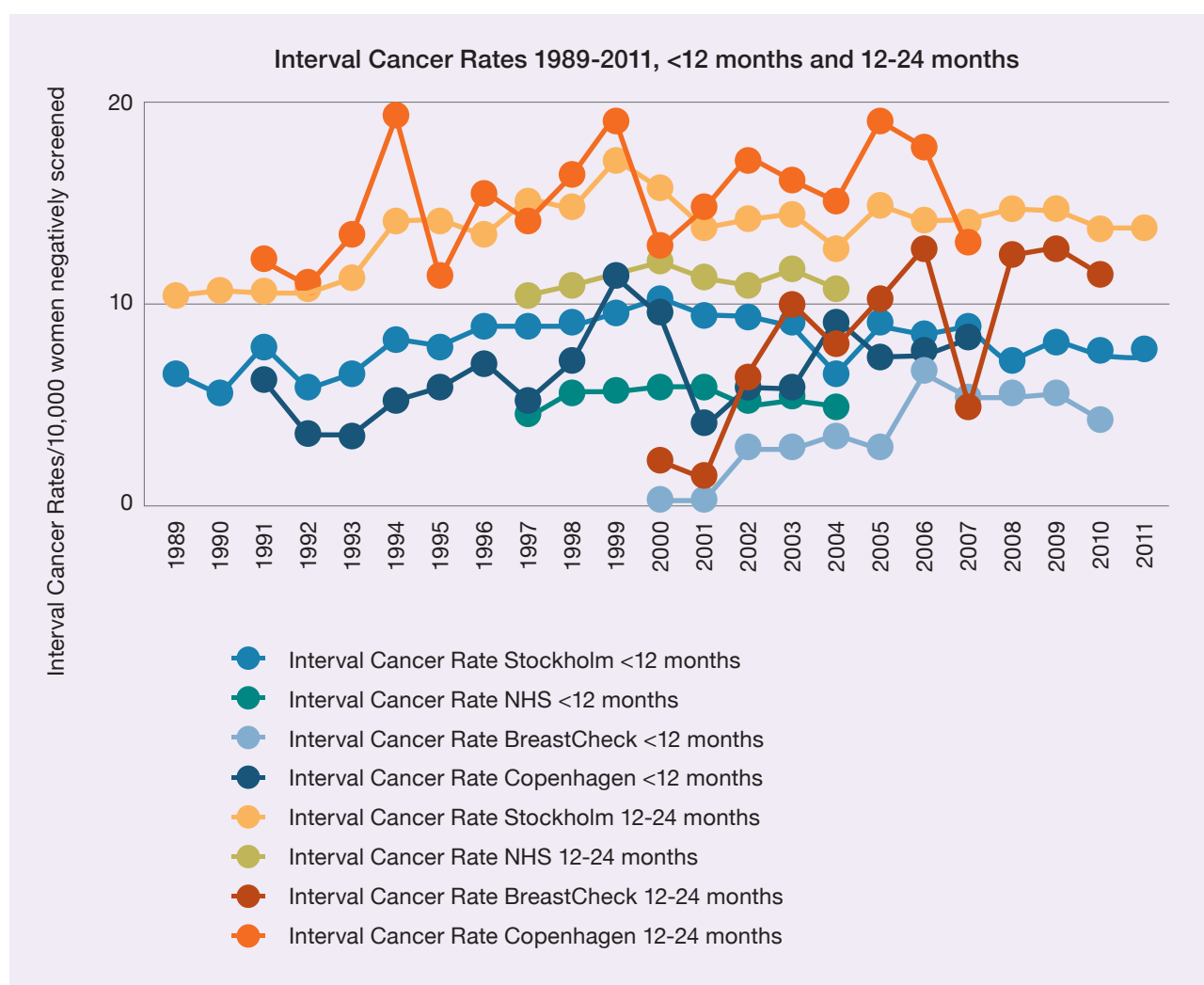
Source: Data sourced from the Programme Evaluation Unit, BreastCheck

International comparison of interval cancer rates

The interval cancer rate within BreastCheck is continually benchmarked against BreastCheck guidelines, European breast screening guidelines and international screening programmes. Multiple factors must be considered when comparing the interval cancer rate across programmes, and international variation in interval cancer rates within European screening programmes has been previously described.⁽²⁹⁾

BreastCheck has performed in line with international benchmarks for interval cancer rates, and has previously described its interval cancer rates in a peer-reviewed publication;⁽¹⁴⁾ a comparison of the rate of interval cancers observed in Ireland with other European countries from that publication is shown in Figure 2. This figure highlights that the interval cancer rate observed within BreastCheck is comparable with other European screening programmes.⁽¹⁴⁾ It is noted that the Irish data include the pilot phase of BreastCheck, before national expansion of the programme.

Figure 2. Interval cancer rate per 10,000 women screened among screening programmes across Europe between 1989 and 2011



Source: Data sourced from the Programme Evaluation Unit, BreastCheck and extrapolated from O'Brien *et al.* Interval cancer rates in the Irish national breast screening programme.⁽¹⁴⁾

BreastCheck and radiological reviews

In addition to calculating the interval cancer rate, BreastCheck has also conducted radiological reviews of previous screening mammograms of women diagnosed with interval cancer following a negative screening result for one of two reasons:

1. On request from a patient or treating clinician, or
2. Educational exercises for education and accreditation purposes.

Unlike the interval cancer rate, radiological review outcomes are not KPIs. Their primary purpose is to meet patient information needs and for radiology feedback, education and accreditation.

Patient-requested case reviews of interval cancers

The *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition* confirm the availability of BreastCheck to discuss any interval cancer case with patients when requested, as “if a woman is diagnosed with an interval cancer and seeks a review or discussion regarding her case, this will be facilitated through the clinical director of the unit concerned”.⁽³⁾ Heretofore, upon request, BreastCheck radiologists reviewed the screening and diagnostic mammograms and communicated their findings to whomever requested the case review. This practice was described in evidence provided to the Joint Committee on Health and referenced in the Scoping Inquiry into the CervicalCheck Screening Programme.^(30, 31)

Patient-requested case reviews of interval cancers and classification represents an opportunity for women diagnosed with interval cancers to have their screening mammograms reviewed and the findings of their mammograms discussed by the radiology team. This allows discussion of the prior BreastCheck negative screening mammogram result, which may help explain why the subsequent diagnosis occurred. It should be noted that the purpose of these reviews is to meet the woman’s request; they are not an indicator of overall programme or radiologist performance.

Women with interval breast cancers are typically diagnosed and managed through the symptomatic breast service and not by the screening programme. Currently, there is no operational or information systems link between the breast screening service and symptomatic breast services that would provide an automatic notification to BreastCheck when an interval cancer is diagnosed. Therefore, BreastCheck is not typically aware of an interval cancer patient at the time of their diagnosis, and thus, by extension, is not involved in any discussion about prior negative BreastCheck screening mammograms until it receives a request by a patient themselves or their treating clinician to conduct a case review, or if it is informed at a later date by the NCRI. All interval cancers notified to the programme are logged using a specific notification form.

Until recently, the methodology for patient-requested case reviews of interval cancers used within BreastCheck had not been standardised, and practices have varied across the four static BreastCheck units. The manner in which the findings of a patient-requested case review of interval cancer were communicated depended on the manner of the request. For example, if the request was made via letter, the results of the review were communicated through a letter; if the request was made verbally, the results of the review were communicated verbally. The results were also communicated to the person (i.e. the patient or clinician) who made the request.

A standardised methodology for patient-requested case reviews of interval cancers is being piloted within BreastCheck; it involves review by a minimum of two consultant radiologists who are incompletely blinded (without the diagnostic/symptomatic mammogram) and who did not read the original screening mammogram. The classification system that NHS England developed in 2017 is being employed. Proposals for further development of a methodology for this classification system are outlined in Section Five.

Educational exercises

A portion of interval cancer cases that were diagnosed following a negative breast screening mammogram result were reviewed and discussed within BreastCheck for education and accreditation purposes. BreastCheck's *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition* identifies the importance of review and sub-classification of interval cancers as "an essential part of continuing education for screening radiologists".⁽³⁾ EUREF requires this of all programmes that apply for accreditation. It asserts that "the presence of an extensive and adequately reviewed interval cancer collection is all the more important in view of the teaching requirements associated with EUREF Certification".⁽²⁷⁾ This is of educational benefit to mammogram readers, as it helps improve radiologists' interpretative skills and hence the overall quality of the service provided to women. For example, by discussing interval cancer cases where the mammograms show very subtle signs of malignancy, readers have been able to improve their skills in detecting small breast cancers.^(10, 32-34)

Records of individual educational exercises were maintained by each BreastCheck unit as part of the documentation required for inspection by the international accreditation team; however, these were not part of the BreastCheck screening or healthcare record and were not collated nationally by the National Screening Service Programme Evaluation Unit (PEU). The process described meets EUREF requirements. Implementation of General Data Protection Regulation (GDPR) legislation in May 2018 should have seen disposal of these records, which did not form part of the healthcare record.⁽³⁵⁾ This has not been implemented, pending the publication of this Expert Reference Group report.

Within each BreastCheck unit, a proportion of diagnosed interval cancers was selected, discussed and classified. EUREF noted that BreastCheck tended to use the UK classification system and that both the European and UK classification systems are currently in use; both are referred to in the *European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth Edition*.⁽¹⁰⁾ Application of different guidelines can yield varying results, but this is acceptable.^(27, 28) The classification methodology varied within and between programme units, and, therefore, completed reviews do not represent a standardised reproducible classification of interval cancers. For the most recent accreditation, initially five cases of each interval cancer category were selected; however, additional cases were sought by EUREF in order to be more reflective of the routine screening environment.

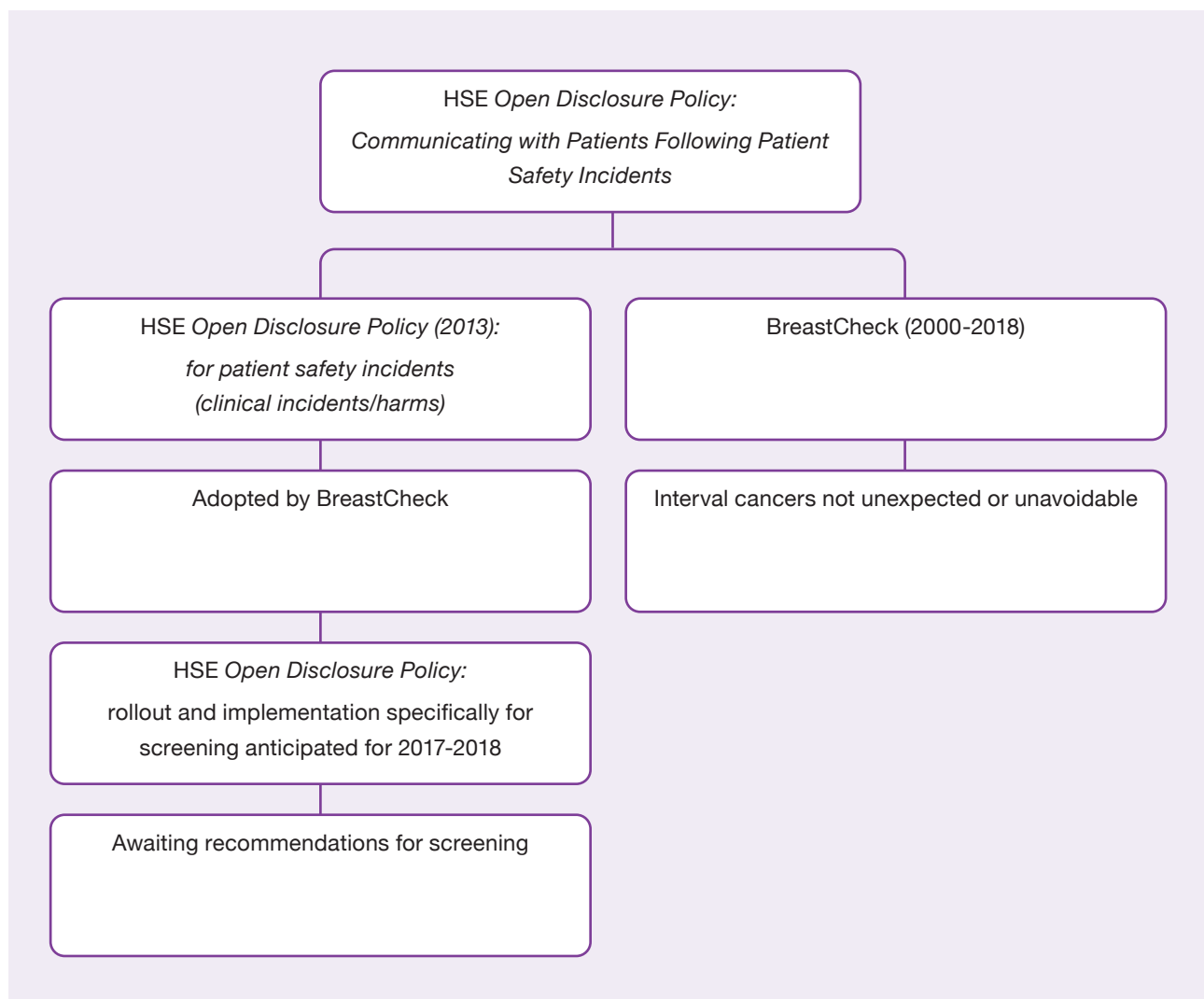
Although the BreastCheck screening guidelines suggest that the false negative rate is defined as "the number of false negative results expressed as a percentage of the total number of carcinomas sampled"⁽³⁾ and that the false negative cancers should not comprise greater than 20% of the total number of interval cancers,^(3, 10) it is recognised that this rate varies widely depending on the classification methods applied.^(36, 37) The literature review performed for the Expert Reference Group identified variation in the proportion of interval cancers classified as false negatives following radiological review. This variation reflects the variability in review methodology, classification systems employed, criteria for classification of each interval cancer category, variability in interpretation between individual radiologists, and the variable number of cases classified across studies.⁽³⁸⁾ When classifying interval cancers, it is also not unusual to find discrepancies across screening units, across screening programmes and over time.^(27, 28, 39) This variability is the reason that classification of interval cancers is not used as a KPI for either the programme's or radiologists' performance.

The classification methods employed and the suggested epidemiological analysis in the BreastCheck *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition*⁽³⁾ were not used in practice, as the historical exercises were performed on a unit basis rather than on a programmatic basis. Furthermore, they did not employ a blind review followed by an informed review of the screening mammogram.

Open disclosure within BreastCheck

The HSE Open Disclosure Policy has been in operation for BreastCheck since 2013, and it is fully endorsed and implemented for patient safety incidents (clinical incidents or harms) which are “unintended or unanticipated”.⁽¹⁶⁾ Disclosure has also taken place following patient-requested case reviews of interval cancers. In keeping with the majority of international screening programmes, BreastCheck has not considered interval cancers as patient safety incidents, as they are an expected and unavoidable occurrence in population-based screening programmes. As such, BreastCheck has not routinely undertaken disclosure for interval cancers apart from the disclosure of the findings of patient-requested case reviews of interval cancers. Figure 3 provides an overview of the management of interval cancers in BreastCheck following the implementation of the HSE’s Open Disclosure Policy in 2013.

Figure 3. Overview of the management of interval cancers in BreastCheck following the implementation of the HSE’s Open Disclosure Policy



As already described, from the establishment of BreastCheck, any programme participant diagnosed with an interval cancer has been able to request to have her prior screening mammogram examinations reviewed so that she can better understand her diagnosis. In addition, women can request copies of their screening mammograms and reports from the programme at any stage – for example, to have their care transferred or their case reviewed outside the setting of the screening programme.

Section Four:

International Practice

International evidence was assessed by investigating best practice from the perspective of international breast screening experts, conducting a survey of international breast screening programmes, and reviewing published literature.

International breast screening expert submissions

In order to investigate international best practices, the Expert Reference Group consulted international breast screening experts to discuss the approach to interval cancer monitoring, clinical audit and disclosure in established European breast screening programmes.⁽⁴⁰⁻⁴³⁾ A summary of each expert opinion is outlined below:

- A breast screening expert from EUREF provided the perspective of EUREF to the Expert Reference Group.⁽⁴⁰⁾ The main messages which were presented to the BreastCheck Expert Reference Group were:
 - “BreastCheck should enhance and strengthen engagement with women to educate them about the limitations and benefits of breast screening, including interval cancers and to ensure that they are making informed decisions.”
 - “BreastCheck must continue to conduct radiological review of interval cancers, as it is an important aspect for radiologist education and improving the quality of the service. It is also an important component of the EUREF accreditation process.”
 - “The programme should support the enactment of legislative measures to ensure that quality assurance practices including radiological reviews are promoted. In addition, this legislation should seek to ensure the protection of individual radiologists who engage in such reflective practices. Such measures would ensure protection for quality assurance and for those who participate in quality assurance activities. In particular, this would allow a programmatic audit of interval cancers thereby helping to ensure consistently high quality radiological practice across the programme.”
- A breast screening expert from the Norwegian Breast Cancer Screening Programme presented an overview of interval cancer management in Norway.⁽⁴²⁾ The main messages as described in the presentation were:
 - “Interval cancers are monitored in Norway by assessing interval cancer rates.”
 - “There are considerable challenges with classifying interval cancers and the proportion of classified as missed can vary from 1.3% to 35.5% according to review design.”
 - “Defining interval cancers is challenging.”

- A breast screening expert from Sweden presented an overview of interval cancer management in Sweden.⁽⁴³⁾ The main messages as outlined in the presentation were:
 - “Audits of interval cancers are conducted for internal learning purposes only.”
 - “An annual review of interval cancer cases that includes classification is conducted.”
 - “There is no open disclosure of the findings of interval cancer reviews in Sweden.”

Audit of interval cancers; NHS Breast Screening Programme experience

As England was identified as a country where an open disclosure policy for interval cancers was recently implemented and with published policies on open disclosure, the Expert Reference Group has focused particular attention on the experience of the NHS Breast Screening Programme (NHSBSP) in England. A breast screening expert from the programme presented to the BreastCheck Expert Reference Group and provided information on the education and communication processes, and on the design of programme-wide standardised radiological reviews of interval cancers to facilitate open disclosure. It was highlighted that even with the extensive education process that preceded its roll-out, the classification of interval cancers remains unavoidably subjective, as evidenced by a publication from the NHS and Public Health England,⁽⁴¹⁾ which states:

“Patients should be advised that no matter how closely the review panel tries to reproduce the original screening conditions, the conditions of a review are different – the fact that a review includes records of a patient known to have a serious condition, such as cancer, will heighten vigilance and increase reports of abnormality...finding discrepancies on review does not mean that the same findings should have been made under routine conditions...hindsight has a significant impact on the interpretation of images...screening tests work within agreed parameters of sensitivity and specificity and cannot detect 100% of abnormalities at the time of screening...the boundary between normality and abnormality is not firmly drawn and this may result in debate between experts as to the appropriate classification or interpretation of the image”.⁽⁴⁴⁾

Direct communication with the breast screening expert highlighted that:

“Interval cancer rates are used as a quality indicator of the breast screening programme. The rates have been within international published norms. Initially the NHSBSP reviewed, but did not classify, interval cancers. The classification of interval cancers was developed in the early 2000s as part of the work on disclosure of audit and was included in quality assurance guidance for radiologists. The method of classification was standardised using blinded [to diagnostic films and findings] assessment by 1–2 radiologists. Notwithstanding the guidelines, there was known variability within the different units with respect to the percentage of interval cancers classified in each category. This is an inevitable result of the variation in interpretation between individual radiologists reviewing screening mammograms.

Documentation related to the audit of each interval cancer is filed with the patient’s screening records. The documentation includes individual patient identification details. Interval cancer classification and data was also included on the electronic screening system in the patient’s data, National Breast Screening Service.

Disclosure of Audit Results in Cancer Screening: Advice on Best Practice was published in 2006.⁽⁴⁵⁾ Guidelines proposed that breast cancer patients be made aware that the results of interval cancer audits were available on request. The principle was to make patients aware, at a suitable time in their treatment, that previous screening mammograms could be reviewed and that they could have the result if they wanted it. The de facto implementation of the guidelines was the disclosure of individual interval cancer audits to patients and clinicians on request. No proactive disclosure of audit results was performed unless requested. The degree to which this was implemented is not known; however, all patient and clinician requests for the results of interval cancer audits were accommodated.”

“Duty of candour legislation was enacted in England in November 2014. Guidance for implementation of this legislation within NHSBSP was undertaken subsequently from 2016-2018. This included the development of a more robust uniform system of interval cancer classification (2017), in particular the classification of a definitive false negative cancer. These false negative cancers are the only interval cancer subtypes that include a notifiable safety incident (‘something has gone wrong’) and are subject to ‘duty of candour’. The percentage of interval cancers, which are false negatives under the new classification system, has not been published, but is anecdotally reported to be 1–3%. This compares to a mean figure of 7% in the previous interval cancer classification system used under ‘Disclosure of Audit’.”

“Public Health England, with guidance from the Care Quality Commission (CQC) advised on ‘Retrospective application of duty of candour regulation for interval cancers’ in June 2017. Public Health England advised “that duty of candour regulations will only apply to interval cancers diagnosed after 27 November 2014 [i.e. prospectively from the enactment of Duty of Candour legislation].”

Table 2. Overview of the categorisation of interval cancers in England to determine the implementation of Disclosure of Audit and Duty of Candour⁽¹⁵⁾

Category	Radiological	Action warranted	Open disclosure action
Satisfactory	Normal or benign mammographic features.	No reason to recall.	Disclosure of Audit
Satisfactory, with learning points	Seen with hindsight, difficult to perceive. Not obviously malignant.	May provide learning. Not all readers would recall.	Disclosure of Audit
Unsatisfactory	Appearance is obviously malignant.	Should have been recalled. All readers reviewing the films agree that they would recall.*	Classify as a notifiable safety incident under Duty of Candour process

* Films in this category should have obvious lesions. If there is any disagreement, or if it is felt that this is only obvious with hindsight, they should be placed in the category of ‘Satisfactory, with learning points’.

Survey of international breast screening programmes

A formal survey was undertaken by the National Screening Service's PEU to gather information from international population-based breast screening programmes on their processes for the audit and review of invasive interval breast cancers. The survey was circulated to 23 international screening programmes in May 2019, 70% (n=16) of which responded. The questionnaire and a summary of the findings are provided in Appendix 7. The main findings of the survey are outlined below:

- Eleven out of 16 responding programmes have an audit process in place for invasive interval breast cancers.
- Ten of the 11 respondent countries calculate the interval cancer rate.
- Ten countries conduct radiological reviews of individual interval cancers. The purpose of the reviews varies, with 7 of the 10 programmes conducting reviews on all cases, and 3 programmes on a sample of cases.
- Two countries (England and Scotland) were identified by the survey as having an open disclosure policy that extends to the results of audits. It should be noted that England has published its policy and Scotland recently introduced its policy.
- Some regions afford legal protection to screening programmes in order to promote quality assurance and clinical audit.

Literature review

The literature review of peer-reviewed publications focused on studies that included a radiological review of interval cancers. The literature review was conducted in order to examine the processes of radiological reviews and aimed to address the following questions:

1. What audit processes are employed for interval cancers in breast screening programmes?
2. What methodologies are used for radiological reviews of interval cancers in breast screening programmes?
3. What is the practice with regard to disclosure of audit findings of interval cancers in breast screening programmes?

The main findings of the literature review are outlined below:

- Overall, the literature review identified multiple studies internationally that conducted radiological reviews of interval cancers within the setting of breast screening programmes.
- The studies varied in the time period examined and the number of interval cancers for which radiological reviews were completed.
- No consistent methodology was used across the studies for the review process. Furthermore, varying interval cancer classification approaches were employed across the studies. Variation was noted in the number of radiologists conducting the review; the level of experience of reviewing radiologists; whether the review was blinded or informed; if cases were seeded among validated negative screens, the ratio of interval cancers seeded among normal mammograms and the definitions used to identify each interval cancer type or subtype, i.e. whether an independent or consensus classification occurred.
- Considerable variation was found among the proportion of interval cancer subtypes classified across the studies. Among studies that identified false negative cancers following radiological review, the proportion of false negatives identified ranged from approximately 4% to 40%.

- The variation in the proportion of false negative cancers identified across the studies included likely reflects differences in the methodology and classification systems utilised to complete the radiological reviews. Studies (Turnbull *et al.*,⁽⁴⁶⁾ Gordon *et al.*,⁽⁴⁷⁾ Ciatto *et al.*,⁽³⁶⁾ and Hofvind *et al.*⁽³⁷⁾) were also identified that showed that the review design or the classification system employed can lead to variability in the proportion of false negative cancers classified.
- Studies that conducted retrospective radiological reviews, including classification of interval breast cancers, were conducted for many reasons, including for the purpose of audit, for research to inform quality assurance, and for research to inform education and learning.
- No screening programme was identified that conducted a retrospective programme-wide review of interval breast cancers for the purposes of open disclosure. However, an abstract was identified that conducted a reclassification of 470 interval cancer cases (from 1989 to 2002) within the Southern Derby Breast Screening Programme in order to address guidelines for disclosure of interval breast cancer audits, with the findings suggesting that the classification system employed can have implications for disclosure.⁽⁴⁶⁾ Furthermore, within the East Midlands Breast Screening Programme, Jenkins *et al.* completed a “retrospective, observational audit to assess outcomes from the screening programme in the East Midlands in terms of screen-detected and interval cancers with previous film-reading history”.⁽⁴⁸⁾ While the aim of the study was to examine differences in the incidence of screen-detected and interval cancers by reading history and differences in prognosis, the authors acknowledged in their discussion that when a false negative is identified, “the programme currently invites women based on informed consent and literature that accompanies appointments specifies that not all cancers are visible on a mammogram or detected by film readers.”⁽⁴⁸⁾

As highlighted in findings published by O’Brien *et al.* and others, most breast screening programmes report the interval cancer rate.^(14, 29)

In addition, the Expert Reference Group examined *Guideline for the Implementation a Look-back Review Process in the HSE*,⁽⁴⁹⁾ which are guidelines published by the HSE that provide guidance on when a look-back process should be considered. The Expert Reference Group has concluded that interval cancers diagnosed to date do not fulfil the criteria for a look-back review, as the interval cancers have already been diagnosed and a look-back review would not change a patient’s treatment or influence a patient’s prognosis.

Section Five:

Proposals for the Management of Interval Cancers in the Breastcheck Screened Population

Consent and informational material in the BreastCheck screening programme

The Expert Reference Group has reviewed both the informational material on the BreastCheck website and the consent form (Appendix 2) provided to women participating in the programme. It is acknowledged that considerable work has been undertaken to enable the BreastCheck website to provide accessible information to people with varying literacy levels.

However, informational material should be further developed so as to ensure that women have sufficient knowledge to help them make an informed decision about whether to participate in BreastCheck. This material should provide an expanded outline of the benefits and limitations of mammography screening and explicitly detail the occurrence of interval cancers.

BreastCheck informational material should highlight how all women can gain access to their records at any stage of their involvement in the programme, or request an individual radiological case review of interval cancer via BreastCheck units or the Client Services unit within the National Screening Service.

Additional informational material should explain data-sharing arrangements between BreastCheck and the NCRI, which are provided for in legislation.

Conclusion: All women voluntarily attending BreastCheck sign a consent form prior to participation in the programme. Accessible information is also available on the BreastCheck website.

Recommendation 1: 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.

Interval cancer rate

The Expert Reference Group noted that the most recently available interval cancer rates are from 2012 and that the most recent EUREF accreditation site visit, valid until 2020, was in 2015.

A detailed overview of how the interval cancer rate is determined is provided in Appendix 8. While there is an inherent and expected 2–4-year time lag before an annual interval cancer rate can be validated and published, the introduction of the GDPR has led to an unanticipated delay in validating more recent data, and work is underway by the NCRI to streamline the process as soon as possible.

Individual notification of interval cancers to BreastCheck can also occur outside of the NCRI updates. In many instances where women have been diagnosed with an interval cancer, the symptomatic services or a treating clinician will contact BreastCheck to notify the programme of an interval cancer diagnosis. A notification form is completed by BreastCheck administrators and records are requested in order to validate each notification. This allows BreastCheck to update its screening register once the breast cancer is confirmed. Updating the register ensures that the patient is removed from the screening register so that they are not invited for breast screening in the future, as they are now cared for within the symptomatic service.

The cases that are confirmed following notifications are then cross-referenced and validated with the NCRI data update when it becomes available. Between 70% and 80% of cases have already been confirmed by each unit by the time an NCRI update is received. Interval cancer validation is therefore an ongoing quality control activity despite the time lag with the NCRI updates. The compilation of this information is resource dependent, and resources are intensified with an NCRI update or in advance of an upcoming accreditation.

Following the most recent accreditation visit, EUREF noted that the Cork and Galway BreastCheck units were relatively new and had not screened sufficient numbers of women to enable experts to meaningfully interpret interval cancer data.

The Expert Reference Group noted that all activity in this regard among all BreastCheck units in Ireland has been paused while awaiting Expert Reference Group recommendations.

In accordance with recommendations in the *Scoping Inquiry into the CervicalCheck Screening Programme*, conducted by Dr Gabriel Scally, the necessary resources should be put in place to improve communication between BreastCheck and the NCRI.⁽³¹⁾ This should ensure timely collation of data by the NCRI, so that BreastCheck can more quickly validate interval cancer diagnoses and calculate the interval cancer rate.

Conclusion: The interval cancer rate is an objective parameter for monitoring programme performance relating to interval cancers. The process of recording and reporting the interval cancer rate is already established between the NCRI and BreastCheck. There is an expected 2–4-year time lag before each annual interval cancer rate can be validated. The interval cancer rate is internationally accepted as the most important and reproducible metric for monitoring interval cancers that can be safely standardised.

Recommendation 2: 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.

Radiological reviews

As detailed in Section Three and Section Four of this report, radiological reviews are undertaken in order to provide information to patients and for educational purposes. The conduct of such reviews is challenging, however, and there are well-recognised issues in relation to classification and bias.

Challenges of radiological reviews

Many challenges must be considered when determining the future conduct of radiological reviews. These challenges include, but are not limited to, the classification protocol used, hindsight bias, and timely notification.

1. Classification of interval cancers

This report has found widespread differences in the protocols, standard operating procedures (SOPs) and methodologies used to classify interval cancers, both in the literature and in international practice. The *European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth Edition* outlines interval cancer classifications to include true negatives, occult, minimal/subtle signs, false negatives, and unclassifiable.⁽¹⁰⁾ These guidelines also acknowledge the UK classification system,⁽¹⁰⁾ which has been developed in the UK based on the same principles, i.e. satisfactory; satisfactory, with learning points; and unsatisfactory (Table 2). However, Public Health England acknowledges that when a “result is based on interpretation of appearances on a scan, slide or mammogram in circumstances where the boundary between normality and abnormality is not firmly drawn – this may result in debate between experts as to the appropriate classification of the sample or the interpretation of the image”.⁽⁴⁴⁾

2. Hindsight bias

A major challenge and difficulty with radiological reviews of interval cancers is hindsight bias. The term hindsight bias describes “the tendency for people with outcome knowledge to believe falsely that they would have predicted the reported outcome of an event”.⁽⁵⁰⁾ It “prevents the realistic assessment of past events, distorts the evaluation of prior decision-making, and discounts the scenario under which the decision-making occurred”.⁽⁵¹⁾

In relation to radiological reviews, once it is known that an interval cancer has been diagnosed, it is almost impossible to review any previous screening mammograms without this knowledge influencing, even subconsciously, the reader’s interpretation and classification.

Hindsight bias is one of the leading reasons why there can be wide intra- and inter-observer variations in the proportion of cases assigned a false negative classification on review. This difficulty with reproducibility is why classification is not consistently utilised as a quality indicator in population screening programmes.⁽³⁸⁾

It is suggested that readers undertaking a retrospective review be unaware – i.e. blind to the knowledge – that an interval cancer is being reviewed.⁽⁵²⁾ The reviewing conditions should, as much as is feasible, resemble the real-time routine screening environment, where the prevalence of breast cancer is extremely low and where mammograms are read in batches over a short period of time.⁽⁵³⁾ This type of interval cancer review setting is rarely, if ever, created in current breast screening practices for reasons including technical difficulties and ongoing workload within screening services. It has been suggested that such an optimised review setting might be a reasonable and acceptable approach in some cases of dispute where a fair result can be reached for all parties,⁽⁵²⁾ in contrast to a learning and education exercise.

During the development of protocols for interval cancer reviews, efforts to replicate the screening environment and minimise hindsight bias should be considered. Many factors can influence the result of a radiological review, including the definition of an interval cancer, the criteria for classification, the protocol used to complete the classification, the radiologist's experience in screening, the age groups of the women included and the criteria for inclusion.⁽³⁶⁾

The interval cancer review process should consider many factors, including, but not limited to: whether the radiologist should be informed of the presence of an interval cancer or, if the cases are blinded, whether reviews should be seeded within routine screening mammograms; whether classification should be made upon consensus or with majority opinion among the reviewers; and whether independent reviewers who have not previously read the mammogram should complete the review. Additional factors regarding the reviews should be considered, including the number of reviewers, their experience of conducting review, their experience in a routine screening setting, their international experience, and their experience within the BreastCheck screening environment.

3. Review types

Completely blinded review

A completely blinded review involves seeding the interval cancer mammogram into a routine screening batch so as to reproduce the screening conditions where “cancer prevalence is low and may in addition to fatigue and loss of attention lead to a false negative report”.⁽³⁶⁾ The reviewing radiologist in this setting is unaware that an interval cancer is part of a routine active screening batch. This design requires a masking technique that would erase the historical date of the prior negative screening mammogram and substitute it with a date that reflects the time frame and imaging characteristics of the routine screening series. As such, blinded reviews are logistically challenging, but technological advances may address this in the future and should be considered on an ongoing basis.

Incompletely blinded reviews

The radiologists are aware that they are performing an interval cancer review, but the screening mammogram is reviewed without the diagnostic or symptomatic mammogram (i.e. the mammogram performed at the time of the interval cancer diagnosis).

Anonymised reviews

Anonymisation of medical X-rays would require masking of the clinical and personal details of interval cancer cases so that the mammogram being reviewed cannot be traced back to the individual patient. By fully anonymising the personal details of the mammogram, the review can be conducted without the intention of sharing the results of the review with the patient, i.e. in the case of a teaching file. The technology required in order to enable complete anonymisation, where the case cannot be de-anonymised (de-coded) and therefore the patient cannot be identified following the interval cancer review, is not available in BreastCheck.

4. Timing

Timely notification of interval cancers to BreastCheck is required in order to allow subsequent timely radiological case reviews for women who want to know more about their interval cancer. Interval cancer radiological case reviews should be done as close to the time of diagnosis as possible. This is recommended for three main reasons:

1. Radiological reviews of previously diagnosed interval cancers within the programme do not alter the course of clinical management, and conducting radiological case reviews close to the time of diagnosis affords timely open disclosure if indicated.
2. It is necessary for logistical reasons, as historic screening records may not be available, complete or interpretable if too much time has passed.
3. It affords interpretation of findings based on contemporaneous policies and standards.

Educational exercises

The Expert Reference Group recognises the importance of educational exercises for improving radiologists' interpretative skills and for better understanding an interval cancer diagnosis. Comparing prior screening mammograms with the interval cancer diagnostic mammograms is one part of a highly functioning training and quality-assured programme. By viewing cases where a mammogram shows very subtle signs of malignancy, readers have been able to improve their skills in detecting small breast cancers.

EUREF emphasises that “the crucial element of Interval Cancer collection is to provide data for epidemiologist review of those cases to provide an irreplaceable learning process, particularly as not taking part in Performs.⁴ The presence of an extensive and adequately reviewed interval cancer collection is all the more important in view of the teaching requirements associated with EUREF Certification at this level”.⁽²⁷⁾

BreastCheck also acknowledges this in its quality assurance guidelines: “The review of interval cancers by radiologists is regarded as mandatory because it is such an excellent feedback and educational process.”⁽³⁾

Ideally, all interval cancers should be reviewed, which is current practice in well-developed screening programmes and in accordance with EUREF recommendations. The Expert Reference Group has noted that this activity has been afforded legal protection in some countries.

Educational exercises have not been undertaken since EUREF's last accreditation site visit, pending the recommendations of this report. BreastCheck cannot currently perform completely blinded or fully anonymised reviews due to logistical challenges. There is currently no legislation in Ireland that will protect, and therefore help support and nurture, medical audit and individual quality assurance processes in a population screening programme. For these reasons, the Expert Reference Group does not currently recommend classification of interval cancers in a programmatic manner.

4 'Performs' is a specific educational software package for reviewing mammograms used in some screening programmes.

While review and classification of interval cancers is clearly an important educational exercise, it is only one of a number of learning methods used by breast screening radiologists. Review of the individual recall and small cancer detection rates, consensus review of recalled patients, small cancer reviews, and review and classification of patient-requested interval cancer reviews are other valuable learning methods used by BreastCheck radiologists. These and other parameters, as outlined in BreastCheck's *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition*,⁽³⁾ also enable the identification of radiologist underperformance.

Conclusion: Ideally, all interval cancers should be reviewed, as is current practice in well-developed screening programmes and is in accordance with EUREF recommendations. The Expert Reference Group has noted that this activity has been afforded legal protection in some countries. However, in the opinion of the Expert Reference Group, non-anonymised radiological reviews are not feasible in the Irish context without affording patients the choice to participate and seeking their consent.

Recommendation 3: 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.

Patient-requested case reviews of interval cancers

Notwithstanding the challenges and difficulties associated with radiological reviews, BreastCheck has developed an SOP for conducting patient-requested radiological reviews. The current BreastCheck SOP, which provides guidelines for methodology and classification, is an adaptation of the NHSBSP protocol ⁽¹⁵⁾ (2017) and is included in Appendix 9.

Conclusion: From the establishment of the BreastCheck programme, any woman with a negative screening result who is subsequently diagnosed with an interval cancer can request to have her prior screening mammograms reviewed so that she can better understand her diagnosis. To date, patients and/or clinicians have requested these reviews at the time of diagnosis or over the course of the woman's treatment. The findings of patient-requested case reviews of interval cancers are communicated to the patient and/or treating clinician following the review. There are many challenges associated with completing radiological reviews, including, but not limited to, protocols for classification, hindsight bias, and logistical challenges. Continually updated, evidence-based, robust SOPs are required for conducting radiological reviews, including an agreed classification system.

Recommendation 4: 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 will be communicated to the interval cancer patient.

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.

Open disclosure

The *Scoping Inquiry into the CervicalCheck Screening Programme*⁽³¹⁾ by Dr Gabriel Scally has recommended that the “National Screening Service should consider, with external assistance, the relevance of the HSE policy on ‘Open Disclosure’ as it develops in light of this Scoping Inquiry, for all of its screening programmes”.⁽³¹⁾ The radiological review of interval cancers in real time represents an opportunity for discussion and disclosure of the findings and the identification of any potential limitations of previous BreastCheck screenings. The Expert Reference Group therefore has considered the requirements for open disclosure.

In 2013, the HSE implemented the Open Disclosure Policy across all healthcare sectors. The most recent version of this policy defines open disclosure “as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident”.^(16, 54)

The HSE National Quality Improvement Team made an interim revision to the HSE Open Disclosure Policy on 12 June 2019,⁽⁵⁴⁾ which replaced the HSE Open Disclosure Policy dated 8 October 2013.⁽¹⁶⁾ The interim policy states that it “will be subject to further review following: (i) the development and publication of operational guidance for clinical audit of interval cancers in screening services by the Expert Working Group of the Clinical Audit of Interval Cancer in the Screening Programmes. This guidance will set out the principles and processes for how audit and individual case review should be undertaken following a diagnosis of interval cancer in the screened population and (ii) the commencement of provisions for mandatory open disclosure in the forthcoming Patient Safety Bill”.⁽⁵⁴⁾

Open disclosure for patient safety incidents is currently implemented in screening programmes. For example, the *Scoping Inquiry into the CervicalCheck Screening Programme* cited the management of disclosure following a cancer screening incident involving BowelScreen.^(30, 31, 55)

The Expert Reference Group acknowledges that the findings of patient-requested interval cancer reviews were disclosed within the BreastCheck programme. Under the revised SOP for the review of interval cancers, BreastCheck should continue to disclose the findings of patient-requested case reviews of interval cancers. This should be reflected in future BreastCheck quality assurance guidance and monitoring systems.

BreastCheck quality assurance documentation should be amended and KPIs developed to validate and monitor interval cancer reviews and the implementation of disclosure. In circumstances where BreastCheck is meeting the relevant KPIs and operating to the required standard, interval cancers, including false negative cancers, should not be considered patient safety incidents as defined by the current HSE Open Disclosure Policy. However, the findings of all patient-requested individual case reviews should be disclosed, as set out in the interim BreastCheck SOPs (Appendix 9), including for those who develop interval cancers post assessment (Appendix 9b).

Implementation of disclosure for patient-requested reviews of interval cancers is resource intensive and will need to be appropriately supported (see the Implementation and monitoring section). The implementation of disclosure in the NHSBSP has been described in Section Three of this report. The NHSBSP’s recent prospective policy was introduced over a 3-year implementation period.

Conclusion: In 2013, the HSE introduced the Open Disclosure Policy, which has been implemented within the BreastCheck programme for patient safety incidents. In circumstances where screening programmes are meeting their KPIs and operating to the required standard, interval cancers, including false negative cancers, should not be considered patient safety incidents as defined by the HSE Open Disclosure Policy. The Expert Reference Group has noted that since 2018, BreastCheck has adapted the interval cancer classification process implemented and published by NHS England, as outlined in BreastCheck's interim SOP, which includes disclosure of the findings of patient-requested individual case reviews.

Recommendation 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.

Conclusion: The Expert Reference Group acknowledges that interval cancers, including false negative cases, are an inevitable and unavoidable part of all screening programmes, and measures to implement a more streamlined disclosure policy for interval cancers in BreastCheck will help to communicate, but not eliminate, their occurrence.

Recommendation 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.

Historic educational exercises

Over the course of its discussions, the Expert Reference Group was asked to make recommendations in relation to historic educational exercises (Appendix 5). In reaching its conclusion, the Expert Reference Group considered:

1. The overall quality of the BreastCheck programme
2. Current management of interval cancers in the BreastCheck programme
3. International practice with regard to educational exercises
4. Utility of educational exercise records, and
5. Equity.

1. The overall quality of the BreastCheck programme

Quality assurance of BreastCheck is continually monitored through the assessment of KPIs. These programme standards against which performance is measured are aligned with the *European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth Edition*,⁽¹⁰⁾ the *BreastCheck Guidelines for Quality Assurance in Mammography Screening, Fourth Edition*⁽³⁾ and the *BreastCheck Women's Charter*.⁽¹³⁾ The BreastCheck programme is performing within agreed quality assurance parameters:

- Interval cancer rates in BreastCheck are in line with international practice standards.
- EUREF has awarded BreastCheck the highest accreditation (Category 4 Reference Centre) status.
- Since its inception, the BreastCheck programme has been delivered within Ireland by an Irish health service team.

2. Current management of interval cancers in the BreastCheck programme

Interval cancers are an expected and anticipated occurrence within all screening programmes. Programme performance in BreastCheck is based on defined population statistics, such as the cancer detection rate and the interval cancer rate. Patient-requested case reviews of interval cancers are not considered a measure of programme performance in BreastCheck or for monitoring the occurrence of interval cancers, similar to other European screening programmes:

- BreastCheck works in collaboration with the NCRI to calculate, publish and monitor interval cancer rates. The documented interval cancer rates are within international accepted standards.
- BreastCheck has had a process in place to respond to patient requests for individual case reviews since its establishment.
- BreastCheck has adapted the interval cancer classification system that NHS England implemented and published in 2017.
- BreastCheck has undertaken educational exercises as part of an educational and accreditation process. The BreastCheck quality assurance guidelines state, "The review of interval cancers by radiologists is regarded as mandatory because it is such an excellent feedback and educational process."⁽³⁾

Educational exercises were undertaken in accordance with accreditation requirements and in compliance with the standards and policies of the time when they were completed. They did not constitute a centrally coordinated, standardised, or reproducible audit.

3. International practice with regard to educational exercises

Records of educational exercises relate to educational activity, which is an essential element of quality improvement in breast screening. EUREF considers active involvement in this practice to be important for teaching requirements associated with Category 4 accreditation.⁽²⁷⁾

Multiple published studies describe the rates, classification and characteristics of interval cancers. Following discussion with international breast screening experts, an international survey and a review of the literature, the Expert Reference Group did not identify any programme that has undertaken retrospective patient notification and disclosure of false negative interval cancers.

The Expert Reference Group was advised that Public Health England considered historic records of educational exercises when implementing updated duty of candour procedures in 2017. Public Health England took the decision to implement new procedures prospectively from the date that the legislation was introduced (Appendix 10).

Most countries do not disclose findings of any interval cancer reviews, including those conducted as part of educational exercises, as they are undertaken for internal quality assurance and quality improvement. The continuous quality improvement and learning generated by these activities ultimately benefit every woman who participates in the programme. In some well-developed programmes, programmatic audit is protected by law (e.g. Canadian provinces).

4. Utility of educational exercise records

Educational exercises undertaken and maintained for the purpose of accreditation did not employ a standardised reproducible methodology across all units; thus, they are unreliable and conclusions cannot be drawn from them.

Retrospective analysis of educational exercises would not yield any clinical benefit to patients or alter the course of their clinical management, and therefore does not meet the criteria for a look-back review as set out in HSE guidance.⁽⁴⁹⁾

Many historic records (radiological film images) are neither available nor interpretable, due to the age of the programme; older records are not available in digital format, and the quality of non-digital images deteriorates over time.

5. Equity

The Expert Reference Group noted that educational exercises account for a subset and not the entirety, of historic interval cancers since the inception of BreastCheck. Any retrospective review process, if it were considered, should be offered to all interval cancer patients in the interest of equity. Such a review would, however, limit operational activity in BreastCheck.

Conclusion: Within BreastCheck, a subset of interval cancer cases underwent review for educational and accreditation purposes. Individual records of educational exercises undertaken for education and accreditation were maintained as proof of participation. EUREF required evidence of this activity at the accreditation visit. Furthermore, during the accreditation visit, EUREF also reviewed a subset of interval cancer cases together with BreastCheck radiologists. This was consistent with all other international screening programmes seeking EUREF accreditation.

Having considered international expert opinion, findings of the international survey, and a literature review, the Expert Reference Group has concluded that records of educational exercises which were part of the EUREF accreditation process do not represent a standardised reproducible classification of interval cancers. As such, the Expert Reference Group concluded that there is no basis to use these records beyond the purpose for which they were gathered.

Further review of historic cases would not alter the clinical course for a woman already diagnosed with and treated for an interval cancer. All patients with interval cancers can avail of a patient-requested review using the new standard review and classification process.

Educational exercises have not been undertaken since EUREF's last accreditation site visit, pending the recommendations of this report. Completely blinded and anonymised reviews are logistically challenging, and the technology that would enable this is not available in breast cancer screening at this time.

Recommendation 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.

Recommendation 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.

Implementation and monitoring

The Expert Reference Group considers the current interval cancer review practices employed by BreastCheck to comply with international practice, and is satisfied that a robust interim SOP is in place.

The Expert Reference Group acknowledges that the technology required in order to completely blind or anonymise reviews is not currently available and, if implemented in future, will require significant modifications to BreastCheck's technical and information systems. It will also require significant changes in operational processes in order to ensure that interval cancer reviews can be performed efficiently and safely without compromising the service for women attending routine screening. The Expert Reference Group recommends that this review process continue, and that BreastCheck continually consider evolving technologies and trends that may be applied in the future.

As outlined earlier in Section Five, full implementation of open disclosure policies for interval cancers is resource intensive and will require appropriate support. Consideration is needed for many aspects, which would include (but are not limited to):

- Updated informational material and consent forms
- Protocols for consent from the patient to have their mammograms reviewed
- Protocols for requesting and obtaining clinical information about the diagnosis
- A standardised, reproducible protocol for the design and implementation of future prospective interval cancer audits
- Educational toolkits/literature/leaflets about interval cancers and the open disclosure policies
- Nursing and administration support
- Consultant support (radiology, surgery and oncology)
- Counselling support for both the patient and clinical team
- A feedback mechanism that BreastCheck, members of the clinical team and the NCRI can learn from in order to continually improve the interval cancer review process, and
- A validation system in order to ensure that the review process is conducted to the highest possible standard.

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

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

Recommendation 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.

Consideration of implications of recommendations

As required by the Expert Reference Group Terms of Reference (Appendix 4), this document provides the “operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population” (Appendix 4), with specific reference to the assessment of overall programme performance, the conduct of individual case reviews, consent, and open disclosure.

This document has outlined practices followed in the past and described current and future practices for interval cancers in the context of open disclosure within BreastCheck.

Consideration must be given to the potential implications of the Expert Reference Group’s recommendations:

- Internationally, Public Health England has led the implementation of open disclosure in its breast screening programme. This process took 3 years to implement in England, although implementation is not complete and individual units continue to be carefully monitored. The adoption of similar processes in the Irish screening setting will therefore require up to 3 years to fully implement.
- The Expert Reference Group recommendations do not allow for educational exercises involving classification of all interval cancers in a programmatic manner. The potential impact of this on future applications for accreditation should be considered. EUREF strongly recommends that such a programmatic approach be implemented in order to qualify for future accreditation beyond 2020. Educational exercises should continue to be performed where patient consent has been explicitly obtained for patient-requested case reviews of interval cancers. The implementation team should monitor the effects of the Expert Reference Group’s recommendations on all aspects of the functioning of BreastCheck, including ongoing delivery of the programme, public trust, patient safety, efficacy and cost-effectiveness.
- The Expert Reference Group wishes to highlight that the implementation of these recommendations will have significant resource implications if BreastCheck is to meet the needs of patients, their families, and clinicians, as outlined in the main report.

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Appendices: Appendix 1

Wilson and Jungner screening criteria

The Wilson and Jungner screening criteria outlined according to the World Health Organization (19, 20) are listed below:

'The condition sought should be an important health problem.

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

Facilities for diagnosis and treatment should be available.

There should be a recognisable latent or early symptomatic stage.

There should be a suitable test or examination.

The test should be acceptable to the population.

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

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

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

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

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

'The screening programme should respond to a recognised need.

The objectives of screening should be defined at the outset.

There should be a defined target population.

There should be scientific evidence of screening programme effectiveness.

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

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

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

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

Programme evaluation should be planned from the outset.

The overall benefits of screening should outweigh the harm.'

Appendix 2

BreastCheck consent form

A copy of the BreastCheck consent form signed by all women prior to participation in the BreastCheck screening programme is shown below.

<u>CONSENT</u>	
<ul style="list-style-type: none"> • Please read this carefully while you are waiting • You will be asked to sign it in the presence of the radiographer • If you have any questions, feel free to discuss them with a member of our staff 	<p><u>I fully understand:</u></p> <ul style="list-style-type: none"> • The BreastCheck service offered to me and I consent to take part • That the mammogram (breast x-ray) does not detect every breast cancer; a small number of cancers may be missed by screening • That in order to ensure I receive comprehensive care and follow-up, and to assist BreastCheck in examining the impact of screening in reducing breast cancer deaths, BreastCheck may need to exchange my health records with other health agencies such as my G.P, hospital records and the National Cancer Registry. I consent to the collection, storage and exchange of my health records as described. • That it is the policy of BreastCheck that my personal data is processed lawfully, fairly and in a transparent manner and is stored, in agreement, with the the General Data Protection Regulation (GDPR), the Data Protection Acts 1988 to 2018 and in accordance with the HSE Data Protection Policy
	<p>Signed: _____</p> <p>Witness: _____</p> <p>Date: _____</p>
<p>BreastCheck DS-001 Rev05</p>	

Appendix 3

BreastCheck follow-up letter

An example of a BreastCheck follow-up letter sent to women communicating a negative screening mammogram result, following participation in the BreastCheck screening programme is shown below.

COM-036 Rev08
Enc COM-050

Your reference number:



I am pleased to tell you that your recent mammogram has detected no evidence of cancer.

BreastCheck will be inviting you for your next mammogram in about two years and I will write to you when the next appointment is due, provided you are still within the age range.

Please remember that in a very small number of instances breast cancers are not detected by mammography, so if you notice anything unusual about your breasts between now and your next screening appointment you should contact your doctor.

Yours sincerely



Prof Ann O'Doherty
Clinical Director

Aonad Mhuirfean, Bóthar Mhuirfean, Baile Átha Cliath 4. Merrion Unit, Merrion Road, Dublin 4.
☎ 01 223 5800 ✉ merrion@breastcheck.ie www.breastcheck.ie



An tSeirbhís Náisiúnta Scagthástála
National Screening Service



BreastCheck
AN CLÁR NÁISIÚNTA SCAGHTÁSTÁLA GIÓCH
The National Breast Screening Programme



CervicalCheck
AN CLÁR NÁISIÚNTA SCAGHTÁSTÁLA GIÓCH
The National Cervical Screening Programme



BowelScreen
AN CLÁR NÁISIÚNTA SCAGHTÁSTÁLA GIÓCH
The National Bowel Screening Programme



Diabetic RetinaScreen
AN CLÁR NÁISIÚNTA SCAGHTÁSTÁLA GIÓCH
The National Diabetic Retinal Screening Programme

Cuid d'Fheidhmeannacht na Seirbhíse Sláinte. Part of the Health Service Executive.

Appendix 4

Expert Reference Group Terms of Reference

Clinical Audit of Interval Cancer In the Screened Population

TERMS OF REFERENCE

Final Draft

11 September 2019

Background

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

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

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

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

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

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

Purpose

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

Objectives

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

Establish the current audit practices of the three cancer screening programmes and compare to international best practice.

Establish any review practices, in relation to interval cancers, of the three cancer screening programmes, and compare to international best practice.

Determine best internationally accepted practice for addressing interval cancers.

Develop, in line with National Standards for Clinical Practice Guidance Development, operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population. This guideline should:

Review standardised informed consent processes

Outline the potential role of audit in such situations in Ireland, such that cancer screening programmes may be assessed with regard to their operation within agreed standards. This will take into account feasibility, safety, practicality, cost-effectiveness, legality and risk. Appraise the various options available and outline the future method of clinical audit and review in Ireland.

Outline the future methodology for individual case review in such situations in Ireland including any data protection requirements.

Establish a process for open disclosure and communication as it pertains to both interval cancer audit and to individual case review for a service user. This will take into account the HSE open disclosure policy, legislative requirements and best practice guidelines. This will also take account of patient's needs, ethical responsibilities, and the impact on healthcare professionals and programme sustainability.

Outline the benefits and challenges for the National Cancer Screening Programmes regarding implementation of the proposed systems of audit of interval cancer.

Recommend the commencement date for the newly proposed system of audit of interval cancer.

Patient Engagement

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

Scope

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

CervicalCheck (the National Cervical Cancer Screening Programme)

BreastCheck (the National Breast Cancer Screening Programme)

BowelScreen (the National Colorectal Cancer Screening Programme)

Deliverables

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

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

Governance

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

The two Expert Reference Groups will be:

Cervical and Bowel Screening

Breast Screening

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

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

Membership

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

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

External Chairperson

Patient Advocates

Patient Representatives

Screening Clinicians

International Screening Experts

Academic and research expertise

National Clinical Programme leads

Clinical Audit expertise

Public Health

Project Secretariat

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

Project Process

The project will be approached in four stages:

Stage 1: International literature searches and communications with other international and regional cancer screening programmes

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

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

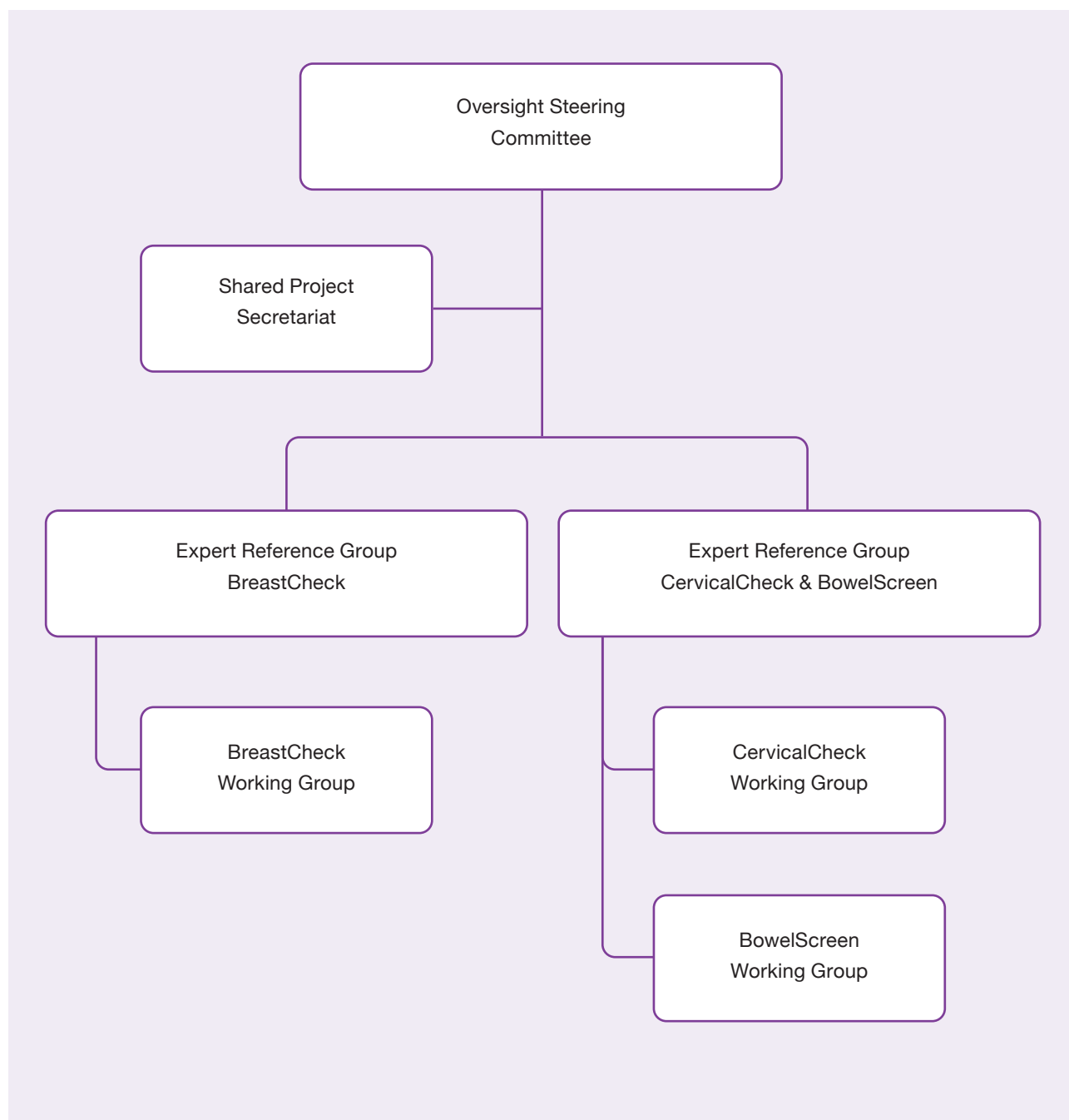
Stage 4: Review and final report

Timeframe

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

Appendices

Clinical Audit of Interval Cancer in the Screened Population



Clinical Audit of Interval Cancer in the Screened Population

Members List

Project Oversight Steering Group

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

CervicalCheck & BowelScreen Expert Reference Group

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

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence

NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

BreastCheck Expert Reference Group

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

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence

HSE: Health Service Executive; NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

CervicalCheck Working Group

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

BowelScreen Working Group

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

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

BreastCheck Working Group

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

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence

HSE: Health Service Executive; NSS: National Screening Service; PEU: Programme Evaluation Unit; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

Project Secretariat

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

NSS: National Screening Service

Appendix 5

Correspondence from the Chief Clinical Officer, HSE



Office of the Chief Clinical Officer
Dr Steevens' Hospital

D08 W2A8

E: cco@hse.ie

Tel : 01 6352322

Oifig an Phríomhoifigigh Chliniciúil Eatramhaigh
Feidhmeannacht na Seirbhíse Sláinte
Seomra 1.01 | Ospidéal Dr. Steevens | Baile Átha Cliath 8 |
D08 W2A8

BY EMAIL ONLY

6th June 2019

Dr Risteard O'Laoidé
Chair
Breast Screening Expert Reference Group
Email Address

Re: Interval Cancer Audit and Review – BreastCheck Expert Reference Group

Dear Risteard

The work of the interval cancer audit and review expert reference group is central to our support for the screening services and to rebuilding confidence in the screening programmes amongst the wider public.

Practices regarding reviews to support quality assurance and / or accreditation processes are included in this work. At our meeting on the 4th June we discussed the necessity to draft an interim report which should provide:

- a) An outline of the historic reviews undertaken within Breast Screening.
- b) A review of this historical practice in Breast Screening as it relates to international best practice.
- c) Recommendations in relation to the review and future practice.

As agreed, the availability of an interim report before Wednesday 17th July will assist the group towards concluding their work within the project timeframes.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Colm Henry', with a long horizontal line extending to the right.

Dr Colm Henry
Chief Clinical Officer

Appendix 6

Letter to Board of HSE post Independent Clinical Panel Review of CervicalCheck

An Roinn Sláinte
Department of Health
Office of the Minister

Mr Ciaran Devane
Chair
Health Service Executive
Dr Steeven's Hospital Dublin 8

2 December 2019



Independent Clinical Expert Panel Review of CervicalCheck

Dear Ciaran

I write in regard to the above Review, the aggregate report of which will be published following the Government meeting tomorrow.

The Expert Panel has made 10 recommendations, primarily relating to audit and to colposcopy services. These are important recommendations, which in many instances will be encompassed within the work already ongoing in HSE in a number of areas.

Recommendation 1, 4, 5 and 6: Interval cancer audit

The Expert Panel has made a number of recommendations regarding interval cancer audit and disclosure in Cervical Check.

As you know, a key recommendation arising out of the Scoping Inquiry into CervicalCheck was that “common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.” I am aware that in response to this recommendation, the HSE established two Expert Groups, one for audit in cervical and bowel cancer screening and one for audit in breast cancer screening, with a view towards implementing auditing (including open disclosure of same) in the National Screening Service. I understand that these Expert Groups are independently chaired and comprise patients, patient advocates, a patient ethicist, screening clinicians and international experts.

The Expert Groups are now requested to incorporate consideration of the Expert Panel's recommendations on interval cancer audit and disclosure in their ongoing deliberations along with international best practice, consideration of the wider environment including the ongoing process on tort reform, and any other expert input the groups deem necessary.

Recommendation 2: Transport of slides in large scale review

The Expert Panel has recommended that transport of slides be done in a manner similar to the process used for this Review, and you are asked to ensure that any future such exercises continue to adhere to these protocols.

An Roinn Sláinte
Department of Health
Office of the Minister



Recommendation 3: Information about the limitations of screening

The Expert Panel has recommended that efforts continue to inform women about the limitations of screening and the performance of CervicalCheck.

Both the National Screening Advisory Committee and the Vaccine Alliance can be expected to contribute significantly to the effective communication of the benefits, strengths and limitations of population-based programmes, including screening and immunisation. I am aware also that the HSE has done considerable work in regard to information for women, following recommendations from Dr Scally's Scoping Inquiry.

You are requested to please ensure that the HSE's materials continue to be updated, refined and improved, particularly in view of the ongoing project for the transition to HPV primary screening, scheduled for implementation in early 2020.

HPV primary screening and vaccination

The Panel also notes that HPV primary screening and HPV vaccination will ensure that cervical cancer becomes a rare disease in Ireland. The introduction of HPV primary screening in Quarter 1 next year continues to be an absolute priority for me. Its commencement will be a key milestone for the programme, building strongly for the future following stabilisation of smear test turnaround times, strong progress in implementation of Dr Scally's recommendations and very strong planning and preparation directed at ensuring the individual reports of participants in the RCOG process are communicated sensitively and appropriately.

The HSE Scally Oversight Group has played an important role in driving forward on all of these issues, and you are asked to ensure this Oversight Group continues to oversee the transition to HPV primary screening to completion. As you know, the HPV primary screening project has also been identified as a standing item in the monthly Department-HSE performance oversight meetings, reflecting its level of priority and the Departmental focus on this issue.

Recommendations 7 and 8: Colposcopy

These recommendations reflect the findings in some cases of suboptimal colposcopy management, notwithstanding the Panel have said this should not be seen as cause for concern. Colposcopy management of abnormal cytology being an integral component of any cervical screening programme, I understand that it is a critical workstream of the project to transition to HPV primary screening. In the detailed work on protocols and QA guidelines underway as part of the HPV project, and as well as in colposcopy capacity planning, the HSE is requested to take full account of these recommendations.

Recommendation 9: Cancer screening database

The Panel has recommended the creation of a dedicated database of cancer screening histories in cases where cancer occurs. I am aware that the creation of an NCSR forms part of the NCRI's work in implementing the recommendations of the Scoping Inquiry, which I understand is engaging with the HSE in that regard. You may wish to know that I intend to request the NCRI to ensure the above recommendation is considered as part of this work.

An Roinn Sláinte
Department of Health
Office of the Minister



Recommendation 10: Learning from experience

I am cognisant of the very considerable planning and engagement undertaken by the HSE in preparing for the communication of individual reports to women and next of kin, and I very much welcome the fact that the process appears to have, by and large, met their needs.

The Expert Panel has recommended the collective experience gained through this process should be reviewed and used to develop best practice guidance for disclosure protocol. I too believe it is essential that the learnings gained through the experience of conducting and communicating this current Review to over one thousand individual participants should be collated and used to ensure improved and enhanced communications to individual participants in the future, and I am in no doubt that those involved in this successful exercise will concur also.

The HSE is requested now to appoint an appropriate person to undertake a review, including through consultation with administrators, the NSS, and clinicians, a representative group of review participants and the patient advocacy services who were involved in this process of communicating results to participants, such that this can inform and shape future best practice.

Yours sincerely,

Simon Harris Minister for Health

Appendix 6b

Letter to Expert Reference Group post RCOG



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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

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

By Email Only

11th December 2019

Dr Risteard O'Laoide
rolaoide@svhg.ie

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

Dear Risteard,

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

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

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

Yours sincerely,

Dr Colm Henry
Chief Clinical Officer

Damien McCallion
HSE National Director
Emergency Management &
Director General CAWT

Appendix 6c

Response letter from Expert Reference Group post RCOG

Grúpa Ospidéal
Oirthear na hÉireann



Ireland East
HOSPITAL GROUP



16 January 2020. By Email Only

Dr. Colm Henry, Chief Clinical Officer HSE.

Mr. Damien McCallion, HSE National Director Emergency Management & Director General CAWT.

Re: Independent Clinical Expert Panel Review of CervicalCheck

Dear Colm and Damien,

Thank you for your letter dated the 11/12/19 concerning the aggregate report of the Independent Clinical Expert Panel Review of Cervical Check, completed by the Royal College of Obstetricians and Gynaecologists (RCOG), which was published 3/12/19.

Recommendations four, five and six from this report pertain to clinical audit of cancers in screening programmes. *You write that the 'Minister is requesting that the Expert Reference group for BreastCheck would consider these recommendations in relation to international best practice and the functioning of the screening programmes'*

The issues raised were discussed at a meeting of the BreastCheck Expert Reference Group (ERG) on 19/12/19.

The group noted that the RCOG recommendations were related to cervical cancer screening and although the screening processes are not analogous, the group considered the matter in reaching its final recommendations. Conclusions related to each of the specific RCOG recommendations are outlined below:

- 1) Recommendation 4: The internationally recognised metric for programmatic audit of interval cancers in breast cancer screening is the Interval Cancer Rate (ICR). The ERG recommends that BreastCheck should continue to monitor interval cancers at the programmatic level through the assessment of the ICR. In breast cancer screening, radiological review and classification of interval cancers is a quality improvement and educational exercise rather than a recognised metric of programme performance. Radiological review and classification of interval cancers, for quality improvement and educational purposes is fully endorsed by the ERG. The report recommends a more robust reproducible method of classification. This is allied to a strengthened process of patient choice and consent which the Expert Reference Group considered to be of importance in the Irish context. BreastCheck will continue to disclose the findings of these reviews.
- 2) Recommendation 5: This recommendation is related to colposcopy findings. A possible analogous situation in breast cancer screening is post-assessment audits. The ERG has developed a Standard Operational Procedure for the management of interval cancers, which is focused on post mammography interval cancers but also includes review of post assessment interval cancers.

Grúpa Ospidéal
Oirthear na hÉireann



- 3) Recommendation 6: The ERG recommends that BreastCheck continue to publish the ICR as per international best practice.

I have also reviewed the letter issued from the Minister of Health to Mr Devane, Chairman of the Health Service Executive, following publication of the RCOG aggregate report, dated 2/12/19.

Notwithstanding their findings regarding bias in Recommendation 1, peer review literature in breast cancer screening identifies hindsight bias is a significant factor in radiological classification of interval breast cancers. Multiple studies have shown that the method of radiological review influences the proportion of interval cancers categorised as false negative.

The letter from the Minister for Health refers to '*consideration of the wider environment including the ongoing process on tort reform*'. The potential impact of litigation on the operational function and cost-effectiveness of breast screening in Ireland was raised on a number of occasions at meetings of the ERG. The significance and importance of these issues for the continuance of breast cancer screening in Ireland should be closely monitored as the recommendations of this report are implemented. The ERG did not feel that there was sufficient data available at this stage, or that the group as constituted had sufficient expertise, to make specific recommendations in this regard. However, these factors, which include litigation, the cost-effectiveness of the programme and the sustainable recruitment of radiologists will require significant consideration in the immediate future. Addressing these issues in an honest and transparent way will allow breast screening to continue to save the lives of Irish women and nurture the trust which is fundamental and essential to the delivery of any healthcare service.

Yours sincerely,

Prof. Risteárd Ó Laoide

Chairman, BreastCheck Expert Reference Group.

Appendix 7

International breast screening survey and results

1. Respondent information

1. Please provide us with the following information *

Your name	<input type="text"/>
Your organisation	<input type="text"/>
Region or Country	<input type="text"/>
Contact email address	<input type="text"/>
Contact telephone number	<input type="text"/>
Screening programme web address	<input type="text"/>

2. About your breast screening programme

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

3. What age groups do you screen? *

4. What is your screening interval? *

5. How many women did your programme screen in 2017? *

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

☐

Yes

☐

No

3. Interval cancers audit

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

8. Please tick appropriate answer(s) that best describes how your breast screening programme undertakes an audit of interval breast cancers in the screened population

☐

Routine programme-wide review, with calculation of interval cancer detection rates

☐

Routine individual patient cancer review

☐

Only on patient/treating physician request

☐

Routine sample of screened population

☐

Other (please give details below)

Other details:

9. If your programme audits a routine sample of the screened population for interval breast cancers, please give details of sample size below

4. Breast cancer notification

10. How is your programme notified of invasive interval breast cancers arising in women screened?*

11. How do you confirm/validate notifications of invasive interval breast cancers? *

5. Radiology review of interval cancers

12. Do you carry out a radiology review of interval cancers?

☐

Yes

☐

No

6. Radiology review of interval cancers

13. How many radiologists review the audit cases?

7. Controls

14. Are control images included with audit cases when sent for radiology review?

☐

Yes

☐

No

8. Controls

15. Please explain how the controls are selected and how many controls are included in the review?

9. Blinding

16. When reviewing the slides of an interval cancer are the radiology reviewers aware that the woman subsequently developed cancer, or are they blinded to this fact?

☐

Yes, radiology reviewers are aware of the woman's cancer status

☐

No, radiology reviewers are not aware of the woman's cancer status

☐

Not applicable

☐

Unknown

15. How is hindsight bias managed in interval breast cancer reviews?

10. Interval cancers audit process

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

☐

Yes

☐

No

11. Interval cancers audit process

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

12. Informing patients

20. Are patients informed that a breast cancer audit is taking place?

☐

Yes

☐

No

13. Informing patients

21. Who contacts the women in respect of telling them that the breast cancer audit is taking place?

22. What processes are in place to facilitate informing women that a breast cancer audit is taking place?

14. Patient choice

23. Do women have a choice to be part of the audit?

☐

Yes

☐

No

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

24. What information do you give women who are participating in an interval cancer audit?

25. How do you inform women that they will be part of an audit?

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

Choose File

Comments

16. Consent**27. Do you capture consent from women to take part in a clinical audit?**☐

Yes

☐

No

28. Where do you capture consent?

At screening event

☐

Yes

After diagnosis of invasive breast cancer

☐

No

17. Consent**29. Does your routine consent procedure for screening cover the audit process?**☐

Yes

☐

No

18. Consent

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

Choose File

Comments

19. Interval cancers audit results

31. Are the results of the clinical audit of breast cancers communicated to the affected women?

☐

Yes

☐

No

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

☐

Yes

☐

No

20. Interval cancers audit results

33. Who communicates the audit results to women (or their next of kin)?

☐

GP/ Family doctor

☐

Treating oncologist/consultant

☐

Screening programme clinical lead

☐

Other (please give details below)

☐

Not applicable

Other details

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

21. Open disclosure/duty of candour

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

☐

Yes

☐

No

☐

Not applicable

22. Open disclosure/duty of candour

36. Is this policy mandatory or voluntary?

☐

Mandatory

☐

Voluntary

☐

Other (please give details below)

Other details

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

☐

Yes

☐

No

23. Open disclosure policy documentation

38. Please upload relevant policy documentation in relation to open disclosure/duty of candour

Choose File

Comments

24. Legal protection for interval cancers

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

☐

Yes

☐

No

25. Legal protection for interval cancers

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

26. Compensation

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

☐

Yes

☐

No

☐

Not applicable

27. Compensation

42. What is the procedure for financial compensation?

- ☐ No fault (routine financial compensation)
- ☐ Adversarial (legal route)
- ☐ Programme/state offers support to women
- ☐ Other (please give details of other below)

Other details:

28. Compensation

43. In what form does the programme/state offer support to women?

- ☐ Free treatment
- ☐ New cancer drugs
- ☐ Other
- ☐ Not applicable

Other details:

29. Publication of interval cancer rates

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

☐

Yes

☐

No

☐

Not applicable

45. Do you publish your interval cancer rates?

☐

Yes

☐

No

☐

Not applicable

30. Format of publication(s)

46. In what format do you publish results?

☐

Annual report

☐

Peer-review publication

☐

On website

☐

Other (please give details below)

Other details:

31. How we will use data from this survey

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

☐

Yes, with programmes identified

☐

Yes, with programmes anonymised

☐

No

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

☐

Yes, with programmes identified

☐

Yes, with programmes anonymised

☐

No

32. Further comments

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

Breast Expert Reference Group - September 2019

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

All comments from respondents are in italics and transcribed verbatim.

Introduction

Sixteen countries/regions completed the survey out of 23 countries invited, giving a response rate of (70%)(Figure 1). Of the sixteen countries/regions that completed the survey, eleven countries/regions have an audit process in place for invasive interval cancers, while five countries/regions do not have an audit process (Figure 2).

Figure 1. Flow diagram of main survey results

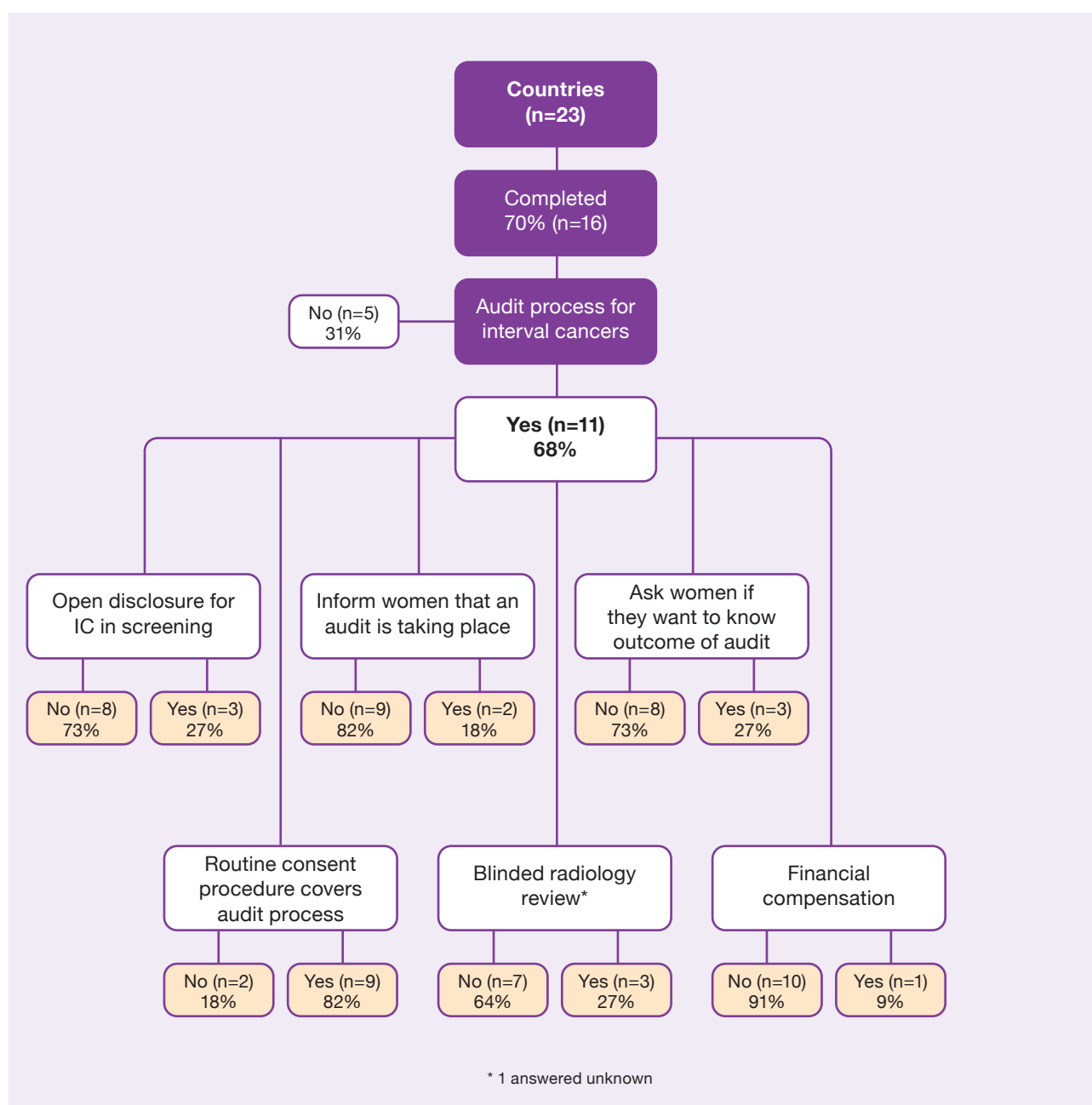
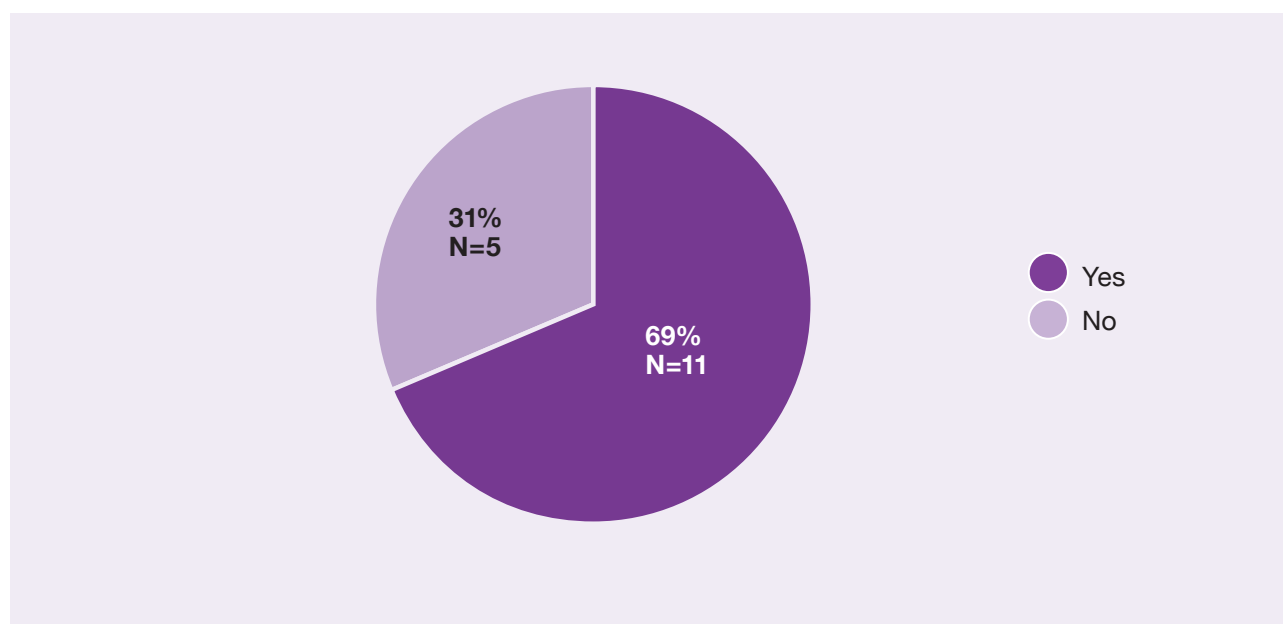


Figure 2. Does your breast screening programme undertake an audit of invasive breast cancers in the screened population?



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

Of the eleven who carry out audit, five carry out both a routine programme-wide review, with calculation of invasive interval cancer detection rates and routine individual patient cancer review. Five countries/regions carry out a routine programme-wide review, with calculation of invasive interval cancer detection rates only while one country carries out audit on an individual basis and does not have a routine procedure in place currently. Ten of eleven respondents who undertake audit carry out radiological review.

Are control images included with audit cases when sent for radiology review?

Four countries/regions use controls when carrying out a radiology review. Additional comments on the use of controls include the following:

- *Controls selected randomly by person coordinating review. Known to have 3 years normal follow up*
- *For review the diagnostic mammograms and all available screening mammograms (last screening round and available screening rounds before) are reviewed*
- *Random selection, but includes various breast density, review sets are enriched up to 30%*
- *Reviews are run a semi-informed scheme, i.e. the images from the last screening examination before diagnosis are shown in a series without information on the site where lesions subsequently developed*

When reviewing the mammograms of an invasive interval cancer are the radiology reviewers aware that the woman subsequently developed cancer, or are they blinded to this fact?

Three countries/regions carry out blinded radiology reviews, where the reviewers is unaware of the woman's cancer status. In eight countries/regions the reviews are not blinded.

How is hindsight bias managed in invasive interval breast cancer reviews?

Of the three countries/regions that carry out a blinded review, one country managed hindsight bias by having a case mix of interval cancer patients and patients with normal mammograms at subsequent screens while the other responded that three out of three blind reviewers must identify the cancer for it to be considered a false negative. The third country/regions states that two screening examinations before diagnosis are blindly reviewed by two experienced radiologists of the audit team. They have no prior knowledge of the clinical diagnostic mammograms, laterality and location of the interval cancer.

Of the eight who do not carry out a blinded review, three countries included details of their strategies to manage hindsight bias which include the following:

- *Having a minimum of two people reviewing each case and subsequent regional review of all category two and three cases*
- *Reviewers look at screening mammography first (unaware of the side and quadrant of interval cancer). Later they open also diagnostic mammography*
- *Training*
- *Only clearly visible lesions are called false negative*

The other two countries/regions:

- *Acknowledge bias rather than managed*
- *Perform audit for learning and quality improvement only*

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

Five countries/regions answered "yes" to this question. Further information provided by those who answered yes in relation to this question is as follows:

- *Individual review may be ordered in a medico legal case. Experts are then selected by the responsible authority (court or arbitration board)*
- *Different and individually for each case, much more time consuming*
- *When a patient asks for review of her interval cancer, the coordinating radiologist will make an appointment. He/she will show the images to the patient and will discuss them with her*
- *Such requests are extremely rare. If there is a legal framework the audit is blind.*

Who contacts the women in respect of telling them that the breast cancer audit is taking place?

Three countries/regions responded to this question as follows:

- *Given information at time of diagnosis that review will take place*
- *This involves women being given a leaflet which we have developed for women with interval cancer which, under “Reviewing your previous screening results” advises that: the programme will routinely review previous test results if you have been screened in the last three years and have an interval cancer. Please tell your key worker/breast care nurse if you’d like to know the results of this review. You can make this choice at any time*
- *It is written literature given at diagnosis*

What processes are in place to facilitate informing women that a breast cancer audit is taking place?

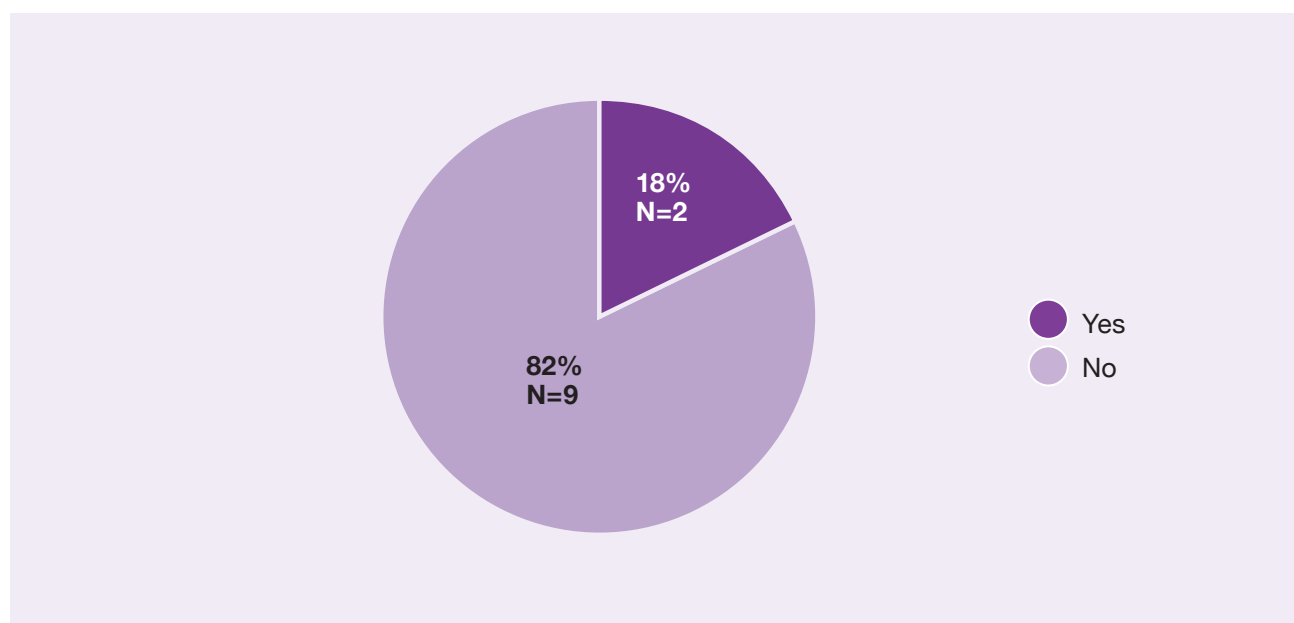
Two countries/regions responded to this question as follows:

- *verbal and written communication*
- *written literature*

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

Of the eleven countries/regions that carry out audit, two countries/regions give women a choice to be part of the audit (Figure 4).

Figure 4. Do women have a choice to be part of the audit?



What information do you give women who are participating in an invasive interval cancer audit?

Seven countries/regions responded to this question as follows:

- *Inform them that their previous screening images will be reviewed*
- *Leaflet is given as above and further information regarding the IC audit can then be given by staff on discussion with the woman, but this is on the woman's request*
- *The only potential shared outcome would be if the review altered their disease management*
- *Until now we didn't have any women requests for further analysing their interval cancer*
- *General informed consent*
- *Women do not participate in the triennial audits performed at the level of the reading unit*
- *They are just told it will happen but can discuss the findings in person on request*

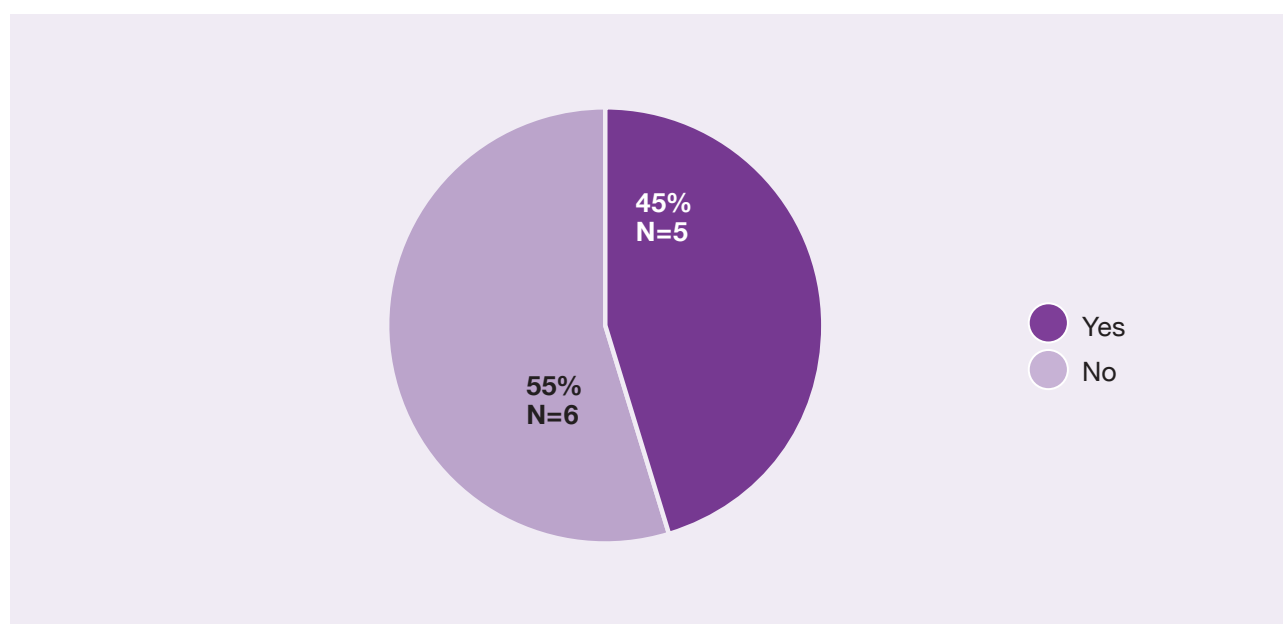
How do you inform women that they will be part of an audit?

- *Information leaflets and verbal communication*
- *Only informed if they have requested a review*

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

Five of the eleven countries/regions that carry out invasive interval cancer audit capture consent from women to take part in a clinical audit. All of these five capture consent at the screening event rather than after a diagnosis of invasive breast cancer (Figure 5).

Figure 5. Do you capture consent from women to take part in a clinical audit?



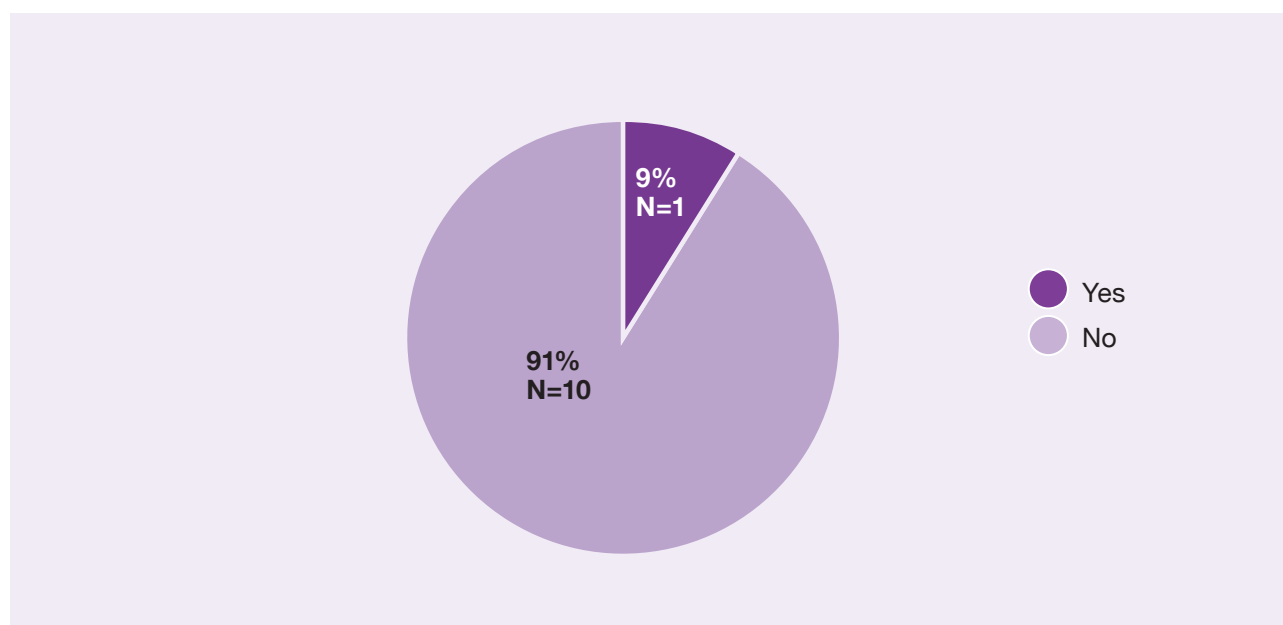
Does your routine consent procedure for screening cover the audit process?

Nine of the eleven countries/regions that carry out invasive interval cancer audit state that their routine consent procedure for screening covers the audit process.

Are the results of the clinical audit of breast cancers communicated to the affected women?

One country communicated the results of clinical audit of breast cancers to the affected women (Figure 6).

Figure 6. Are the results of the clinical audit of breast cancers communicated to the affected women?



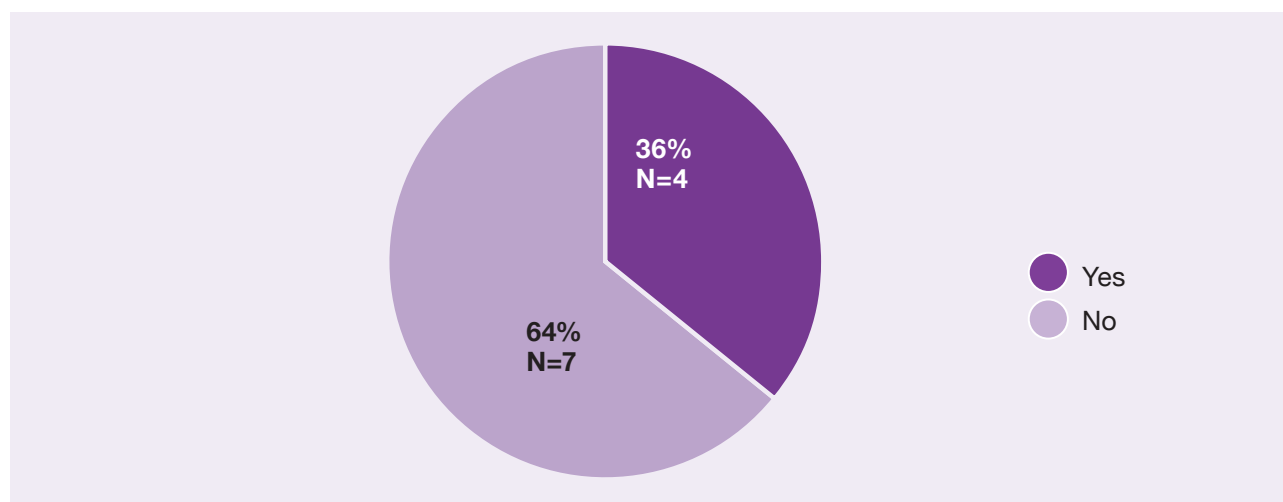
Are women asked if they want to know the outcome of the audit?

Three countries/regions ask women if they want to know the outcome of the audit.

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

Of the eleven countries/regions that carry out audit of invasive interval cancers, four countries have an open disclosure policy for medical incidents. All of these are mandatory policies. Seven countries do not have an open disclosure policy for medical incidents (Figure 7).

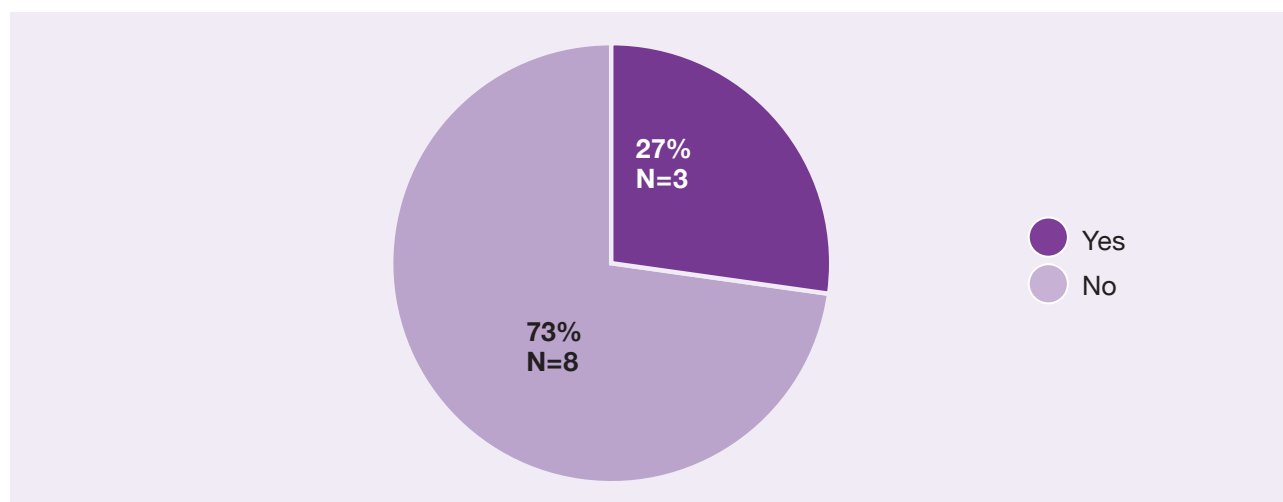
Figure 7. In Ireland we have an open disclosure policy for medical incidents. Do you have such policy(s) in your country?



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

Of the four countries/regions that have an open disclosure policy for medical incidents, two countries answered “yes” to having an open disclosure policy that applies to invasive interval cancers in screening. Additionally, one other country has an open disclosure policy for category 3 invasive interval cancers only (“Suspicious” on review) as this is deemed a clinical incident (Figure 8).

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

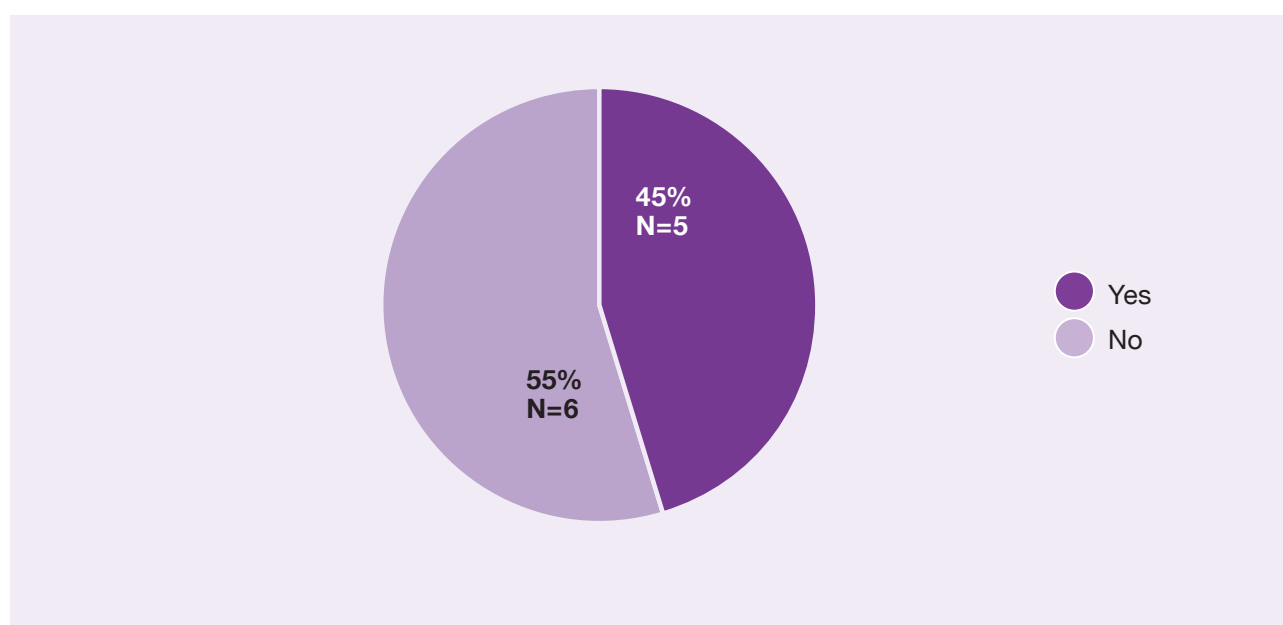


Is there any legal protection for the breast screening programme in relation to cancers arising post screening?

As shown in figure 9, five countries/regions have legal protection in place for invasive interval cancers arising in the screened population by means of the following:

- *Operating standard states that all interval cancers be reported to the state government's insurer*
- *Proceedings of the blind review of interval cancers remain confidential under an Evidence Act, which is designed to facilitate open quality initiatives*
- *In the context of screening, the re-review procedure was introduced in 2018. Documents for interval cancers are scarce*
- *Insurance for the health unit and the single specialist*

Figure 9. Is there any legal protection for the breast screening programme in relation to cancers arising post screening?



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

Only one country/region has financial compensation for invasive interval cancers, whereby financial compensation depends on the decision of the insurance company and it may or may not include a re-review organised by the expert centre for screening. All other countries do not have financial compensation for invasive interval cancers.

Do you capture invasive interval cancer rates for an internal report?

All eleven countries/regions capture invasive interval cancer rates for internal reporting, for example one country/region reports their rates to their national quality management committee.

Do you publish your invasive interval cancer rates?

Five of the countries/regions publish their invasive interval cancer rates in their annual report. Three countries/regions also publish their invasive interval cancer rates in peer reviewed publications and one country/region publishes their rates on their website.

	Country/Region										
	1	2	3	4	5	6	7	8	9	10	11
Audit of invasive breast cancers in the screened population	*	*	*	*	*	*	*	*	*	*	*
Routine programme-wide review, with calculation of IC detection rates	*	*		*	*	*	*	*	*	*	*
Routine individual patient cancer review	*			*	*	*		*			
Only on patient/treating physician request											
Routine sample of screened population											
Radiology review of invasive interval cancers	*	*	*	*	*	*	*	*	*	*	
Control images used	*		*		*				*		
Radiology reviewers are blinded to cancer status of woman	*				*			*			
Audit procedure is different for cases requested for review by an individual patient	*		*				*	*	*		
Patients are informed that a breast cancer audit is taking place		*								*	
Women have a choice to be part of the audit					*					*	
Capture consent from women to take part in a clinical audit	*				*		*	*			*
At screening event	*				*		*	*			*
Routine consent procedure covers the audit process	*			*	*	*	*	*	*	*	*
Results of the clinical audit are communicated to the affected women	*										
Women are asked if they want to know the outcome of the audit	*	*								*	
Have an open disclosure policy for medical incidents	*			*	*					*	
Mandatory policy	*			*	*					*	
Open disclosure extends to the results of audit of invasive interval cancers in screening programme	*			*						*	
Legal protection for invasive interval cancers				*	*	*		*	*		
Financial compensation for invasive interval cancers								*			
Capture invasive interval cancer rates for an internal report	*	*	*	*	*	*	*	*	*	*	*
Publish invasive interval cancer rates			*	*	*		*	*			
Annual report			*	*	*		*	*			
Peer-review publication			*				*	*			
Publish On website							*				

Additional questions July/Aug 2019

	Country/Region					
	1	5	6	8	9	10
Do you seek consent to do a review/audit of invasive interval cancers?	Implied	Implied	No	Implied	No	Do not consent to review invasive interval cancers
Do you routinely disclose the results of invasive interval cancer audits or do you only disclose on patient request?	No, only disclose on request	No disclosure required, audit protected by law	No routine disclosure, no requests from patients to date	No, only disclose on request	No, only disclose on request	routinely disclose false negative results only
Do you have documented standardised method for invasive interval cancer classification?	3 categories	This is currently under review - see attached doc. use 0-3/3 score of how many blind reviewers identified the cancer	7 categories*	No	5 categories are per EU guidelines 4th edition	Not answered
Do you routinely disclose the classification to women who have developed an invasive interval cancer?	On request for Cats 1 & 2, DOC for Cat 3	No	No	No	No, only disclose on request	Do not routinely disclose the classification
Do you seek consent for disclosure?	No	No	No	No	No	do not seek consent for disclosure
When was the policy introduced?	2006	n/a	n/a	n/a	n/a	Not answered
Was there or do you plan to do any retrospective review of historical invasive interval cancers that occurred prior to the introduction of the policy?	no answer	n/a	n/a	n/a	n/a	not planning a retrospective review

* unknown, (no diagnostic mmg to compare), occult, new, minimal sign-unsignificant, minimal sign significant, overlooked and misinterpreted

Appendix 8

Processes for the assessment of the interval cancer rates within BreastCheck

BreastCheck requires that all eligible women aged 50 to 69 years are invited for routine breast screening appointments at intervals of 24 months. In practice, women may be invited just before the age of 50 and they may be re-invited for a subsequent screen at either less or more than 24 months following their last screen. To ensure comparability between all screening services, BreastCheck have outlined guidelines for calculating the interval cancer rate. The interval cancer rate is expressed as a rate per 10,000 women screened. The population included in the numerator and denominator for calculating the rate are outlined below.

Numerator: The number of women who have been screened and subsequently presented with an invasive interval cancer within 24 months of a negative screen (no abnormality detected).

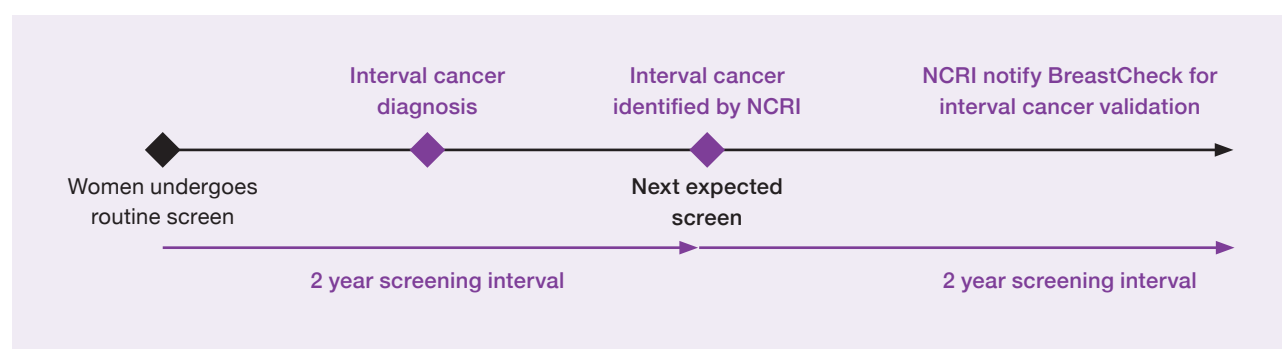
Denominator: The total number of eligible women screened with a negative screening outcome (no abnormality detected) within the same time period.

Women will have their final routine screening appointment between the ages of 68 and 70 years. Any invasive breast cancers diagnosed within the 24 months following their screening episode are defined as an interval cancer and should be counted in the rates of interval cancers. For example, if a woman is screened routinely at age 70 and is not diagnosed with cancer, her diagnosis will be counted as an interval cancer up to the age of 72, even though the programme would not invite her back for routine screening at this age.

Prior to any participation in BreastCheck, each woman signs a consent form (Appendix 2), permitting their BreastCheck screening information to be exchanged with other agencies including the NCRI, hospitals and symptomatic breast units. This allows BreastCheck to carry out a retrospective systems review through a periodic data exchange with NCRI to identify interval cancers.

The NCRI collects data on all cancers diagnosed in Ireland. This information is collated from pathology laboratories in hospitals across the country. It can take between 2-4 years following a breast cancer diagnosis, for the NCRI to identify interval cancers for validation by BreastCheck. This process takes this amount of time as a timeline equivalent to the routine screening interval (24 months) must occur after the negative screen (Figure 1).

Figure 1. Schematic showing an overview of the timeline for validation of an interval cancer diagnosed following a negative routine screening mammogram.



Upon identification of interval cancers by NCRI, the Programme Evaluation Unit along with the four static BreastCheck units subsequently confirm that the interval cancer was an invasive breast carcinoma and that the diagnosis was made within 2 years of a normal screening mammogram i.e. the data is validated (Figure 1).

The target interval cancers rates for BreastCheck as outlined by the BreastCheck '*Guidelines for Quality Assurance in Mammography Screening*', 4th Edition⁽³⁾ are shown below (Table 2.). These rates equate to <20 interval cancers per 10,000 women screened in the two year interval following screening.

Table 2. Overview of minimal and achievable interval cancer rates within BreastCheck.

Interval cancer rate per 10,000 women screened in the two years following a normal screening episode:	Minimum	Achievable
Year 1	<7.5/10,000	≤5/10,000
Year 2	<12.5/10,000	≤7.5/10,000

The identification process for determining and validating the interval cancer rate, is a complex process but fundamental to the monitoring of performance. The NCRI provides information to the National Screening Service Programme Evaluation Unit and the four BreastCheck units, as close to the date of diagnosis as possible, however there is a time-lag in the exchange of information. It can take up to 2-4 years after diagnosis for the NCRI to identify an interval breast cancer and provide the information to BreastCheck to validate. A period of 2 years must elapse following a normal screening result of an individual woman before an interval cancer can occur, be documented and before data can be provided to BreastCheck to ensure complete ascertainment of the clinical data by NCRI. Using the information provided by the NCRI, BreastCheck confirms that the interval cancer was an invasive breast carcinoma and that the diagnosis was made within 2 years of a normal screening mammogram report, thus validating the cancer against the agreed interval cancer definition. Once this has been confirmed for all cases, it becomes possible for BreastCheck to calculate the interval cancer rate. This process is routine and labour intensive and can take many years to complete. Therefore, BreastCheck also monitors key performance indicators.

Appendix 9

BreastCheck interim requested individual interval cancer review guidelines

Requested Individual Interval Cancer Review Guidelines



An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Written /Revised By (Title)	Name	Signature	Date
Prof Fidelma Flanagan			
Validated By (Title)	Name	Signature	Date
Prof Fidelma Flanagan Clinical Director Eccles			
Prof Ann O'Doherty Clinical Director Merrion			
Approved By (Title)	Name	Signature	Date
Prof Fidelma Flanagan Clinical Director Eccles			
Prof Ann O'Doherty Clinical Director Merrion			
Dr Aideen Larke Clinical Director Galway			
Dr Alissa Connors Clinical Director Cork			
Damien McCallion Interim National Director, NSS			
Celine Fitzgerald Interim CEO, NSS			

Document Revision History

Rev	Change Details	Revised By	Date Effective
1	Initial Release	N/A	
2			
3			
4			

1. Purpose & Scope (including Quality Standards)

Guidelines to follow when reviewing interval cancer cases

2. Responsibility

Responsibility for Implementation of document: Clinical Directors

Responsibility for Upkeep of document: Clinical Directors

3. References;

4. Method

- A. Introduction and background information**

- B. Guidelines when undertaking requested local unit review of interval cancers**

- C. Guidelines on communicating results of individual Interval Cancers review**

A. Introduction and background information

Women who receive a diagnosis of breast cancer have a number of questions about their prognosis and treatment options. If the cancer develops soon after they have had a negative screening mammogram, they may have additional questions about how the cancer was not detected by BreastCheck. This SOP contains some important information about screening results and breast cancer which may help with an Interval Cancer Review.

What is the purpose of Breast Cancer Screening (BreastCheck)?

Breast cancer screening is a public health tool designed to reduce population mortality from breast cancer. It is one of many health care initiatives introduced in this county to improve breast cancer survival. We can already see after almost 20 years of screening in this country that it has contributed to the reduction in breast cancer mortality. Screening has, along with better treatment options and increased public awareness contributed to a steady improvement in breast cancer survival from an average of 70% for 1994 - 1999 to 85% 2010 - 2015. This represents on average an approximate halving of the five year mortality risk for that time.

How can I be assured that BreastCheck is quality approved?

BreastCheck has screened over 1.7 million women and has detected 11,500 cases of breast cancer. Approximately 70,000 women have been called back to assessment. Every step along the screening pathway is monitored and compared to international standards i.e. the rate of cancer detection in the initial round is expected to be over 7 per thousand. This target is usually 8 or 9 per thousand year-on-years in BreastCheck. The percentage of tumours less than 15 mm is expected to be 20%, this is over this target for the programme year on year. Strict quality criteria are in place to define targets that must be met by the programme if it is to achieve its goals. These targets have been met by the programme which was recently awarded the highest level of accreditation (Reference Centre) by a European review group (EUREF). This is an acknowledgement of the high quality of the service provided.

What is the difference between a Screening and Diagnostic Mammogram?

A diagnostic mammogram is part of a group of tests and interventions such as ultrasound, clinical examination and biopsy used to exclude cancer in the individual patient setting where the patient has a symptom such as a lump. This is known as Triple Assessment. Diagnostic mammograms are therefore part of the Symptomatic Breast Service. This entire process can take 30 to 45 minutes and the chances of not picking up a significant finding or not diagnosing a cancer is minimal (less than 1-2 per 100).

Women invited for screening do not have a symptom. A screening mammogram is a Population Breast Screening Service aimed at reducing the population mortality from breast cancer in the country. Approximately 60 mammograms are read by a radiologist in an hour in screening. This is an expected rate. While many breast cancers are detected in this way the most of which are not clinically detectable or palpable, the chances of not detecting a cancer in this setting is higher than after triple assessment in the symptomatic service as described above.

What is an Interval Cancer?

Interval cancers are cancers which develop or are found in the two year period after a normal screening mammogram report. In general the Irish screening programme BreastCheck, will detect 7 breast cancers for every 1,000 women who have a screening mammogram. However, approximately 2 women from this same cohort will develop an interval cancer prior to their next screening appointment.

In the vast majority of interval cancers, even in retrospect, no sign of cancer will be seen on the prior negative screening mammogram. This group is composed of true negatives, occult cancers and cases with subtle signs:

- a) The tumour developed after the screening mammogram was performed (true negative).
- b) The tumour remains undetectable by mammography (occult).
- c) Subtle changes were present but were not suspicious for cancer or distinguishable from benign breast tissue changes.

In a minority of interval cancers, a suspicious abnormality will be seen in retrospect on the prior screening mammogram. These interval cancers are known as false negatives. There are many reasons for this, including the limitations associated with mammography as a breast screening test.

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

Interval Cancer Review

When doctors are asked to review the previous screening mammogram in women who have subsequently developed an interval cancer, they find that 70-80% show no features of cancer. In approximately 10-15%, there may be subtle changes that are very difficult or indeed impossible to distinguish from background breast changes and are only identifiable in retrospect by comparing the previous mammogram with the clinical or mammographic features at the time of the interval cancer diagnosis. When a person doing the review knows that the woman has in fact developed cancer, that knowledge can influence the retrospective review and categorization of the screening or original mammogram. This can sometimes convert a subtle change to be seen as a clear change, or result in a mammogram where normally nothing would have been seen but will now be reclassified as a subtle change. The remaining 10-15% shows a finding that could or should have allowed for an earlier diagnosis to be made. This last group of interval cancers are known as false negatives.

On average, out of every **1,000** women screened for breast cancer



7 will be
diagnosed
with cancer

993 will receive a normal result.

For around **2** of these women,
they will ultimately have a cancer
that is not detected.

What is the rate of Interval Cancers?

The overall interval cancer rate is approximately 2/1000 women screened, implying that approximately 2/10,000 women screened are “false negatives. This is an expected and anticipated part of all breast cancer screening programmes and although it is a very low rate, all efforts are made by the programme to keep this rate as low as is possible. BreastCheck’s Interval Cancer Rate (ICR) is within the Internationally recognised ICR for a population-based breast screening program. This figure is published and is benchmarked against international standards.

How is a review carried out?

All BreastCheck screening mammograms are “double-read”, meaning that two radiologists see the mammogram and contribute to the result which is communicated to the woman and her General Practitioner. When a review of the previous mammogram is requested by a woman with an interval cancer, this original screening mammogram is examined by two different radiologists from those who initially reported it. Such reviews are not perfect as there is inevitably some subjectivity and hindsight bias. The boundary between normality and abnormality is not firmly drawn and this may result in debate between experts as to the appropriate classification or interpretation of the image.

B. Guidelines when undertaking local unit review of interval cancers on request

When requested to review previous screening mammograms on a patient who has developed an Interval Cancer, the following guidelines have been agreed by the Clinical Directors:

- Once consent for a radiological review has been obtained and is available, a review will be performed by the screening programme (usually within the unit that performed the most recent screening mammogram).
- Upon notification, BreastCheck will create an interval episode for each interval cancer case.
- A minimum of two consultant radiologists should review the screening mammogram.
- The prior negative screening mammogram will be reviewed by two radiologists not involved in the primary reading. The diagnostic or symptomatic mammogram is not available at this time (in-complete blinded review).
- If the prior screening mammogram is deemed normal upon review, the patient is informed.
- Women who have consented and have requested the results of an interval cancer review should receive them in a timely fashion.
- If the last screening mammogram requires further clarification or is indeterminate then all imaging and pathology data relating to the interval cancer is obtained.
- The previous screening mammograms, with all prior images that were available at the time of screening, should be reviewed by the readers independently - this should be done without sight of the mammograms taken at diagnosis (in-complete blinded review)
- The presence of any abnormal mammographic sign or feature on the previous negative screening image should be recorded and the radiological level of suspicion for malignancy reported.
- The diagnostic images should then be reviewed to confirm that any subtle or suspicious signs detected on the previous screening images match the site of the confirmed breast cancer on the diagnostic images.

- There should be very few images that fall into the false negative category. These are images where the appearance is obviously malignant and all readers reviewing the images agree that they would recall.
- If the diagnostic symptomatic images are unavailable for review, these are regarded as unclassifiable and should be reported as such.
- If the screening mammogram is deemed 'satisfactory with subtle signs' they should be informed that the last screening mammogram was a satisfactory read in the screening context.
- If the last screening mammogram is deemed a 'false negative, obviously malignant' then the woman is invited to a meeting with the Clinical Director and/or other members of the multidisciplinary team including counselling support for patients and their families.
- All details of the review are maintained in the BreastCheck folder. The results of the review are disclosed to the woman either by letter and or a visit to the unit.

Classification of interval cancer after review

At the end of the review process, interval cancers may then be classified into the following categories:

1. Satisfactory not seen or occult

- Normal or benign mammographic features.

2. Satisfactory with subtle signs

- Seen only with hindsight and difficult to perceive or distinguish from background breast tissue. Not obviously malignant. Not all readers would have recalled woman for assessment if presented with this screening mammogram.

3. False Negative

- Films in this category should have obvious lesions. If there is any disagreement or it is felt that this is only obvious with hindsight they should be placed in category 2 above. All readers reviewing the films agree that they would recall.

Interim Interval Cancer Review

Date of Contact:

Name:

ID Number:

Date of Screening:

Date of Cancer Diagnosis:

Classification of Screening Interval Cancers

	Category	
I.	Satisfactory not present or occult	
II.	Satisfactory with minimal sign	
III.	False Negative	

Date of Review:

Reviewed by:

Consultant Radiologist

Consultant Radiologist

Follow up Action:

Films sent

Unit Visit Requested

Letter sent

Signed

Clinical Director

D. Guidelines on communicating results of individual Interval Cancers review

Effective communication will ensure disclosure can be provided. For cases where a letter will be used to describe the findings of the review, contents of the letter should include the following:

- Information that screening mammography tests are not 100% accurate and that false positive and false negative result are a feature of all screening programmes.
- Information about the process of review of previous screening films.
- The offer of a visit to discuss the outcomes of the radiological review.
- The offer for the woman to bring her partner, family member or a friend if desired.
- Contact details of a breast care nurse specialist or other suitable individual to arrange the review (where requested).
- Details of the clinician who will meet with the woman on request (this could be the Clinical Director, or designated radiologist, with the offer to discuss it with her treating surgeon if preferred).
- The offer to send the results of the review in writing if preferred.
- Information to specify that the woman may not want to know the outcome of the review at this time but can change her mind at any point by contacting their GP or hospital Consultant to arrange this.

Women who request a consultation to discuss the outcomes of the radiology review should be seen in a timely way.

To aid effective communication:

- The meeting between the interval cancer patient, Clinical Director and other members of the multidisciplinary team should take place in confidential, comfortable surroundings with no interruptions.
- The patient should be encouraged to bring a friend or family member with her.
- It must be remembered that most interval cancers are not seen on previous imaging following review. However, clinicians should include as much information as possible to provide context.
- The patient should be invited to express her concerns and raise any questions she may have.
- The effectiveness and limitations of the screening programme should be described.
- There should be an open discussion about whether the cancer could have been found earlier.
- Clinicians are encouraged to include apologies where appropriate.
- After the meeting the mammogram reviewers should have a memo to reflect the main points of the meeting.

Quality Control & Audit

Quality control measures to be referred to the Clinical Director

Appendix 9b

BreastCheck interim individual interval cancer post assessment review guidelines

BreastCheck Interval cancers following assessment



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Document Revision History

Rev	Change Details	Revised By	Date Effective
1	Initial Release	N/A	21/11/2019
2			
3			
4			

Purpose & Scope (including Quality Standards)

Guidelines to follow when reviewing interval cancer cases following assessment.

Responsibility

Responsibility for Implementation of document: Clinical Directors

Responsibility for Upkeep of document: Clinical Directors

References;

QP-061 Requested Individual Interval Cancer Review Guidelines

NHS Breast Screening Programme Reporting, classification and monitoring of interval cancers and cancers following previous assessment

Method

Requested Individual Interval Cancer Review Guidelines following Assessment

A small percentage of women screened are recalled for further assessment to one of the 4 Screening Units. This assessment usually occurs within 3 weeks of the screening mammogram result and can include additional imaging, ultrasound and biopsy.

Interval cancers following assessment are breast cancers diagnosed in the symptomatic service within 2 years of a screening assessment i.e. women who have been previously assessed by the screening programme and who were returned to routine screening.

The interval cancer rate used to report on the interval cancer KPI standard for the programme incorporates interval cancers occurring after assessment. In addition a number of others elements of the assessment process are monitored and recorded as part of ongoing quality assurance and improvement i.e., biopsy rate, cancer detection rate, time to assessment. All assessment work-ups are reviewed by a minimum of 2 breast screening radiologists at the time of assessment. All women who have a biopsy performed at assessment are discussed at the weekly MDM and are seen by the breast surgeon and breast care nurse. Interval cancers occurring following a negative assessment are extremely rare. A false negative assessment represents a missed opportunity to detect breast cancer and all measures are taken to keep false negative assessments to an absolute minimum.

However well assessment is conducted in a screening programme, cancers will occasionally occur at the same site as that previously assessed, either presenting as interval cancers or screen detected at the next screening appointment.

Women who develop an Interval cancer and have undergone assessment following their last screening mammogram can have their assessment and screening mammograms reviewed following consent.

Prior interval cancer assessments can be grouped into:

- Interval cancers occurring in the opposite breast to the side on which assessment took place.
Assessment cancers occurring in the opposite breast to the side on which assessment took place should be reviewed according to the standard interval cancer review SOP (QP-061 Requested Individual Interval Cancer Review Guidelines)

- Interval cancers on the same side (ipsilateral) as the assessment
 - but at a different site to the site on which assessment took place
 - or at the same side and site as previously assessed.

As these are known cancer cases, reviewers should be aware that hindsight can bias the review and this should be acknowledged when reviewing assessment cancers. When the previous assessment was at the same site as the subsequent cancer diagnosis, it does not necessarily mean that the previous assessment was flawed. It is recognised that in the majority of such cases adequate assessment has been undertaken.

When undertaking unit review of same side assessment cancers

- When requested to review previous screening mammograms/assessment on a patient who has developed an Interval Cancer after assessment, the following guidelines have been agreed by the Clinical Directors.
- Upon notification, BreastCheck will create an interval episode for each interval cancer case.
- Once consent for a radiological review has been obtained and is available, a review will be performed by the screening programme
- This review will be performed in a screening unit that did not assess the patient.
- the review of the previous assessment episode and current diagnostic images should be undertaken by two radiologists
- the review should be undertaken on the most recent assessment episode
- the individual involved with the previous assessment should not undertake the review, but should be made aware of the outcome
- the following information should be available: –
- original screening images, all documentation from assessment, all additional views and/or ultrasound images from assessment, documentation of multidisciplinary team opinion, symptomatic images and/or ultrasound – pathology reports
- If the cancer has been diagnosed at the same site, then the case should be carefully reviewed to document whether each aspect of the assessment was carried out according to expected processes and met national guidance on breast cancer screening assessment or not.
- If there is any aspect of assessment that is felt to be imperfect, the reviewer(s) need to consider whether this is a slight difference to what they would have done/expected. In this circumstance it should be classified as ‘satisfactory with learning’.
- If all reviewers agree that there was a failure either to follow guidance, or in the interpretation or investigations or multidisciplinary team decision-making, this should be classified as ‘false negative assessment’.
- If there is insufficient information to be sure about an aspect of a previous assessment this should be accurately recorded as ‘don’t know’ or ‘uncertain’. The reason why this is unclear may be important also, for example is there is poor or inadequate documentation of what has been done/not done at assessment. Even if the information available is incomplete a decision should be made to the best of the reviewers’ ability as to whether the assessment was satisfactory or not.

- An outcome of the review for same side, same site reviews should be documented. This should be either: 1 - satisfactory assessment 2 - satisfactory with learning or 3 - False negative assessment.
- Women who have consented and have requested the results of an interval cancer review should receive them in a timely fashion.
- There should be very few assessments that fall into the false negative category. These are assessment work ups that clearly fall below acceptable standards and all reviewers agree.
- If the assessment is deemed a 'false negative assessment' then the woman is invited to a meeting with the Clinical Director and/or other members of the multidisciplinary team including counselling support for patients and their families.
- All details of the review are maintained in the BreastCheck folder. The results of the review are disclosed to the woman either by letter and or a visit to the unit.

Classification of interval cancer after assessment

At the end of the review process, interval cancers may then be classified into the following categories:

- **Satisfactory**
- **Satisfactory with learning**
- **False negative assessment**

Interim Interval Cancer Review following assessment

Date of Contact:

Name:

ID Number:

Date of Screening:

Date of Cancer Diagnosis:

Classification of Interval Cancers following assessment

	Category	
I.	Satisfactory assessment	
II.	Satisfactory with learning	
III.	False Negative assessment	

Date of Review:

Reviewed by:

Consultant Radiologist

Consultant Radiologist

Follow up Action:

Films sent

Unit Visit Requested

Letter sent

Signed

Clinical Director

Guidelines on communicating results of individual Interval Cancers after assessment review

Effective communication will ensure disclosure can be provided. For cases where a letter will be used to describe the findings of the review, contents of the letter should include the following:

- Information that screening mammography tests are not 100% accurate and that false positive and false negative result is a feature of all screening programmes.
- Information about the process of review of previous screening films and assessment.
- The offer of a visit to discuss the outcomes of the radiological review.
- The offer for the woman to bring her partner, family member or a friend if desired.
- Contact details of a breast care nurse specialist or other suitable individual to arrange the review (where requested).
- Details of the clinician who will meet with the woman on request (this could be the Clinical Director, or designated radiologist, with the offer to discuss it with her treating surgeon if preferred).
- The offer to send the results of the review in writing if preferred.
- Information to specify that the woman may not want to know the outcome of the review at this time but can change her mind at any point by contacting their GP or hospital Consultant to arrange this.

Women who request a consultation to discuss the outcomes of the radiology review should be seen in a timely way.

To aid effective communication:

- The meeting between the interval cancer patient, Clinical Director and other members of the multidisciplinary team should take place in confidential, comfortable surroundings with no interruptions.
- The patient should be encouraged to bring a friend or family member with her.
- It must be remembered that most interval cancers are not seen on previous imaging following review. However, clinicians should include as much information as possible to provide context.
- The patient should be invited to express her concerns and raise any questions she may have.
- The effectiveness and limitations of the screening programme should be described.
- There should be an open discussion about whether the cancer could have been found earlier.
- Clinicians are encouraged to include apologies where appropriate.
- After the meeting the mammogram reviewers should have a memo to reflect the main points of the meeting.

Quality Control & Audit

Quality control measures to be referred to the Clinical Director

Appendix 10

Audit of Interval Cancers in NHSBSP (NHS Breast Screening Programme) process outlined by UK breast screening expert to the BreastCheck Expert Reference Group

- 1) Interval Cancer Rates: Interval cancer rates are used as a quality indicator of the breast screening programme. The rates have been within international published norms.
- 2) Initially the NHSBSP reviewed, but did not classify, interval cancers (IC). The classification of IC was developed in the early 2000's as part of the work on disclosure of audit (see 3 below) and was included in QA guidance for radiologists. The method of classification was standardised using blinded assessment by 1-2 radiologists. Notwithstanding the guidelines, there was known variability within the different units with respect to the percentage of interval cancers classified in each category. This is an inevitable result of the variation in interpretation between individual radiologists reviewing screening mammograms.
- 3) Documentation related to the audit of each IC is filed with the patient's screening records. The documentation includes individual patient identification details. Interval cancer classification and data is also included on the electronic screening system in the patient's data, National Breast Screening Service.
- 4) 'Disclosure of Audit Results in Cancer Screening' was published in 2006. Guidelines proposed that breast cancer patients be made aware that the results of IC audits were available on request. The principle was to make patients aware, at a suitable time in their treatment, that previous screening mammograms could be reviewed and that they could have the result if they wanted it. The de facto implementation of the guidelines was the disclosure of individual IC audits to patients and clinicians on request. No proactive disclosure of audit results was performed unless requested. The degree to which this was implemented is not known, however all patient and clinician requests for the results of IC audits were accommodated.
- 5) 'Duty of Candour' legislation was enacted in England in November 2014. Guidance for implementation of this legislation within NHSBSSP was undertaken subsequently from 2016 -2018. This included the development of a more robust uniform system of IC classification (2017), in particular the classification of a definitive false negative cancer. These false negative cancers are notifiable safety incidents ('something has gone wrong') and are subject to 'duty of candour'. The percentage of IC which are false negative under the new classification system has not been published to date, but is anecdotally approximately 1-3%. This compares to a mean figure of 7% in the previous IC classification system used under 'Disclosure of Audit'.
- 6) Public Health England, with guidance from the Care Quality Commission (CQC) advised on 'Retrospective application of Duty of candour regulation for interval cancers' in June 2017. PHE advised 'that duty of candour regulations will only apply to interval cancers diagnosed after 27 November 2014'.



An tSeirbhís Náisiúnta Scagthástála
National Screening Service


BreastCheck
An Clár Náisiúnta Scagthástála Gíoch
The National Breast Screening Programme