Health
Information
and Quality
Authority

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Information
and Standards

Review of information management practices at BreastCheck

March 2018

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services –** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation –** Registering and inspecting designated centres.
- **Monitoring Children's Services –** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality –** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment –** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information –** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of the health information function of HIQA

Health is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore very important that information is managed in the most effective way possible in order to ensure a high-quality safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has an important role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving its quality and filling in gaps where information is needed but is not currently available.(1)

Information and communications technology (ICT) has a critical role to play in ensuring that information to promote quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in health and social care services in Ireland is highly fragmented with major gaps and silos of information. This results in individuals being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is over-reliance on memory. Equally those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders — patients and service users, health professionals, policy makers and the general public — to make choices or decisions based on the best available information. This is a fundamental requirement for a highly reliable healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services.

HIQA has a broad statutory remit, including both regulatory functions and functions aimed at planning and supporting sustainable improvements. In 2017, HIQA published standards in the area of health information — *Information Management Standards for National Health and Social Care Data Collections* (2) — as per HIQA's remit under the Health Act 2007.(1) The standards provide a framework of best practice in the collection of health and social care data. HIQA has developed a structured review programme to assess compliance with the standards.(3) The aim of this review programme is to improve the information management practices of national health and social care data collections in Ireland by assessing compliance with the standards in each national data collection. Ultimately, the review programme will drive improvements by identifying areas of good practice and areas where improvements are necessary across the range of national data collections.

Table of Contents

Executive summary

The aim of this review is to assess the compliance of BreastCheck with the *Information management standards for national health and social care data.*(2) This review is part of an overall review programme being undertaken by HIQA to assess compliance with the Information Management Standards in all major national health and social care data collections within the HSE in Ireland*.* A considerable amount of data is collected on a regular basis about health and social care services in Ireland. This data is used for many important purposes, such as to guide clinical decision-making, monitor diseases, organise services, inform policy making, conduct high-quality research and plan for future health and social care needs, both at national and local levels. Ultimately, the review programme aims to drive quality improvements by identifying areas of good practice and areas where improvements are necessary across national data collections.

BreastCheck was established with the remit of providing a population-based breast screening programme for women aged 50 to 64. The service is currently being extended to women aged 50 to 69, and, by the end of 2021, all women within this age group will be invited for routine screening. BreastCheck currently provides screening through a network of four static units and 19 mobile units throughout the country. It has a workforce of almost 200 whole-time equivalent staff members, of which 70% are clinical staff. The implementation of a population-based cancer screening programme is recommended by the World Health Organization and the European Union, provided the service is comprehensive and of high-quality.(4) A comprehensive and high-quality service can only be assured if the organisation manages its information appropriately.(5)

BreastCheck is an extremely valuable national health data collection. In the context of screening, information management is crucial as a comprehensive screening service can only be delivered if the programme has a complete and accurate population register.[*] This means that all eligible individuals need to be identified, and accurate demographic information acquired, to provide a personal invitation for screening to each individual. A complete and accurate register means that individuals can have confidence that they will be invited for screening once they meet the eligibility criteria.(5) Furthermore, to provide a high-quality and safe screening service, it is necessary for clinical information to be handled and processed efficiently. The process of screening generates large volumes of personal health information and relies heavily on accurate documentation and communication of information about health status, processes of care and outcomes of care. Service users want to be assured that their information will be managed correctly so that they will receive timely, efficient and effective care if a cancer is detected.(5)

In addition, a high-quality screening service can only be assured if the organisation has the appropriate information to plan and manage services. Good information management practices are necessary to provide assurances that the organisation is achieving its objectives through careful strategic and business planning, and monitoring performance against these targets. Performance monitoring involves a number of dynamic processes such as identifying and reviewing key performance indicators, undertaking regular audits to review practice, and

---

[*] A population register is a comprehensive list of all individuals that meet the criteria for screening.

managing risk. The key to achieving a high level of performance is having timely, accurate and reliable data to identify any issues and to use this information as a mechanism to continuously drive improvements. For example, one aspect of monitoring performance for screening involves setting targets in line with international best practice and regularly benchmarking performance data at both the level of the clinician and screening unit to ensure high-quality care is consistently delivered.(6) It also involves setting and reviewing targets in respect of the accuracy and completeness of the population register, and the quality of the clinical data.

The general benefits of good information management practices for the screening service is to instil confidence in service users, clinicians and all other stakeholders that decisions are based on high-quality information, the availability of which will ultimately improve the outcomes of screening.(2) It is widely recognised that effective information management improves services through enhanced knowledge and understanding for all involved in providing and using the service. Furthermore, good information management helps: to assure the public that information will be held securely; to safeguard an individual's privacy and confidentiality; to facilitate greater empowerment and involvement by communicating effectively with the public; and to create a culture in which information will be used more effectively.(7)

The findings of this review of information management practices in BreastCheck will focus on three key areas: governance, leadership and management; use of information; and information governance. A summary of findings will be detailed in turn below before outlining the summary of recommendations.

Governance, leadership and management

To achieve good information management practices, organisations need to implement a range of robust measures, including formalising governance structures and clearly outlining responsibilities throughout the organisation in respect of information management; developing an information management strategy; preparing detailed business plans to outline how the organisation will successfully achieve this strategy; developing a system to effectively assess the delivery of the business plans by monitoring information-related performance indicators; undertaking necessary audits to provide assurance of good practice; and identifying and controlling information-related risks by implementing an integrated risk management policy.

The governance structures in BreastCheck are not clearly defined in respect of information management. At the time of the review, the Head of Screening had established a new Clinical Leadership Board to be the senior decision-making body of the National Screening Service. In light of the changing governance structures, it is important to streamline existing structures in order to provide clarity of function for all teams in respect of information management. Formalised governance arrangements are also necessary to ensure that there are clear lines of accountability and reporting throughout the organisation, so that each staff member is aware of their particular responsibilities in this area. In particular, it is important that there is executive-level responsibility and accountability for information management and a scheme of delegation to assign responsibility for information management across the service. Specifically, responsibilities should be assigned for information and communications technology (ICT), information governance, data quality and the use of information both internally and externally.

Furthermore, a clear strategy for information management is essential to outline a vision and direction that is accompanied by detailed yearly business plans to explain how the organisation is going to achieve its objectives. A robust performance assessment framework is also necessary to provide assurances to senior management that BreastCheck is achieving its objectives in respect of information management, which should be aligned to strategic and business plans. Furthermore, organisations need to maintain regularly updated data sharing agreements with all external organisations with which they share data, and establish appropriate monitoring and auditing procedures for these agreements. In addition, a statement of purpose should be published to promote transparency by informing the public about the purpose and objectives of the national data collection.

Use of information

Data can be considered to be of good quality when the correct data is available to decision makers in a timely manner and they can confidently rely on it. In reviewing the theme of 'Use of information', HIQA acknowledges that BreastCheck is undertaking a significant amount of work to improve the quality of the data collected within the screening units. An overarching data quality framework would enhance this work further.

International best practice recognises the importance of harnessing the true potential and value of sharing information effectively while ensuring that the appropriate safeguards are in place to protect privacy. BreastCheck should include a section within an information management strategy on the accessibility and dissemination of data, to make data and information more accessible to all stakeholders, in line with relevant legislation and government policy. Furthermore, in light of the implementation of the Knowledge and Information Plan(8) in the HSE and the eHealth Strategy(9) in the wider health service, it is important that all national data collections continuously review how health information standards and terminologies are adopted. In addition, organisations should publish a data dictionary in order to promote data quality and enhance the sharing and use of information.

Information governance

Reliable and well-structured information governance practices cover the four following areas: maintenance of privacy and confidentiality of individuals, appropriate arrangements to ensure information security, collection of high-quality data and appropriate safeguards for the secondary use of information.

While HIQA found that there is an awareness of the significance of information governance within BreastCheck and that there are identified individuals for aspects of information governance, there is a need to formalise arrangements for information governance. An individual should be appointed with delegated executive responsibility for information governance within the organisation, and enhanced arrangements should detail specific roles and responsibilities in relation to data quality, privacy and confidentiality, information security and the use of information throughout the service. Organisations should also strengthen assurance arrangements for reviewing adherence to information governance policies and procedures and current and forthcoming legislation including the General Data Protection Regulation (GDPR). Explicit reporting arrangements to senior management through the routine use of key performance indicators, the development and review of a comprehensive audit schedule, and the implementation of effective risk management arrangements are necessary to effectively manage information governance.

Finally, organisations operate most effectively when the right people with the right knowledge, skills and competencies are deployed appropriately to deliver quality data. In line with this, a workforce planning exercise should be conducted in relation to information management to ensure that the appropriate skilled workforce is in place. A comprehensive and dynamic training plan in this area is also essential to promote a culture of effective information governance.

The 11 recommendations outlined in this report should be considered in conjunction with the findings of this review in order to improve information management practices in BreastCheck. The National Screening Service is responsible for preparing and implementing quality improvement plans to ensure that the areas for improvement are prioritised and implemented to improve compliance with the Information Management Standards. National data collections should continue to assess their adherence to these standards in between reviews by HIQA to assure that they are meeting the requirements of the Information Management Standards.

Summary of recommendations

These recommendations have been developed by HIQA following the review of compliance with the *Information management standards for national health and social care data collections* in BreastCheck.(2) As BreastCheck is a unit within the National Screening Service, which has a single governance model for all four screening programmes, the recommendations are relevant to both the National Screening Service and BreastCheck.

Governance, leadership and management	
1.	**Governance structures in relation to information management**
	The National Screening Service should implement an appropriate governance structure in order to effectively address information management[†] within BreastCheck. Specifically, existing governance and management structures for information management need to be reviewed in light of the newly established Clinical Leadership Board. As part of this structure, executive responsibilities for information management should be clearly defined, documented and implemented.
2.	**Strategy for information management**
	The National Screening Service should develop a strategy for information management which clearly describes how effective information management will support and enhance screening; this should be based on international best practice and aligned to the Health Service Executive's eHealth Strategy. The strategy for information management should have clearly defined objectives and associated annual business planning.
3.	**Monitoring of performance in relation to information management**
	The National Screening Service should develop a performance assurance framework for information management which is embedded within the governance structures. This should include monitoring performance against the annual business plan, measurement and reporting of key performance indicators (KPIs), conducting internal and external audit against aspects of information management, and risk management. A culture of risk management needs to be embedded at all levels of the organisation, particularly in relation to information management.

[†] Information management is defined as the process of collecting, storing, managing, using and sharing health and social care information. It is a broad definition that includes the aspects of governance and management arrangements, data quality, information governance and use of information.

4.	**Compliance with legislation and privacy risk assessment**
	A formalised review of compliance against relevant legislation including the forthcoming General Data Protection Regulation (GDPR) should be undertaken. As part of this review, an assessment of privacy risks for BreastCheck should be conducted.
5.	**Formalised data sharing agreements**
	The National Screening Service should identify and develop formalised data sharing agreements as appropriate. These should be fully implemented and regularly monitored to ensure that information sharing is governed effectively.
6.	**Statement of purpose**
	BreastCheck should develop and maintain a publicly available statement of purpose that accurately describes its aims and objectives.
Use of information	
7.	**Data quality framework**
	To enhance ongoing work within BreastCheck in relation to data quality, an overarching data quality framework[‡] should be developed and implemented. The wider National Screening Service should be part of this process.
8.	**Health information standards and data dictionary**
	The use of health information standards and terminologies for BreastCheck should be assessed as part of the information management strategy of the National Screening Service. In addition, BreastCheck should develop and implement a data dictionary to ensure consistency and to enable accurate use and interpretation of data. This should be kept updated regularly and made publicly available.
9.	**Accessibility and dissemination of information**
	In line with legislation and government policy, BreastCheck should make data and information more accessible in a timely manner to all stakeholders, including patients, clinicians, policy makers and researchers, in order to address their needs. This should be developed incrementally and aligned to an information management strategy.

[‡] Guidance for a Data Quality Framework for health and social care is currently being developed by HIQA in conjunction with all major national data collections in Ireland and will be published in 2018.

Information governance

10. Effective arrangements in place for information governance

As part of an information management strategy and annual business plan for the National Screening Service, effective arrangements should be put in place for information governance within BreastCheck. This includes:

- assigning an individual with responsibility for information governance within the National Screening Service
- providing assurance in relation to adherence to policies and procedures, and current and forthcoming legislation for information governance through reporting of KPIs, audit and risk management
- developing and implementing a training plan for staff to embed a culture of information governance within BreastCheck.

Workforce

11. Skilled workforce in relation to information management

BreastCheck should conduct a workforce planning exercise in relation to information management to ensure that the appropriate skilled workforce is in place, to include the following areas:

- data quality
- information governance, including the impact of legislative changes
- data analytics and the use of information.

1. Overview of HIQA's review programme for national data collections

This review is part of an overall review programme being undertaken by HIQA to assess compliance with the *Information management standards for national health and social care data.*(2)

A considerable amount of data is collected on a regular basis about health and social care services in Ireland. This data is used for many important purposes such as to guide clinical decision-making, monitor diseases, organise services, inform policy making, conduct high-quality research and plan for future health and social care needs, both at national and local levels.

All stakeholders (the general public, patients and service users, health professionals, researchers and policy makers) need access to high-quality information in order to make choices and decisions. It is vital that there is confidence in this information as the delivery of safe and effective healthcare depends on access to and use of information that is accurate, valid, reliable, timely, relevant, legible and complete.

Based on international best practice, four key overarching objectives relating to health information have been identified to maximise health gain for the individual and the population:

1. Health information is used to deliver and monitor safe and high-quality care for everyone.
2. Health information should be of the highest quality and, where appropriate, collected as close as possible to the point of care.
3. Health information should be collected once and used many times.
4. Data collection should be 'fit for purpose' and cost-effective.

National health and social care data collections are national repositories of routinely collected health and social care data, including administrative sources, censuses, surveys and national patient registries, in the Republic of Ireland.

Managing organisation is defined as the organisation, agency, managing unit, institution or group with overall responsibility for the national health and social care data collection.

National health and social care data collections provide a national overview of data relating to a particular health or social care service. Examples of national data collections include BreastCheck, the Hospital In-Patient Enquiry (HIPE) scheme, the Computerised Infectious Disease Reporting (CIDR) system and the Irish Hip Fracture Database (IHFD). There is little point in investing considerable time, effort and resources into producing a high-quality data collection if the data is not used to the maximum benefit of the population it serves. Therefore, it is essential to promote, encourage and facilitate the use of data.

HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information under the Health Act 2007.(1) A number of key documents have been published by HIQA in recent years in relation to national health and social care data collections (See Appendix 1).

Furthermore, the *National Standards for Safer Better Healthcare,(10)* published in 2012, describe a vision for quality and safety in healthcare which includes the use of accurate and timely information to promote effectiveness and drive improvements. One of the eight themes, 'Use of Information', emphasises the critical importance of actively using information as a resource for planning, delivering, monitoring, managing and improving care. These nationally mandated standards apply to all healthcare services (excluding mental health) provided or funded by the Health Service Executive (HSE).

In 2017, HIQA published specific standards in the area of information management — *Information management standards for national health and social care data collections.*(2) The purpose of these standards is to improve the quality of national health information. The standards provide a framework of best practice in the collection of health and social care data. The *Information management standards for national health and social care data collections,* therefore, complement the *National Standards for Safer Better Healthcare.(10)* Together, these standards provide a roadmap to improve the quality of health information and data, which should ultimately contribute to the delivery of safe and reliable healthcare.

HIQA has developed a structured review programme to assess compliance with the *Information management standards for national health and social care data collections.*(2) Prior to commencing the review programme, the *Guide to the Health Information and Quality Authority's review of information management practices in national health and social care data collections*(3) was published by HIQA.

For the remainder of the report:

Information Management Standards will be used for the *Information Management Standards for National Health and Social Care Data Collections*

Review Programme will be used for the review programme to assess compliance of national health and social care data collections against the Information Management Standards

1.1 Aims of the review programme

The aim of this review programme is to improve information management practices of national health and social care data collections in Ireland by assessing compliance with the Information Management Standards in individual national data collections. Ultimately, the review programme was developed to drive improvements by identifying areas of good practice and areas where improvements are necessary across national data collections.

1.2 Assessment and judgement framework

HIQA has adopted a standard Authority Monitoring Approach (AMA) to carry out its functions. HIQA staff involved in the review programme use this approach and any associated procedures and protocols. HIQA's monitoring approach does not replace professional judgement. Instead, it provides a framework for staff to use professional judgement and supports them in reviewing compliance against the standards. The use of AMA and an assessment and judgement framework ensures:

- a consistent and timely assessment of compliance with standards
- a responsive approach to performing reviews.

1.3 Phase 1 of the review programme

Due to the large number of national data collections, the review programme is being carried out using a phased approach. Phase 1 includes major national data collections within the Health Service Executive (HSE). Prioritisation criteria were developed to determine the schedule for reviews in the first phase of the review programme, which included the quality and safety impact, the policy impact and other operational factors which may impact on the review programme.

There are four main stages involved in the review process:

1. Self-assessment tool
2. Information request
3. On-site assessments
4. Reporting of findings.

1.4 Quality improvement plans

Managing organisations are responsible for preparing and implementing quality improvement plans to provide assurance that the findings relating to areas for improvement are prioritised and implemented to comply with the Information Management Standards.

National data collections should continue to assess their adherence to the standards in between reviews by HIQA, to provide assurance that they are meeting the requirements of the Information Management Standards.

Where opportunities for improvement have been identified by the review team during the review, checks will be carried out during future reviews to ensure that the necessary improvements have been implemented.

1.5 HIQA's legislative remit

HIQA has a specific remit in relation to health information as laid out in the Health Act 2007.(1) The review programme falls within this legislative remit. The relevant sections of the Act are as follows:

- **Section 8(1)(k)** — to set standards as the Authority considers appropriate for the Health Service Executive, the Child and Family Agency and service providers respecting data and information in their possession in relation to services and the health and welfare of the population
- **Section 8(1)(l)** — to advise the Minister, the Minister for Children and Youth Affairs, the Executive and the Agency as to the level of compliance by the Executive and service providers with the standards referred to in paragraph (k)
- **Section 12** — The Authority may require the Executive, the Agency or a service provider to provide it with any information or statistics the Authority needs in order to determine the level of compliance by the Executive, the Agency or by service providers with the standards set by the Authority in accordance with section 8.

1.6 Methodology to assess compliance – BreastCheck

This report is based on the assessment of compliance with the Information Management Standards in BreastCheck. The stages of the BreastCheck review are outlined below.

1.6.1 Stages of BreastCheck Review

Stage 1: Self-assessment tool

The self-assessment tool is a questionnaire which enables national health and social care data collections to determine the extent of their compliance with the Information Management Standards. The tool highlights areas where action is required and where improvements can be made. All of the national data collections in Phase 1 of the review programme were contacted in March 2017 and asked to complete the self-assessment tool. The designated contact person in each organisation was asked to complete and return the self-assessment tool within three weeks.

Based on the results of the self-assessment tool and the prioritisation criteria, HIQA performed a focused review of BreastCheck.

Stage 2: Information request – BreastCheck

Following a review of the self-assessment tool, a request for additional information was sent to BreastCheck and the relevant information was returned to HIQA within 10 working days. The information received was used to verify the findings of the self-assessment tool and to identify gaps in the evidence in order to provide clarity of focus for the on-site assessment.

Stage 3: On-site assessment – BreastCheck

Two on-site assessments were conducted in the head office of the National Screening Service in Dublin. The aim of the on-site assessment was to gather additional evidence to assess compliance with the Information Management Standards through further documentation reviews, observations and interviews with management and staff.

Stage 4: Report of findings – BreastCheck

The findings of the assessment of compliance with the Information Management Standards in BreastCheck are outlined in this report.

1.6.2 Factual accuracy

HIQA provided a copy of the confidential draft of the report of findings to the Head of Screening to complete a factual accuracy review in December 2017. Every comment received from BreastCheck was carefully considered by HIQA prior to the publication of this final report.

Developments or changes implemented by BreastCheck after the draft report was sent to the Head of Screening for the factual accuracy stage of the review are not included in this report. The implementation of these changes will be assessed in any follow-up review of information management practices in BreastCheck or the National Screening Service.

1.6.3 Scope of this review of information management practices in BreastCheck

The scope of this review is to examine the findings of compliance with the Information Management Standards in BreastCheck.

The review **does not** include an assessment of the clinical effectiveness of the screening service. This is outside the scope of Section (8)(1)(l) of the Health Act 2007.

2. Overview of BreastCheck screening

This chapter will provide background information on BreastCheck, including an overview of the National Screening Service, which is the managing organisation with responsibility for BreastCheck; an overview of the BreastCheck screening service; a description of the information system and data flows in BreastCheck; and the significance of information management practices for a screening service.

2.1 The National Screening Service

The managing organisation with responsibility for BreastCheck is the National Screening Service within the Health Service Executive (HSE).

The National Screening Service was established in January 2007 following the launch of *A Strategy for Cancer Control in Ireland* in 2006.(11) Screening was outlined as one of the key elements of the cancer control policy programme in Ireland, along with the appropriate prevention, detection, treatment and management of cancer.(12)

The role of the National Screening Service is to:

- carry out or arrange to carry out a national breast screening service for the early diagnosis and primary treatment of breast cancer in women
- carry out or arrange to carry out a national cervical cancer screening service for the early diagnosis and primary treatment of cervical cancer in women
- carry out or arrange to carry out a national colorectal screening service for the early diagnosis and primary treatment of bowel cancer in men and women
- carry out or arrange to carry out a national diabetic retinopathy screening service for the early diagnosis and primary treatment of diabetic retinopathy in men and women
- advise on the benefits of carrying out other cancer screening programmes where a population health benefit can be demonstrated
- advise the Minister, from time to time, on health technologies, including vaccines, relating to the prevention of cervical cancer
- implement special measures to promote participation in its Programmes by disadvantaged people.(12)

The National Screening Service currently includes four programmes:

- *BreastCheck*, the National Breast Screening Programme, established in 1998
- *CervicalCheck*, the National Cervical Screening Programme, established in 2008
- *BowelScreen*, the National Bowel Screening Programme, established in 2012
- *Diabetic RetinaScreen*, the National Diabetic Retina Screening Programme, established in 2013.(12)

The structures of the screening programmes have undergone significant changes since the first service, BreastCheck, was established in 1998 (see Figure 1). Breast screening was initially governed under the National Breast Screening Board. This Board was dissolved on 31 December 2006 after the launch of the Strategy for Cancer Control, and a new Board, known as the National Cancer Screening Service Board, was established on 01 January 2007. The next change occurred on 01 April 2010, when the existing Board was dissolved and governance of the National Cancer Screening Service was moved within the National Cancer Control Programme of the HSE. On 01 January 2014, the National Cancer Screening Service became the National Screening Service and responsibility for it moved to the Health and Wellbeing Directorate of the HSE. The four screening programmes operate under a single governance model within the National Screening Service.[§]

2.2 BreastCheck screening service

BreastCheck was established with the remit of providing a population-based breast screening programme for women aged 50 to 64.(13) The service is currently being extended to women aged 50 to 69, and, by the end of 2021, all women within this age group will be invited for routine screening. The objective of the programme, as outlined by BreastCheck, is to provide an effective screening service of the highest possible quality so that the maximum number of breast cancers can be detected at the earliest possible stage. The programme aims to:

- protect the dignity and privacy of women and provide women with a choice and involvement in their own care
- deliver a high-quality programme dedicated to excellence and meeting the highest international clinical standards
- be women centred, accessible and free of charge.(13)

It is a government-funded programme that provides free mammograms to eligible women every two years. Mammography is the breast imaging technique used to screen for disease by BreastCheck.(13) BreastCheck currently provides screening to women through a network of four static units and 19 mobile units. The four static BreastCheck units are:

- The Merrion Unit, Dublin
- The Eccles Unit, Dublin
- The Southern Unit, Cork
- The Western Unit, Galway.

The mobile units are located around the country in the areas where screening is scheduled in order to provide convenience of access for individuals in each region. To provide the screening service, BreastCheck has a workforce of almost 200 whole-time equivalent staff members, of which 70% are clinical staff. BreastCheck provides mammography and diagnosis but works in partnership with other providers to deliver treatment for service users.(14)

BreastCheck has received accreditation for its screening service through the European Reference Centre for Breast Screening. Programme standards for screening quality are based on the BreastCheck *Guidelines for Quality Assurance in Mammography Screening*.(15)

[§] In 2018, the National Screening Service will be repositioned under the remit of the National Cancer Control Programme. The transfer of governance is to be implemented by 31 March 2018.

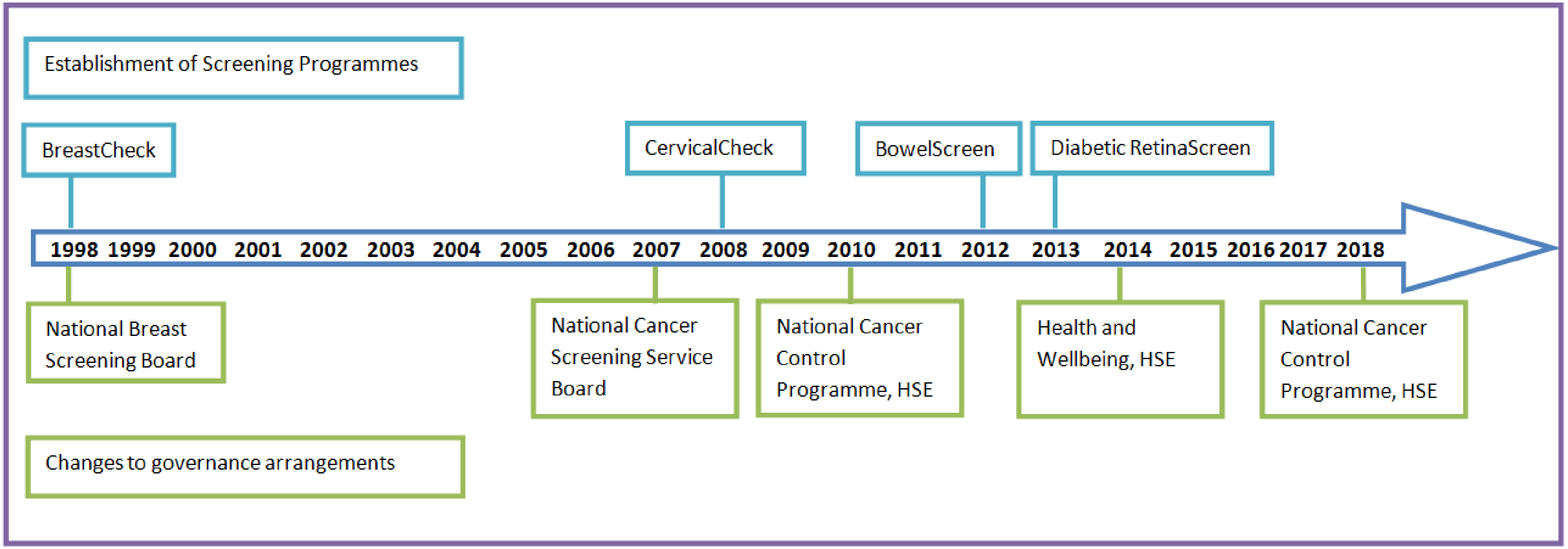

Figure 1. Establishment of screening services in Ireland

2.3 Information system and data flows in BreastCheck

BreastCheck has a legislative remit to acquire information under the Health (Provision of Information) Act, 1997 "for the purposes of compiling and maintaining a record of the names, addresses and dates of birth of persons who, for public health reasons, may be invited to participate in that programme".(16)

2.3.1 Information system

BreastCheck maintains an information system, the National Breast Screening Programme (NBSP), to manage service user information for the entire screening process. The NBSP acts as both the population register and patient information management system. The NBSP programme is used to identify eligible women for screening, generate invitations and appointments for screening, track uptake rates and manage all the clinical information if the individual is positively diagnosed with breast cancer. The types of data collected include demographic, radiological, surgical and pathology data.

2.3.2 Data flows

To establish and maintain the population register, BreastCheck receives demographic information of women within the age range for screening from external sources.
At the time of the review, six organisations were providing data to BreastCheck to populate the register:

- Department of Social Protection (DSP)
- General Medical Services (GMS), Primary Care Reimbursement Service
- Aviva
- Irish Life
- Laya Healthcare
- Vhi Healthcare.

Furthermore, eligible women can self-register with the programme if they are not known to any of the data providers by providing their information online.

BreastCheck has a data transfer process which details how demographic information is managed once it is received from the data providers. This process includes updating address information for individuals on an ongoing basis.

BreastCheck outsources the validation of address information to an external data processing company. The data processing company assigns Electoral Division (ED) codes to each address as invitations for screening are based on location. In addition, the data processing company identifies duplicates. Removing duplicates is required as data is provided from six organisations; therefore the same person could be present in the dataset multiple times. The steps used to identify the target population are outlined in Appendix 2.

On a monthly basis, the register is checked to identify new individuals that enter the age range for screening eligibility and the status is changed to 'Awaiting Invitation'. Invitations for screening are organised by area, and letters of invitation for screening and scheduling of appointments are sent to eligible individuals on a phased basis according to EDs. BreastCheck outsources the management of a helpline to an external company, and individuals can ring the helpline if they have queries about the invitation for screening.

Once the individual attends for screening, they are asked to complete a questionnaire to find out any history of hormone replacement therapy and previous breast surgery. This information is updated on the NBSP by the administrator within the screening unit. Consent is obtained at this stage to give BreastCheck permission to collect, store and exchange health records in line with the process required to provide an effective screening service. This includes the exchange of health records with other health agencies such as general practitioners (GPs), hospitals and the National Cancer Registry Ireland (NCRI).

Clinical data is updated by numerous healthcare professionals along the screening pathway. Clinical staff complete forms for each individual if additional tests or procedures are performed detailing any pathology or surgery results. These are sent to a Data Officer in the screening unit, who retrospectively inputs the results into the NBSP.

The results of normal screening are sent to the individual's GP via Healthlink in order to ensure that the GP has an up-to-date and accurate healthcare record. If follow-up treatment or any oncology treatment is required, referral letters are sent to the relevant consultant or clinic and clinical information, such as mammograms and pathology results, are transferred to the relevant hospital. This is to ensure that the new consultant has the correct results and information to effectively treat the patient.

BreastCheck and the NCRI share specific information to validate the population registers and perform quality assurance checks. BreastCheck sends the NCRI a list of individuals screened and a list of individuals who have been diagnosed with cancer. The NCRI send BreastCheck a list of individuals diagnosed with interval cancers[**] to ascertain the number of interval cancers diagnosed between screening rounds and a list of individuals diagnosed with cancer who were not screened.

Lastly, BreastCheck receives data and supplies data to an external company which specialises in radiation safety monitoring and outsources services to a number of information and communications technology (ICT) companies.

2.4 Significance of information management in BreastCheck

Screening is a process for identifying apparently healthy people who may be at an increased risk of disease or condition.(17) The rationale for breast cancer screening programmes is to detect a potentially fatal cancer earlier in its natural history as early diagnosis of breast cancer with optimal treatment reduces mortality from the disease.(15) The implementation of a population-based cancer screening programme has been recommended by the World Health Organization and the European Union, provided the service is comprehensive and of high quality.(4) A comprehensive and high-quality service can only be assured if the organisation manages its information appropriately.(5)

[**] Breast cancers diagnosed in the interval between scheduled screening episodes in women screened and given a 'normal' screening result, that is, the previous screening episode was negative.

To achieve good information management practices, organisations need to implement a sequence of robust arrangements, including formalising governance structures and clearly outlining responsibilities throughout the organisation in respect of information management; developing an information management strategy; preparing detailed business plans to outline how the organisation will successfully achieve this strategy; developing a system to effectively assess the delivery of the business plans by monitoring information-related performance indicators and undertaking necessary audits to provide assurance of good practice; and identifying and controlling information-related risks by implementing an integrated risk management policy. Like all other resources within an organisation, information is a resource that must be strategically and effectively managed.

In the context of screening, information management is crucial as a comprehensive screening service can only be delivered if the programme has a complete and accurate population register.[††] This means that all eligible individuals need to be identified and accurate demographic information acquired to provide a personal invitation for screening to each individual. As the cohort for screening is constantly changing, the register has to be regularly updated with information about individuals that fall within the age bracket for screening. In addition, the screening programme needs a process to identify and update changes to demographic details for the individuals in the register that may move address during the screening period. A complete and accurate register means that individuals can have confidence that they will be invited for screening once they meet the eligibility criteria.(5)

Furthermore, to provide a high quality and safe screening service, it is necessary for clinical information to be handled and processed efficiently. The process of screening generates large volumes of personal health information and relies heavily on accurate documentation and communication of information about health status, processes of care and outcomes of care. This is particularly relevant for BreastCheck as it has four static units and 19 mobile units. Service users want to be assured that their information will be managed correctly so that they will receive timely, efficient and effective care if a cancer is detected.(5)

In addition, a high-quality screening service can only be assured if the national data collection has the appropriate information to plan and manage services. Good information management practices are necessary to provide assurances that the organisation is achieving its objectives through careful strategic and business planning and monitoring performance against these targets. Performance monitoring involves a number of dynamic processes such as identifying and reviewing key performance indicators, undertaking regular audits to review practice, and managing risk. The key to achieving a high level of performance is having timely, accurate and reliable data to identify any issues and to use this information as a mechanism to continuously drive improvements. For example, one aspect of monitoring performance for screening involves setting targets in line with international best practice and regularly benchmarking performance data at both the level of the clinician and screening unit to ensure high-quality care is consistently delivered.(6) It also involves setting and reviewing targets in respect of the accuracy and completeness of the population register, and the quality of the clinical data.

[††] A population register is a comprehensive list of all individuals that meet the criteria for screening.

The general benefits of good information management practices for the screening service is to instil confidence in service users, clinicians and all other stakeholders that decisions are based on high-quality information, the availability of which will ultimately improve outcomes of screening.(2) It is widely recognised that effective information management improves services through enhanced knowledge and understanding for all involved in providing and using the service. Furthermore, good information management promotes assurance that information will be held securely, it puts in place the necessary precautions to maintain an individual's privacy and confidentiality, it facilitates greater empowerment and involvement by communicating effectively with the public and, ultimately, it creates a culture in which information will be used more effectively.(7)

3. Governance, leadership and management

To achieve compliance with the Information Management Standards, the managing organisation of a national data collection must have effective governance, leadership and management structures in place. These structures should promote good information management practices throughout the organisation. It is not necessary to have separate governance structures for information management; instead, these practices should be an intrinsic part of the existing governance structures of the managing organisation and national data collection. Effective governance arrangements for information management are necessary to ensure that processes, policies and procedures are developed, implemented and adhered to in respect to information management.

Features of good governance, leadership and management include:

- A well-governed organisation is clear about what it does, how it does it and is accountable to its stakeholders. Formalised governance arrangements ensure that there are clear lines of accountability for individuals and teams so that everyone is aware of their responsibilities in respect to information management. The organisation should be unambiguous about who has overall executive accountability for the national data collection, and there should be identified individuals with responsibility for information governance and data quality. There is also an onus on senior management to develop the required knowledge, skills and competencies within the organisation to manage information effectively and to ensure compliance with relevant legislation.

- Organisations should demonstrate strong leadership by strategically planning and organising resources to achieve their objectives. Strategic and business planning need to specifically address the area of information management given the ever evolving health information landscape in the wider health service, which should be aligned with the broader health information strategies in Ireland.(18) Organisations often outline the information management strategy within the overall strategic plan.(17) However, increasingly, organisations with a core data and information function are choosing to develop a specific information management strategy. An information management strategy should set out how the organisation aims to improve the management of information in order to achieve its overall strategic objectives. It should include the technological infrastructure requirements, information governance, data quality and the use of information.(7)

- A well-governed and managed service can only be achieved if the organisation has robust processes in place to monitor its performance for information management. Senior management require information on performance to be assured that practices are consistently of a high standard within the organisation. This involves using key performance indicators to measure and report on performance, undertaking regular audits to assess practice and having a comprehensive risk management framework in place throughout the entire organisation to help identify, manage and control information-related risks.

- Another key feature of good governance, leadership and management involves having formalised data sharing agreements in place with external organisations. The formalised agreements outline the responsibilities of both parties and the associated timelines for the completion of tasks. Data sharing agreements are necessary to support the provision of good quality data, and the legal and secure handling of data.

- Organisations with robust governance structures promote transparency by informing individuals about whom data is being shared about any data sharing agreements in place, and they accurately describe the aims and objectives of the national data collection in a published statement of purpose.

The HIQA review team assessed the governance, leadership and management arrangements at BreastCheck against Standard 2, 3 and 4 of the Information Management Standards.

In reviewing the governance, leadership and management arrangements in BreastCheck in respect to information management, HIQA acknowledges that significant changes have occurred in recent years. BreastCheck was initially an autonomous agency with its own board; however, the governance structures have transformed as the wider National Screening Service evolved.

As BreastCheck sits as a unit within the National Screening Service, which has a single governance model for all four screening programmes, the report will provide an understanding of the information management arrangements of the National Screening Service through the lens of BreastCheck.

The findings of governance, leadership and management will be presented in the following sections:

- Governance structures of BreastCheck
- Strategic vision, planning and direction
- Performance and risk management
- Formalised governance structures for data sharing agreements
- Transparency

3.1 Findings — Governance structures of BreastCheck

This section will outline the governance structures in BreastCheck at the time of the review, including the positioning of BreastCheck within the Health Service Executive (HSE); an outline of a recent review which was sanctioned by the Director General of the HSE to assess the overall functionality and governance of the HSE National Screening Service; governance arrangements in BreastCheck in respect of information management; and a summary of the significance of findings on governance arrangements for information management.

3.1.1 Current positioning of BreastCheck within the HSE

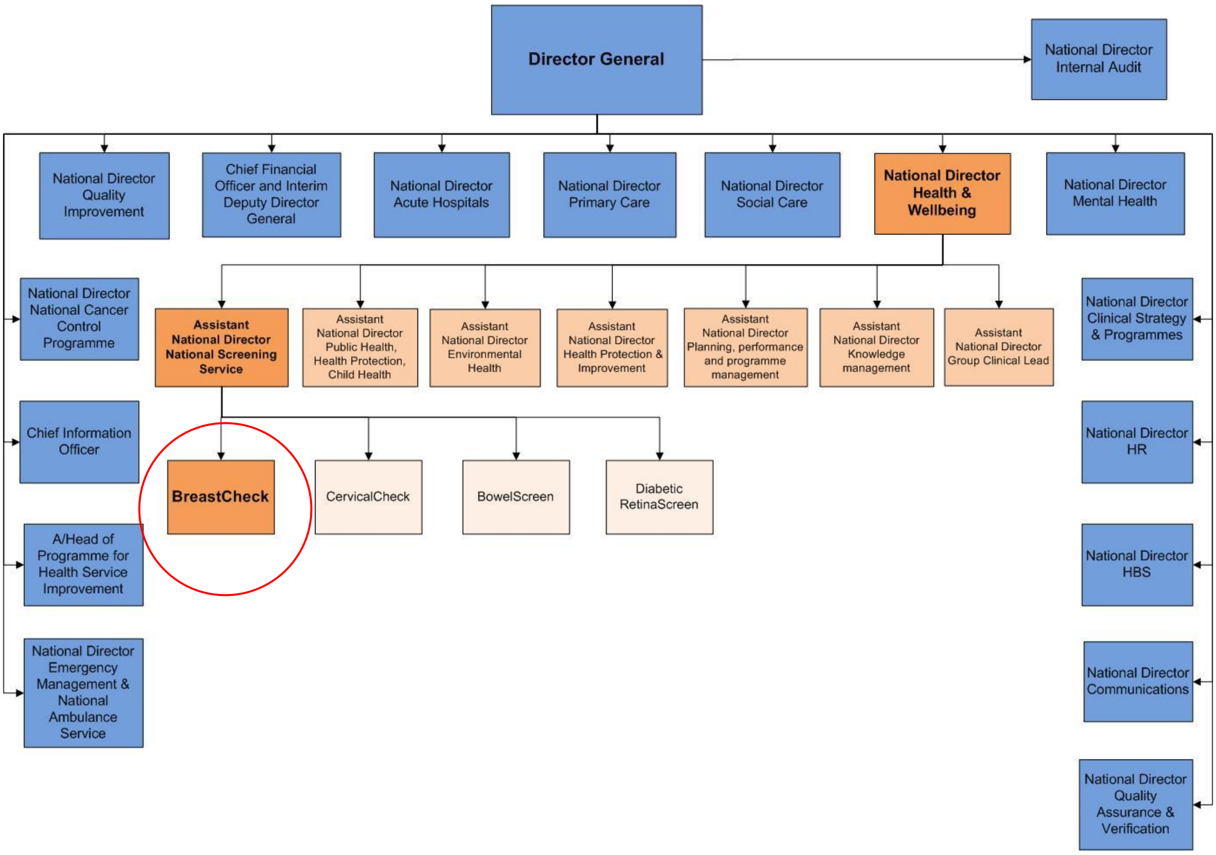

Figure 2. Current governance structures of the positioning of BreastCheck within the HSE.

3.1.1.1 Health and Wellbeing Directorate, HSE

At the time of the review, the National Screening Service was one of seven services under the governance of the Health and Wellbeing Directorate (see Figure 2).[‡‡] The aim of the Health and Wellbeing Directorate is to support the population to stay healthy and well, reduce health inequalities and protect people from threats to their health and wellbeing.

The National Director of Health and Wellbeing is a member of the HSE Leadership Team and reports to the Director General of the HSE. The National Director of Health and Wellbeing is responsible for the services within the Health and Wellbeing Directorate, which are:

- National Screening Services
- Public Health, Health Protection, Child Health
- Environmental Health
- Health Promotion and Improvement
- Planning Performance and Programme Management
- Knowledge Management (incorporating Health Intelligence)
- Group Clinical Lead Health and Wellbeing Division.

[‡‡] In 2018, the National Screening Service will be repositioned under the remit of the National Cancer Control Programme. The transfer of governance is to be implemented by 31 March 2018.

Each of these seven services is led by an Assistant National Director. The seven Assistant National Directors report to the National Director of Health and Wellbeing, and they sit on the Senior Management Team within the Health and Wellbeing Directorate.

3.1.1.2 National Screening Service

The National Screening Service is responsible for the four screening programmes as detailed in Section 2.1. The Assistant National Director of the Health and Wellbeing Directorate with responsibility for the National Screening Service, also referred to as Head of Screening, was appointed in 2016 and has overall executive accountability, responsibility and authority for the National Screening Service (see Figure 3).

> The Assistant National Director with responsibility for the National Screening Service will be referred to as the Head of Screening for the remainder of this report.

Although the four screening programmes are positioned within the National Screening Service governance model, the programmes operate as four distinct units. Each programme has the autonomy to decide on the operational aspects of the service provided.

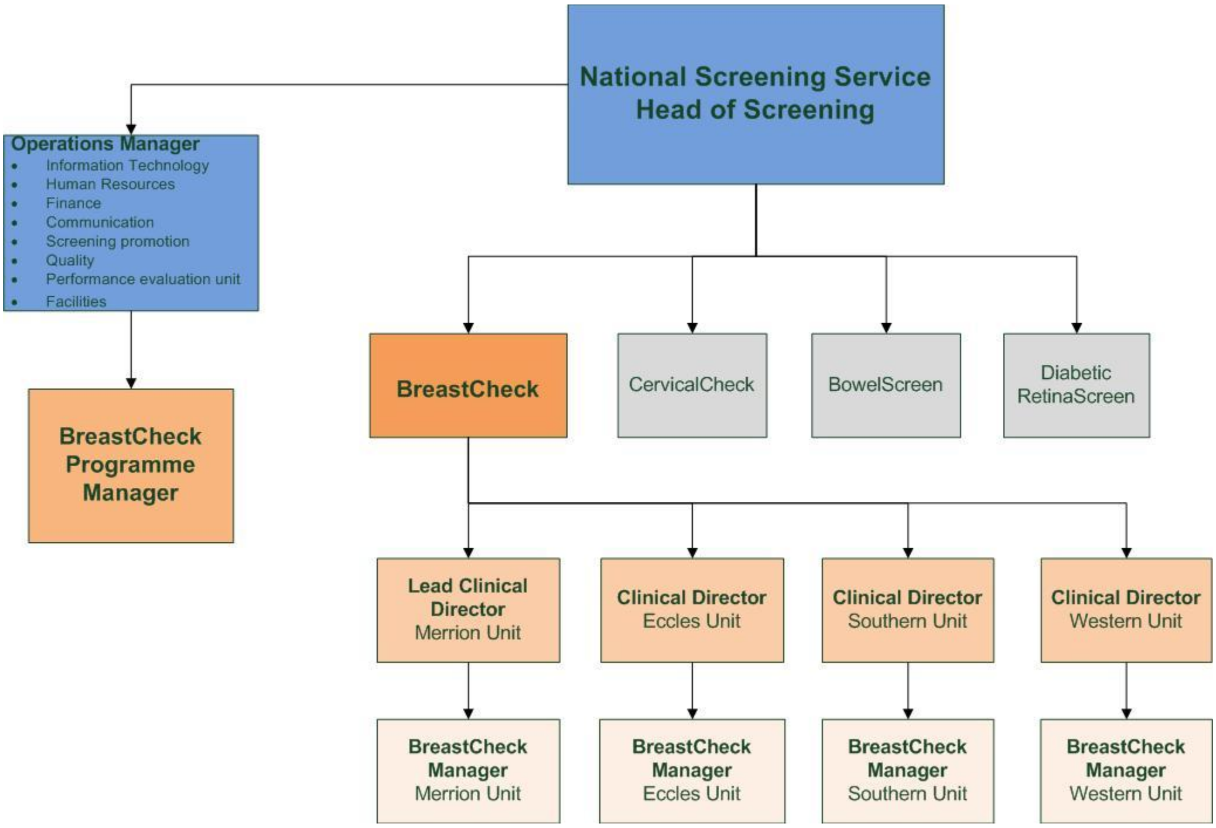

Figure 3. Detailed governance structures of BreastCheck within the National Screening Service.

There is a Lead Clinical Director within each of the four screening programmes with overall responsibility for the quality assurance of each programme. The Lead Clinical Directors report to the Head of Screening.

In addition, there is a Programme Manager for each screening programme who is responsible for the operational aspects of the service. The Programme Managers report to the Operations Manager.

The Operations Manager in the National Screening Service is responsible for managing the operational aspects common to all four screening programmes. The departments under the remit of the Operations Manager are:

- Information Technology
- Human Resources
- Finance
- Communications
- Screening Promotion
- Quality
- Performance Evaluation Unit
- Facilities.

The Operations Manager reports to the Head of Screening and is the chair of the Senior Management Team (SMT), the purpose of which is to manage the delivery and development of the four screening programmes. The responsibilities of the SMT will be further outlined in Section 3.1.3.2. The manager of each of the departments listed above report to the Operations Manager.

3.1.1.3 BreastCheck

The Head of Screening has overall executive accountability, responsibility and authority for BreastCheck.

The programme-level organisational structures include a Programme Manager; four Clinical Directors, one from each of the four units; and four Unit Managers, one from each of the four screening units. One of the Clinical Directors holds the responsibility of Lead Clinical Director for BreastCheck (See Figure 3).

The Head of Screening chairs the BreastCheck-Executive Management Team (B-EMT), the purpose of which is to oversee the clinical governance of BreastCheck and to ensure the effective management of the programme. The responsibilities of the B-EMT will be further outlined in Section 3.1.3.2.

3.1.2 National Screening Service — Governance and functionality review

HIQA was informed during the review that an independent governance review of the National Screening Service had been completed in early 2017. The review was sanctioned by the Director General of the HSE to assess the overall functionality and governance of the HSE National Screening Service. The report outlined eight recommendations which, if implemented, would "better position the screening services to function more effectively and efficiently and ensure a more coherent governance structure in the years ahead". The eight recommendations outlined in the report are to:

1. enhance the National Screening Service leadership structure
2. develop an National Screening Service strategic plan with a shared vision and understanding across the programmes
3. examine integration opportunities, efficiencies and key relationships within the National Screening Service to boost cross-programme integration
4. undertake initiatives to strengthen the National Screening Service brand
5. develop external quality assurance
6. increase patient and public involvement
7. stabilise the funding approach
8. address governance and positioning (within HSE).

HIQA was informed that these recommendations had been accepted by the Head of Screening. At the time of the review, the Head of Screening was in the process of developing plans to address the recommendations as outlined in the governance and functionality review.

3.1.3 Governance arrangements for information management

Good governance of an organisation requires formalised structures with clear lines of responsibility and reporting. Formalised governance structures also require clear lines of responsibility and reporting for executive and management teams which have an information management function. This section will describe the lines of reporting and responsibility within the organisation, as well as the governance structures for the executive and management teams within BreastCheck.

3.1.3.1 Clear lines of reporting and responsibility

In interview, the Head of Screening identified that he had overall accountability for the National Screening Service. A scheme of delegation was not in place to assign executive responsibility for information management functions across the service.

HIQA was not provided with a clear organisational chart outlining the lines of reporting among employees within BreastCheck. However, during an interview, the review team were informed that the Lead Clinical Director reports to the Head of Screening, the Unit Managers of the four static units report to the Clinical Directors, and the Programme Manager reports to the Operations Manager. On review of the job descriptions, the roles and responsibilities of core management positions — the Clinical Directors, the Programme Manager, and the Unit Managers — were not clearly defined in respect to information management.

3.1.3.2 Executive and management teams

During the review, the Head of Screening informed the review team of plans to establish a Clinical Leadership Board for the National Screening Service and subsequently provided evidence that the board had officially met for the first time in September 2017. The Clinical Leadership Board was established as the senior decision making body of the National Screening Service (see Figure 4).

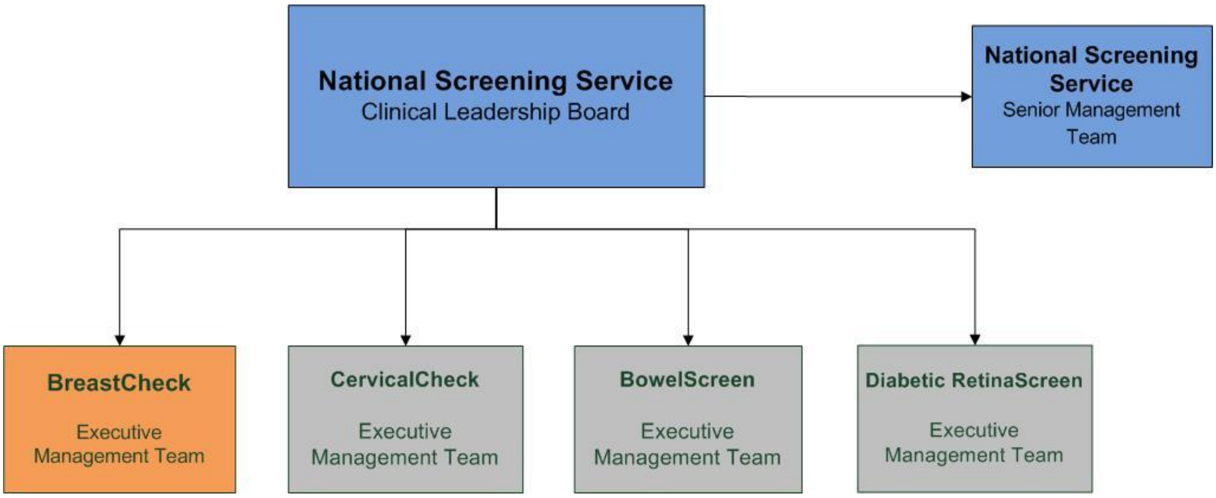

Figure 4. Executive and management teams in the National Screening Service

Each of the four screening programmes has an individual Executive Management Team, and their principal function is to ensure the delivery of a quality assured screening programme.

A SMT is also in place for the National Screening Service. The aim of this team is to manage the delivery and development of the four screening programmes.

The lines of reporting, the responsibilities, the composition and the functioning of the Clinical Leadership Board, the SMT and B-EMT are outlined in Table 1.

Table 1. Evidence and documentation on the Clinical Leadership Board, the SMT and B-EMT

	Clinical Leadership Board	**Senior Management Team (SMT)**	**BreastCheck-Executive Management Team (B-EMT)**
Lines of reporting	**Chair:** Head of Screening **Reporting:** The board reports to the National Director of Health and Wellbeing.	**Chair:** Operations Manager **Reporting:** The team reports to the Head of Screening.	**Chair:** Head of Screening. **Reporting:** The team reports to the Clinical Leadership Board. All teams and committees within BreastCheck report to the B-EMT.
Responsibilities	• setting the strategic direction of the organisation • overseeing the monitoring of performance against objectives and ensuring corrective action is taken when necessary • ensuring effective financial stewardship • ensuring high standards of clinical and corporate governance • overseeing the management of clinical and corporate risk • ensuring effective communication with relevant stakeholders	• preparing the service and operational plans • managing resources to achieve screening targets • managing organisational development and succession planning • reviewing future planning for programmes • ensuring cross-programme co-ordination, efficiency, cost-effectiveness and value for money • promoting health and safety • reviewing the risk register	• delivering a quality assured breast screening programme in accordance with government policy • maximising participation amongst the target population and monitoring the delivery of the programme • decision making and policy formulation • developing and monitoring the service plan • setting and evaluating clinical and operating standards • ensuring robust quality assurance is in place • providing oversight of major change in the service delivery of the programme and identifying and optimising synergies with other programmes
Composition	Head of Screening (Chair) Clinical Directors, BreastCheck (x4) Clinical Director, Diabetic RetinaScreen Clinical Director, CervicalCheck Clinical Director, BowelScreen Medical Director, Screening Policy	Operations Manager (Chair) Medical Director Screening Policy Programme Managers (x4) Communications Manager Finance Manager Human Resource Manager IT Manager Performance Evaluation Unit Manager Director of Evaluation Screening Promotion Manager	Head of Screening (Chair) Lead Clinical Director, Merrion Unit Clinical Director, Eccles Unit Clinical Director, Southern Unit Clinical Director, Western Unit Programme Manager — BreastCheck

	Clinical Leadership Board	**Senior Management Team (SMT)**	**BreastCheck-Executive Management Team (B-EMT)**
Functionality	**Frequency:** At least 3 times a year. Recently established, met in September 2017 and November 2017. **Documentation:** HIQA received an agenda for meetings in September and November 2017 and the minutes of the meeting held in September 2017. **Quorum:** The chair and 3 members. The quorum was achieved for the first meeting.	**Frequency:** At least on a monthly basis. In the previous year, the group met eleven times. **Documentation:** The terms of reference are reviewed annually. There is a structured agenda and minutes are recorded for each meeting to document decisions and actions arising. **Quorum:** The chair and 5 members. Out of the three meetings for which minutes were supplied to HIQA, one did not have sufficient attendees to meet the quorum.	**Frequency:** Every 6 weeks. From April 2016 to March 2017, the group met 7 times **Documentation:** The terms of reference was last updated in 2010 and had not been edited to reflect the significant governance changes in recent years. During the course of the review, the terms of reference were updated. There is a structured agenda and minutes are recorded for each meeting to document decisions and actions arising. **Quorum:** The chair and three members. The minutes of three meetings provided to HIQA had sufficient attendees to meet the quorum.
Information Management	The board was at early stages of development and implementation so it was not possible to assess the impact on information management practices in BreastCheck.	On review of the agendas supplied as part of the information request, the General Data Protection Regulation (GDPR) was included for routine discussion in June 2017 on the agenda.	On review of the minutes supplied as part of the information request, issues relating to information management such as data protection, sharing of information, data quality and technology issues were discussed in the B-EMT. However, this information is not discussed on a routine basis as information management did not feature as a standing item on the agenda.

3.1.4 Significance of findings — Governance arrangements for information management

New governance structures

- At the time of the review, new leadership arrangements were being put in place as the traditional governance structures were not fit-for-purpose. The Clinical Leadership Board was established in September 2017 as the most senior decision-making body of the National Screening Service. At the time of the review, it was not possible to assess the impact of the newly established Clinical Leadership Board on information management practices in BreastCheck as it was in the early stages of development and implementation. The traditional governance model facilitated a silo-effect as Lead Clinical Directors did not have a forum to discuss cross-programme information management issues. For the National Screening Service to operate more effectively and efficiently there is a need for greater integration of the four programmes into the current governance arrangements in respect of information management.

Lines of responsibility and reporting

- While the Head of Screening identified himself as being accountable for all aspects of the screening services, there was no scheme of delegation[§§] in place to assign executive responsibility for information management across the service, in particular in the areas of information and communications technology (ICT), information governance, data quality and the use of information both internally and externally. This means that there is an over-reliance on the Head of Screening to identify and address cross-programme matters. A scheme of delegation should provide clear guidance on who is responsible for escalating an issue and how to communicate decisions effectively within the organisation for the different areas of information management.

- HIQA could not determine, through interview or information request, if the responsibility for identifying and managing various information-related risks or issues is the responsibility of Unit Managers, Clinical Directors, Lead Clinical Director or the Programme Manager. Clear lines of reporting are essential for information management, as if an information-related risk is identified by an employee, it should be obvious who has responsibility for managing the risk and escalating the risk if necessary.

[§§] A scheme of delegation is a document defining which functions have been delegated and to whom. This document provides clarity about who has responsibility for making which decisions.

Responsibility of teams in relation to information management

- At the time of the review, HIQA noted that information management was not a core responsibility in the terms of reference of the Clinical Leadership Board, the SMT or the B-EMT. Information is a common resource across all programmes, and the use of information is required to support a safe and high quality service and is necessary for planning, developing, evaluating and accrediting the quality of the programmes. Given the impending implementation of the eHealth Strategy, the dynamic nature of health information, the ongoing evolution of ICT in the area, the increased risk of cyber security threats and the changing legislative landscape, information management within the National Screening Service and BreastCheck should feature as an explicit responsibility of the executive and management teams.

- Furthermore, HIQA was unable to establish the unique responsibility of the executive and management teams in respect to information management. In reviewing the minutes of meetings, HIQA identified an element of duplication of responsibilities across the teams. This is important for information management as dual responsibilities across teams can blur lines of accountability, increase the demand on resources and create inefficiencies in the functioning of the teams due to a lack of clarity and focus. In this respect, there is a need to review current governance and management structures in light of a change to the governance structure of the National Screening Service.

- Information management should be a key priority for senior management to ensure significant changes and developments are identified and addressed without delay. HIQA identified that information management issues were not a standing item on the agenda or in the minutes of any of the three teams until June 2017, when the General Data Protection Regulation (GDPR) was included on the agenda of the SMT. A symptom of the latter is that important information management issues are not prioritised or addressed in a timely manner.

3.2 Findings — Strategic vision, planning and direction

Strategy and corporate plans are the foundation on which all business activities can be connected and aligned. The strategy should be underpinned by regularly updated business plans which specify how the National Screening Service is going to achieve the strategic objectives.(18)

3.2.1 Strategy

High-level policy direction for effective screening programmes in Ireland is developed by the Department of Health and the HSE. The expansion of the screening programmes was initially outlined in the 2001 health strategy *Quality and Fairness*.(19) The screening service also features in the recently published *National Cancer Strategy 2017-2026,(20)* which predicts that personalised and tailored cancer screening approaches will evolve over the period of the strategy, particularly in cancer control and surveillance services such as screening for inherited familial predisposition to breast, ovarian and colorectal cancer. In 2008, the HSE Transformation Population Health Strategy also set out plans to prioritise and invest in screening programmes that are evidence-based and that meet the best international quality standards.(21)

HIQA was informed through the information request and during interview that, at the time of the review, the National Screening Service did not have a strategic plan that outlined the vision and direction of the four programmes and the potential to expand the National Screening Service further. Furthermore, it did not have any specific strategic plans for the service in relation to information management.

The governance and functionality review, detailed in Section 3.1.2, recommended that the National Screening Service develop a strategic plan with a shared vision and understanding across programmes. A key feature of this strategy should be how the organisation is going to achieve effective information management in order to deliver the overall strategy.

3.2.2 Business planning

HIQA was informed through the information request and in interview that business or operational plans for the National Screening Service are published at a number of levels within the current structures, including the annual *HSE National Service Plan,*(22) the annual *Health and Wellbeing Operational Plan,*(23) and the *National Screening Service Business Plan.*(24) These business plans address each of the four screening programmes. However, the plans include high-level priorities such as achieving screening target rates, implementing extensions to programmes and reducing significant backlogs within the programme.

An example of the plans outlined for BreastCheck within the *HSE National Service Plan* relate to the delivery and expansion of screening services in Ireland. Specifically for BreastCheck, the plan outlines an intention to maximise uptake rates for the programme (>70% of women aged 50–64) and to continue to extend the service to women aged from 65–69 years.(22) The *Health and Wellbeing Operational Plan* and the *National Screening Service Business Plan* for 2017 include similar high-level priorities for BreastCheck. The National Screening Service

Business Plan for 2017 includes plans to deliver a subsequent round of screening to women aged 50–64 years, in line with available resources (based on a >70% participation rate); to continue age extension implementation to women aged 65+; and to reduce the backlog of women waiting to be invited greater than 24 months of becoming eligible for the programme or since their last screening appointment.(23,24) At the time of the review, BreastCheck or the National Screening Service did not have any objectives in the business plans regarding building capacity and capability for information management.

3.2.3 Significance of findings — Strategic vision, planning and direction

Strategy

- BreastCheck currently does not have a strategy to outline the aims and objectives, legal responsibilities and future needs of the organisation in respect of information management. A strategy involves creating a vision and direction that is clear and simple. Furthermore, the strategy needs to be aligned to the HSE eHealth Strategy and to annual business plans. The strategy should also consider the implications of the imminent changes to the health information legislative framework, which will drive increased transparency and accountability in regards to the collection, use and storage of personal health information. The development of strategic plans, which outline how the organisation plans to build capacity and capability through enhanced knowledge and information, is in line with international best practice.(17) As the National Screening Service houses four large national data collections and vast amounts of personal health information, it would ultimately benefit from developing an information management strategy both in the short-term and long-term.

- An information management strategy can be outlined in the organisation's overall strategic plan or in a specific information management strategic plan. An information management strategy is important specifically given the significant pressure to move away from paper-based processing of information in the healthcare sector, the need to make activities more efficient and effective through improved ICT systems, and the growing expectation from all stakeholders for services to use information as a key resource to facilitate informed and considered decision-making. Organisations should approach the development of a strategy as an opportunity rather than an obstacle as a strong information management strategy has the potential to implement significant cost savings for services as new technologies will provide the opportunity to implement efficient information systems at a lower cost. For example, considering whether cloud-based solutions are more appropriate, evaluating the use of business intelligence for internal use of data, using online interactive data manipulation tools for external sharing of data and realising the value of the new individual health identifier. Furthermore, a strategy will help the service to focus attention on major information governance risks like cyber security threats and retention of data.(25,26)

Business Planning

- At the time of the review, BreastCheck or the National Screening Service did not have any objectives in the business plans regarding building capacity and capability for information management. Annual business plans are necessary for BreastCheck to detail how they will achieve their strategic objectives for information management.

3.3 Findings — Performance and risk management

A well governed and managed organisation monitors its performance to ensure it meets its objectives in relation to information management. The aim of an effective performance management framework is to produce the necessary information to assure senior management that the organisation is being managed effectively. A robust performance management framework promotes accountability to all stakeholders by facilitating informed decision-making and improvements through continuous and rigours self-assessment.(6) Performance management involves a number of key processes, including identifying and reviewing key performance indicators (KPIs); commissioning necessary audits, both internal and external, to assess compliance with relevant legislations and the organisation's policies and procedures; and reviewing the risk management policy and risk register.

The use of KPIs, audit and risk management will be addressed in turn in the following sections.

3.3.1 Key performance indicators

3.3.1.1 KPIs — information management

BreastCheck informed HIQA, through the documentation request and in interview, that indicators in relation to information management, such as data quality and information security, were not being routinely collected and reported to senior management.

BreastCheck provided evidence to HIQA of measures used to assess the quality of the National Breast Screening Programme (NBSP) which is the population register. These measures are outlined in the BreastCheck *Guidelines for Quality Assurance in Mammography Screening*.(15) The accuracy of the population register is measured by the proportion of:

- duplicates on the register
- consent letters returned by An Post
- changes made to the register either before or at attendance for mammography.

These measures of accuracy are not linked to any KPIs for the quality of the population register. Furthermore, although BreastCheck are undertaking a significant amount of work in the area of data quality (See Section 4.1), there are no specific KPIs linked to these measures of quality.

3.3.1.2 KPIs — Screening service clinical performance

In interview, HIQA was informed that the Head of Screening and Operations Manager are responsible for liaising with management within the Health and Wellbeing Directorate to decide on appropriate KPIs for each screening programme. After deciding and agreeing on the appropriate KPIs, BreastCheck collates the information and provides the statistics to the Health and Wellbeing Directorate. The Health and Wellbeing Directorate report these statistics within the HSE Performance Reports, which are published on the HSE website.(27)

In addition, BreastCheck has a quality assurance process in place for the clinical aspects of the service which involves identifying, monitoring and reporting standardised performance metrics. BreastCheck has a Quality Assurance committee which is tasked with implementing the *Guidelines for Quality Assurance in Mammography Screening*.(15) The guidelines outline specific KPIs for BreastCheck. BreastCheck publishes an annual report on their website which includes indicators derived by the quality assurance programme in relation to the overall performance of the screening service.(15) Examples of the KPIs reported for the BreastCheck screening service clinical performance are included in Appendix 3.

3.3.2 Internal and external audit

BreastCheck provided HIQA with information about audits that were completed in the following areas: clinical data, population register and information security.

3.3.2.1 Clinical data audits

BreastCheck undertake a comprehensive set of audits on a regular basis to review the quality of the clinical data collected throughout the screening process. Clinical data is entered and validated on a weekly basis by Data Officers in each unit. The Performance Evaluation Unit also produce validation reports with predefined quality measures, on a monthly and annual basis, which allows the Data Quality Manager to review practices and the quality of data across all four units.

3.3.2.2 Population register audits

BreastCheck provided evidence to HIQA of three audits which aimed to assess the completeness and accuracy of the population register:

- BreastCheck assesses the completeness of the register by reviewing the number of women in the population register on the day of the census compared to the number of women in the age bracket for screening which are recorded by the census. The population register is validated against the census each time a national census is carried out. This exercise was last carried out in 2017 for the 2016 census. An improvement in discrepancy rates from 2011 to 2016 may be attributed to a clean-up project on the BreastCheck register in 2015, which resulted in over 4,000 women being deactivated from the population register.
- A specific working group was developed to address the accuracy of the population register in 2015. The group carried out an analysis of the overlap and differences

between common age bands across Cervical Screening Register (CSR) and the BreastCheck register. Specifically, it examined multiple versus single sources of data for programme registers and it evaluated the options for de-duplication and data cleansing. Recommendations from this report included conducting a cost-benefit analysis of using a single source external data supplier for the BreastCheck register, to consider using the CSR as a source of demographic data, and to identify 'real' women in one register and exporting these to the other register to cross-check accuracy. HIQA was provided with evidence that the cost-benefit analysis was completed, the results of which recommended a move to a single external data provider model.

- BreastCheck also monitors de-duplication rates across each unit on an ongoing basis. HIQA received a report which provided evidence of findings from 2005 to 2016.

The HIQA review team noted that each of the reports for these audits did not include actions or recommendations for change, and, therefore, the impact of these audits on practice could not be assessed. Other than the audit which monitors de-duplication rates across units, the frequency of audits to review the quality of the population register is periodic. HIQA identified that there is no process in place to identify and monitor audits to assess the quality of the population register on a systematic and continual basis.

3.3.2.3 Information security audits

BreastCheck provided evidence that a network security audit is carried out annually. The audit focuses on the networks under the management of an external company. In interview, BreastCheck acknowledged that they do not have the full range of expertise internally to undertake all of the necessary information security audits. In line with this, the Head of Screening has the authority to sanction external audits. The Head of Screening identified that the National Screening Service need to complete an assessment of information security to identify the current requirements for audit.

3.3.3 Risk management

The National Screening Service, within the HSE, is required to follow the HSE Integrated Risk Management Policy.(28) This policy encourages management to adopt a proactive approach to risk management by identifying risks that threaten the achievement of objectives and compliance with governance requirements. An example of such risks is the failure to comply with legal and regulatory requirements. The policy clearly outlines that it is the responsibility of all staff members to identify and manage risk within the context of their work. Furthermore, it is the line manager's responsibility to manage and control risk. In order to manage risk, formal identification of risks and implementation of controls should be part of the daily working flow and a risk register should be systematically maintained and reviewed by management.

3.3.3.1 Risk management policy

BreastCheck provided evidence that the National Screening Service has adopted the new HSE Risk Management Policy. HIQA was informed that organisational-level risks are reviewed by senior management and programme management, and serious or high scoring risks are escalated as outlined in the Safety Incident Management Policy, which includes some information management risks. However, HIQA identified during interview that information management risks are documented and communicated to the executive and management teams when they cannot be resolved at a local level. This demonstrates that staff are identifying and assessing risk but the systematic documentation and reporting of potential or actual risk is not consistently occurring throughout the organisation.

3.3.3.2 Risk register

At the time of the review, a risk register was maintained and reviewed by the SMT within the National Screening Service for all four screening programmes. The risk register is reviewed routinely at each SMT meeting, and risk management appears as a standing item on the meeting agenda and within the minutes. HIQA identified through interview that risks can be reported to the HSE through the Health and Wellbeing Senior Management Team. This practice is based on the Safety Incident Management Policy, which outlines the criteria for escalating risks. In 2017, a group was assembled to perform an in-depth risk assessment. Furthermore, the review team were informed that the Picture Archiving and Communications System (PACS) Oversight committee also discusses information management issues.

BreastCheck provided HIQA with a copy of the BreastCheck risk register which was reviewed by the SMT for the period January 2017 to February 2017. These risks related to uptake rates for screening, insufficient human resources, mammography and clinical equipment replacement, and funding for BreastCheck age range extension. The status of the former three risks were 'Monitors', which indicates that they are ongoing risks for the programme and were entered on the register between 2011 and 2014. The status of the risk on funding was 'Open' and was entered on the register in 2014. Control measures were identified for each of the four risks. HIQA noted that there were no information management-related risks on the register reviewed by the SMT in the period of January 2017 to February 2017.

After reviewing the documentation, HIQA requested clarification as to whether there had been any specific information management risks on the BreastCheck risk register in the 12 months prior to the review. BreastCheck provided HIQA with further documentation indicating that one risk had been entered on the risk register in relation to information management in this period. This risk involved a delay in producing performance reports used to identify underperformance in relation to quality assurance or other performance standards. The action required was to continue to develop and build analytical capability within the National Screening Service. It was unclear when the risk had been placed on the register. An action update noted that a statistician had commenced employment in April 2017 to a post that had been vacant for over two years. The risk remained on the register with a due date of 31 December 2017 to implement the necessary provisions to mitigate the risk. Subsequently, HIQA was informed that a risk of a potential cyber attack was added to the risk register in December 2017. A control for this risk included scheduling an IT systems audit to establish whether there are potential risks to security/hacking from outside sources. This action is to be completed by July 2018.

3.3.4 Significance of findings — Performance and risk management

KPIs

- BreastCheck has an established quality assurance process in place for the clinical performance of the service which involves identifying, monitoring and reporting standardised performance metrics. BreastCheck *Guidelines for Quality Assurance in Mammography Screening* outline specific KPIs for the BreastCheck screening clinical performance.(15)

- However, BreastCheck currently does not use KPIs to provide assurance to senior management that the programme is managing information appropriately. In comparison, HIQA noted that the *Guidelines for Quality Assurance in Cervical Screening*(5) have detailed KPIs for information management such as data quality, the accurate identification of women and documentation management.

- In line with best practice, a systematic process is required to identify, develop, collect and review KPIs for information management. Senior management need assurance that there is a carefully planned process in place to derive the appropriate KPIs as relevant, reliable and accurate indicators are essential for good governance. A performance report, detailing the KPIs, should be reviewed at management and executive meetings and actions decided upon if performance drops below the pre-specified target at any point. Information management KPIs should be linked to the strategic and business plan objectives as this enables senior management to regularly review whether the organisation is on-target to achieve what it set out to accomplish for that period.

Audit

- BreastCheck undertakes a comprehensive set of audits on a regular basis to improve the quality of the clinical data collected throughout the screening process. However, although BreastCheck is undertaking some activity to review the quality of the population register, a plan to identify, perform and review audits of the quality of the population register on a regular and systematic basis is required to drive continuous improvement.

- Furthermore, regular review of IT systems is necessary in light of the ongoing change in the nature of technology and security. Currently, regular audits of compliance to IT policies are not undertaken. It is essential to complete an assessment of information security requirements for audit and develop an audit schedule based on the findings.

- The audit schedules, including external audits, should be reviewed and agreed by senior management. External audits can be commissioned when a specific area of expertise, which may not be available in-house, is required or when an extra level of independence is considered necessary. The findings of the audits should be presented regularly to senior management to highlight areas of good practice and to identify areas which need improvements. Audits should also be used to identify specific training needs and to ultimately identify and implement improvements to information management practices based on the findings.

Risk management

- Currently, risks are discussed at the SMT, which is not chaired by the Head of Screening. The Head of Screening and the Clinical Leadership Board need assurance that the risk management policy is being implemented within the organisation by regularly reviewing the risk register and assessing whether risks are being managed appropriately within the organisation.

- While there was evidence that National Screening Service has a system in place to review organisational-wide risks, a culture of managing information risks needs to be embedded at all levels of the organisation. It is important to create a culture of openly and routinely discussing risks with all employees. This ensures that there is a strong emphasis on identifying, documenting and effectively managing risks throughout the organisation, including immediate and potential risks.

- Good risk management practices are intrinsically linked to clear lines of responsibility and reporting by enhancing communication and rapid response to a risk. Further awareness could be fostered through education and sharing information on lessons learned to create the ideal situation where all employees have the knowledge and skills to recognise potential risks and respond appropriately to mitigate the likelihood of a negative event occurring.

3.4 Findings — Formalised governance structures for data sharing agreements

Data sharing between organisations is encouraged if it is for the benefit of the service user and public health and in line with legislation and best practice guidelines. The use of data sharing agreements is recognised as good practice in this area. Data sharing agreements define a common set of rules to be adopted by the various organisations involved in a data sharing operation. It is essential that robust governance structures are in place to allow appropriate data sharing to occur. These include having oversight, assurance and transparency for all data entering and leaving the organisation. The governance of data sharing should ensure personal information is shared in a way that is fair, transparent and in line with the rights and expectations of the individuals whose information is being shared.

3.4.1 Formalised data sharing agreements in BreastCheck

BreastCheck receives and shares a significant amount of personal data which is essential in order to provide a high-quality, efficient and comprehensive service.

The National Screening Service has a Data Processing Agreement in place with three organisations which process data on behalf of BreastCheck. Contracts are also in place with five organisations with which BreastCheck shares data and all private hospitals which provide mammography services. These contracts contain a confidentiality clause.

While BreastCheck has arrangements to share data with external organisations which are contained within contracts, HIQA identified that BreastCheck does not have formalised data sharing agreements in place (see Appendix 4 for further details on data sharing agreements). In addition, the review team were informed during interview that BreastCheck has not completed a review to establish the need to conduct a privacy impact assessment (PIA) on data sharing practices.

3.4.2 Significance of findings — data sharing agreements

Formalised data sharing agreements

- While BreastCheck has a process in place to share data with external organisations, it does not have formalised data sharing agreements in place. The use of data sharing agreements is recognised as good practice in this area.
- Robust governance structures for all data sharing with external entities should include maintaining regularly updated data sharing agreements with all organisations sharing and receiving data; outlining which staff member(s) are responsible for ensuring the data sharing agreements are maintained; undertaking an assessment to identify if a PIA is required to review data sharing processes; and establishing appropriate monitoring and auditing procedures for the agreements as well as being ready to respond to any failure to adhere to a data sharing agreement.

Privacy Impact Assessment

- BreastCheck has not completed a review to establish the need to conduct a PIA on data sharing practices. Before entering a data sharing agreement, it is also recognised as good practice to carry out a PIA.(29) Organisations have a responsibility to be transparent regarding data sharing practices, which will become a mandatory requirement under GDPR.(30)

3.5 Findings — Transparency

Organisations with robust governance structures promote transparency by publically reporting a statement of purpose which clearly outlines the aims and objectives of the national data collection.

3.5.1 Statement of purpose

At the time of the review, BreastCheck did not have a statement of purpose, but management recognised the value of publishing such information. However, BreastCheck does have the Women's Charter, which clearly details the aim of the programme in respect to the screening service.

3.5.2 Significance of findings — Transparency

Statement of purpose

- Although BreastCheck has the Women's Charter, which clearly details the aim of the programme in respect of the screening service, a statement of purpose has a very different function. A statement of purpose provides specific detail on why the national data collection exits and clearly outlines its overall function and objectives. Publishing this information promotes transparency by informing the public and people who use the data about the national data collection.

3.6 Recommendations — Governance, leadership and management

Governance, leadership and management	
1.	**Governance structures in relation to information management**
	The National Screening Service should implement an appropriate governance structure in order to effectively address information management[***] within BreastCheck. Specifically, existing governance and management structures for information management need to be reviewed in light of the newly established Clinical Leadership Board. As part of this structure, executive responsibilities for information management should be clearly defined, documented and implemented.
2.	**Strategy for information management**
	The National Screening Service should develop a strategy for information management which clearly describes how effective information management will support and enhance screening; this should be based on international best practice and aligned to the Health Service Executive's eHealth Strategy. The strategy for information management should have clearly defined objectives and associated annual business planning.

[***] Information management is defined as the process of collecting, storing, managing, using and sharing health and social care information. It is a broad definition that includes the aspects of governance and management arrangements, data quality, information governance and use of information.

3.	**Monitoring of performance in relation to information management**
	The National Screening Service should develop a performance assurance framework for information management which is embedded within the governance structures. This should include monitoring performance against the annual business plan, measurement and reporting of key performance indicators (KPIs), conducting internal and external audit against aspects of information management, and risk management. A culture of risk management needs to be embedded at all levels of the organisation, particularly in relation to information management.
4.	**Compliance with legislation and privacy risk assessment**
	A formalised review of compliance against relevant legislation including the forthcoming General Data Protection Regulation (GDPR) should be undertaken. As part of this review, an assessment of privacy risks for BreastCheck should be conducted.
5.	**Formalised data sharing agreements**
	The National Screening Service should identify and develop formalised data sharing agreements as appropriate. These should be fully implemented and regularly monitored to ensure that information sharing is governed effectively.
6.	**Statement of purpose**
	BreastCheck should develop and maintain a publicly available statement of purpose that accurately describes its aims and objectives.

4. Use of Information

BreastCheck is an extremely valuable national repository of health information, maintained for the purpose of routine breast screening. The database includes demographic data, information on screening invitations and attendance, and clinical data associated with the screening process for women in Ireland within the age range for screening. This is a rich source of data which should be used to improve the quality of the service being provided to these women. It is also an important source of data for the public, clinicians, policy-makers and researchers, who may be interested in using the data or information. Health information is a valuable resource — wherever possible, it should be collected once and used many times — provided the appropriate protections and safeguards are in place.

It is now widely recognised that the appropriate sharing and effective use of information can bring enormous benefits.(31,32) In the healthcare sector, effectively using information is the key to driving quality improvements, leading to safer, more integrated care and greater prevention of ill health. Timely access to good quality information benefits a range of stakeholders by enabling individuals to make informed choices about their health; professionals to make better and safer decisions; managers to effectively deliver a high-quality service; policy-makers to strategically plan services; and researchers to establish best practice. In essence, there is a growing expectation that data held by national data collections will be shared and used optimally for the benefit of the service user and public health.(31,32)

For organisations that aim to maximise the use of information, there are two important considerations: the underlying data must be of good quality so that all stakeholders can confidently use the information to inform decisions and the data should be aligned with health information standards and nationally agreed definitions to enable comparability and support interoperability.

The HIQA review team assessed the theme 'Use of Information' at BreastCheck against Standards 5, 6 and 7 of the Standards for Information Management.

The findings of 'Use of Information' will be presented in following sections:

- Data Quality
- Accessibility and dissemination of information
- Use of health information standards and terminologies

4.1 Findings — Data quality

HIQA identified during the review that there is a strong emphasis on data quality within BreastCheck. Data quality is a key component of information management as it is essential that data is accurate, valid, reliable, timely, relevant, legible and complete.

As identified in Chapter 3, a Clinical Leadership Board has recently been established for the National Screening Service. It was not clear whether the Clinical Leadership Board, Senior Management Team (SMT) or BreastCheck-Executive Management Team (B-EMT) currently has responsibility for overseeing information management. As a result, the direction in relation to oversight and strategy in respect to data quality is not clear. Furthermore, as there is no scheme of delegation in place, there is no one with executive responsibility for data quality. However, HIQA identified that a Data Quality Manager position does exist and the position has responsibility for managing data quality within BreastCheck. During the review, HIQA was informed that the Data Quality Manager recently retired from her position and a contingency plan for a replacement was not in place. It was noted on the second site visit that a replacement for this position had not yet been identified. This is a key role within the organisation as identified through the information request and interviews with staff. The Data Officers received comprehensive training in data quality as well as a good level of support from the previous Data Quality Manager, which helped to promote and maintain continuous improvements in practice.

BreastCheck provided HIQA with 23 standard operating procedures (SOPs) in relation to data quality, which are used primarily by Data Officers to guide entry, editing, maintenance and validation of data. It was noted through the onsite assessments that a significant amount of activity is undertaken to improve data quality within the BreastCheck units. The review team received evidence, through the information request and in interview, to confirm that there is a culture within BreastCheck which encourages and supports data quality improvement, particularly for clinical data. Clinical data is entered and validated on a weekly basis by Data Officers in each unit, and the Performance Evaluation Unit runs reports on a monthly and annual basis to perform predefined quality checks. The role of the Data Quality Manager is to use these reports to review practices across all units. HIQA also identified a willingness to improve practice and acknowledge attempts to customise processes to incorporate data quality checks into the National Breast Screening Programme (NBSP). For example, the system prompts the user if the data entered appears to be incorrect and it will not allow the user to progress in the system until all mandatory fields are completed at each stage. Where possible, this helps to ensure data is accurate and complete on entry into the NBSP.

As outlined above, BreastCheck has many SOPs in place to evaluate, monitor and improve the quality of data; however, an overarching data quality framework had not been developed to plan a strategic and coordinated approach to data quality across the organisation and to incorporate all of the data quality dimensions into practice. In interview, BreastCheck acknowledged that a strategic approach would add value to current processes.

In interview, BreastCheck recognised that a challenge faced in regards to data quality is ensuring the population register is complete and accurate. The limiting factor for BreastCheck and the National Screening Service is that an Individual Health Identifier (IHI) is not yet available for the service. The population register team reported that they spend a considerable amount of time correcting information and checking for duplicates in the register. HIQA found some evidence that BreastCheck collaborates across programmes to improve the quality of data in each of the four registers. For example, the screening programmes share data on mortality at monthly meetings. However, the potential to further integrate practices across the four programmes was also recognised, particularly in the development of a data quality framework and in respect to improving the accuracy and completeness of the registers.

4.2 Findings — Accessibility and dissemination of data

HIQA identified that BreastCheck disseminates information by means of an annual report. The annual report is published online each summer for the previous year. The report contains summary statistics on overall screening activity, screening activity by invitation type, screening activity by age group, cancer detected by year, tumour grade, screening quality parameters, screening outcome by age group, cancers with non-operative diagnosis and BreastCheck Women's Charter parameters. The report is published on the BreastCheck website. The data is not available on the website in other formats. BreastCheck do not publish a data quality statement to accompany the report.

The review team were informed in interview that requests for access to BreastCheck's data are generally submitted by medical staff working in the screening units. BreastCheck have a policy and a document to outline the procedure for the release of data; however, these are not published online. The data request forms are available to employees within the organisation by contacting the Data Officers or the Performance Evaluation Unit. These forms are completed by the person requesting the data and reviewed by the Clinical Directors prior to the data being released.

Overall, in respect to sharing data, BreastCheck has not adopted an open data approach: it does not publish data on Ireland's Open Data Portal(33); it does not provide web-based tools for data user analysis and manipulation; and, in general, data is not shared externally, other than for the purposes of validating the population register, for example, with the National Cancer Registry Ireland.

4.3 Findings — Use of health information standards and terminologies

HIQA reviewed practices at BreastCheck to assess the use of health information standards and nationally agreed definitions to enable comparability and sharing of information.

BreastCheck informed HIQA through the self-assessment tool and in interview that they have recently adopted the use of the messaging standard Health Level 7 (HL7), which transfers clinical information between the Picture Archiving and Communication System (PACS) and Radiology Information System (RIS). BreastCheck has not adopted the use of any other health information standards or standard terminological systems, and it also does not publish a data dictionary.

4.4 Significance of findings — Use of information

Data Quality

- In reviewing data quality practices within BreastCheck, HIQA acknowledges that a significant amount of work is being undertaken to improve the quality of the data collected within the screening units. However, an overarching data quality framework was not in place to outline a coordinated approach to data quality across the organisation and to incorporate all of the data quality dimensions. The use of a data quality framework is recognised as good practice to establish the approaches which are necessary to systematically assess, monitor, evaluate and improve data quality. A data quality framework should include a data quality strategy, an audit schedule and KPIs which are used to monitor data quality and assess improvements overtime. In addition, as there is no scheme of delegation in place, there is no one with executive responsibility for data quality, which is a key element of a data quality framework.

- The Data Quality Manager has a key role in promoting and maintaining continuous improvements in practice. However, the person in this role retired during the review and a contingency plan for a replacement was not in place.

- The review team found some evidence that BreastCheck collaborates across the four screening programmes to improve the quality of data in each of the individual population registers. For example, the screening programmes share data on mortality at monthly meetings. The potential to further integrate practices across the four programmes was also recognised, particularly in the development of a data quality framework and in respect to improving the accuracy and completeness of the registers.

Accessibility and dissemination of information

- BreastCheck disseminates information by means of an annual report and, in general, the data is used by employees working within the organisation. The appropriate sharing and effective use of information, both internally and externally, can benefit a range of stakeholders by providing information to enable informed decision making. National data collections, including BreastCheck, should acknowledge a shift in practice and recognise the true potential and value of sharing information externally on a more extensive scale.

- To promote the effective use of information, it is important to include a section within the information management strategy on the accessibility and dissemination of data to make data and information more accessible to all stakeholders, which should be in line with relevant legislation and government policy. For example, NHS Digital publish data tables with information on women invited for breast screening, coverage, uptake of invitations, outcomes of screening and cancers detected. This data enables a range of stakeholders to use the data. It also provides data to enable service users to review practices across units, which promotes individual choice.(34) In 2015, NHS Digital published its Information and Technology Strategy which outlines an intention to make better use of health information by making more data and information available online. This information will allow citizens to make more informed choices about their health, it will help professionals to make better and safer decisions, support policy makers and encourage greater innovation and research.(35)

Compliance with health information standards

- BreastCheck has recently adopted the use of the messaging standard HL7 which is used for the transfer of clinical information between PACS and RIS.[†††] The benefit of adopting this messaging standard is that it provides BreastCheck with the capacity to share images and reports across different settings. The use of health information standards, such as healthcare messaging standards and standard terminological systems, bring a standardised approach to the sharing and comparability of health information. Health information standards not only benefit the organisation internally, as they help to maintain consistency in the collection of data and improve data quality, but they also facilitate the use of data across different services so data collected in one setting can be shared, combined or compared with data in another setting.

- BreastCheck does not publish a data dictionary. The publication of a data dictionary is recognised as good practice for enhancing data quality and maximising the use of information. The use of a data dictionary is also central to maintaining and improving the quality of data, as well as promoting the sharing of data, as it contains a descriptive list of names, definitions and attributes of data elements collected in an information system or database. Furthermore, a data dictionary facilitates the electronic sharing of information and improves communication and understanding for those collecting and using the data as it supports a shared understanding of the definitions.(36)

- In light of the implementation of the Knowledge and Information Plan(8) in the HSE and the eHealth Strategy(9) in the wider health service, it is important for BreastCheck to continuously review the approach to adopting health information standards and terminologies. A new information management strategy for the National Screening Service should address these requirements.

[†††] HL7 is an international healthcare messaging standard which outlines the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of clinical, administrative and service-user information.

4.5 Recommendations — Use of information

Use of information	
7.	**Data quality framework**
	To enhance ongoing work within BreastCheck in relation to data quality, an overarching data quality framework[‡‡‡] should be developed and implemented. The wider National Screening Service should be part of this process.
8.	**Health information standards and data dictionary**
	The use of health information standards and terminologies for BreastCheck should be assessed as part of the information management strategy of the National Screening Service. In addition, BreastCheck should develop and implement a data dictionary to ensure consistency and to enable accurate use and interpretation of data. This should be kept updated regularly and made publicly available.
9.	**Accessibility and dissemination of information**
	In line with legislation and government policy, BreastCheck should make data and information more accessible in a timely manner to all stakeholders, including patients, clinicians, policy makers and researchers, in order to address their needs. This should be developed incrementally and aligned to an information management strategy.

[‡‡‡] Guidance for a Data Quality Framework for health and social care is currently being developed by HIQA in conjunction with all major national data collections in Ireland and will be published in 2018.

5. Information governance

National data collections, such as BreastCheck, are repositories for large volumes of sensitive and important health information. Health information is considered to be the most sensitive form of information and, therefore, extra precautions need to be taken to protect privacy. The process of collecting, using, storing and disclosing personal health information can present a risk to privacy and confidentiality of service users. National data collections have an obligation, under legislation, to protect personal health information. Information governance provides a means of bringing together all the relevant legislation, guidance and evidence-based practice that apply to the handling of information.

Robust information governance arrangements focus on the following areas: the maintenance of privacy and confidentiality of individuals; the protection of information security; the generation of high-quality data; and the implementation of appropriate safeguards for the secondary use of information. In Chapter 4, the use of information and the generation of high-quality data were discussed in detail due to the significance of enhancing the appropriate use of good-quality data for a wide range of stakeholders. However, data quality will be further considered in this chapter in the context of developing good information governance practices.(36,37)

Good information governance enables personal health information to be handled legally, securely, efficiently and effectively in order to deliver the best possible service. The main aim of information governance is to create a balance between effectively using information and meeting the needs of the service user while also respecting an individual's privacy. To develop good information governance practices, it is necessary for an organisation to have the structures and processes in place to provide clear direction to staff:

- Responsibility and accountability for information governance must be clearly defined, and the appropriate governance and management structures should be outlined. These arrangements should align to and integrate with the organisation's overall governance structure. Formalised arrangements are essential to ensure that there are clear lines of accountability for information governance. All staff should be aware of their responsibilities for information governance, and management should assign specific tasks to named staff members.

- A culture of information governance is embedded within the organisation through the development of policies and procedures to help all staff to comply with legislation and information governance requirements as well as identifying training requirements on a routine basis. Employees should be promoted and supported by management to engage in good information governance practices as part of their routine working schedule.

- Organisations need to perform information governance assessments to identify good practice and to highlight areas that need improvements. Self-assessments — in the form of internal and external audits, monitoring of key performance indicators (KPIs) and assessing risk — are necessary to examine compliance with policies and procedures, to identify specific training needs of employees and to ultimately identify and implement improvements to information governance practices based on the findings.

The HIQA review team assessed the information governance and person-centred arrangements at BreastCheck against Standards 1 and 8 of the Information Management Standards.

The findings will be presented in following sections:

- Information governance structures in BreastCheck
- Effective arrangements to assess and manage information governance

5.1 Findings — Information governance structures in BreastCheck

As identified in Chapter 3, a Clinical Leadership Board has recently been established for the National Screening Service. It was not clear whether the Clinical Leadership Board, the Senior Management Team (SMT) or the BreastCheck-Executive Management Team (B-EMT) currently has responsibility for overseeing information management. As a result, the direction in relation to oversight and strategy in respect to information governance is not clear. Information governance is a key component of information management as it is essential to maintain the privacy and confidentiality of individuals, to protect information security, to generate high-quality data and to implement the appropriate safeguards for the secondary use of information.

As there is no scheme of delegation in place, there is no one with executive responsibility for information governance. However, HIQA identified a number of individuals with responsibility for specific elements of information governance: the IT Manager and the Database Administrator share responsibilities for information security; the Data Quality Manager, when the position is filled, holds responsibility for managing data quality; and a recently appointed Data Protection Officer is responsible for protecting the privacy and confidentiality of service users.

HIQA was informed that BreastCheck has a Data Team, the function of which includes information governance management such as database management and governance; promoting information security; maintaining and improving data quality; and data protection and patient confidentiality. This team also reviews any suggested or required change to the National Breast Screening Programme (NBSP) and are responsible for updating relevant policies. The specific responsibilities of the team are listed in Table 2. The membership of the data team, as outlined by BreastCheck, includes:

- Unit Managers (x4)
- IT Manager
- Director of Evaluation
- Head of Program Evaluation Unit
- Register Manager

- Database administrator
- QA Co-ordinator
- Data Officers
- Data Quality Manager
- Research Officers
- Statistician.

The Data Team manages its functions through two groups: the Policy Group and the Database Group. At the time of the review, the chair of the Policy Group was the Head of Program Evaluation Unit and the chair of the Database Group was the Database Administrator. The groups aim to meet every six weeks, and they record minutes and actions arising from meetings. The specific purpose and membership of the Policy Group and the Database Group were not documented. Although the Data Team manage elements of information governance, other teams, such as the Record Retention Team, also address specific information governance issues. BreastCheck provided HIQA with a list of teams for which information governance is a core responsibility, albeit not the primary functions of the teams (See Appendix 5). HIQA noted that, at the time of the review, the Data Protection Officer sat on the Record Retention team but not on the Data Team even though HIQA was informed that the Data Team had responsibility for data protection.

The Data Team reports to the B-EMT. However, the specific reporting arrangements were not clear, such as who has overall responsibility for escalating issues and risks to the B-EMT and by what means the B-EMT is kept informed of developments or issues.

Table 2. Data team functions

Specific functions of the Data Team
Oversight of all data issues and governance
Manage and evaluate the database
Ensure correct matching of client data
Ensure clinical data quality
Ensure demographic data completeness and accuracy
Ensure data security
Evaluate programme standards/report KPIs
Produce annual report
Carry out audits

5.2 Findings — Effective arrangements to assess and manage information governance

HIQA reviewed the arrangements within BreastCheck used to assess and manage information governance. In interview, the review team identified that information governance was a high priority within the organisation and that many processes are in place;

however, management acknowledged that the programme lacks a strategic and coordinated approach to managing information governance. Senior management also acknowledged that they are undertaking a significant amount of activity in this area but they are not systematically and consistently documenting practices.

5.2.1 Legislation, policies and procedures

In respect to demonstrating compliance with relevant legislation, BreastCheck identified three pieces of legislation that apply to the programme, namely, the Data Protection Act 1988, the Data Protection (Amendment) Act 2003 and the Health (Provision of Information) Act 1997. Another key piece of legislation relevant to the management of information is the Freedom of Information Act 2014. The review team identified that necessary preparations for the forthcoming General Data Protection Regulation (GDPR) were at an initial stage of development and implementation.

BreastCheck provided a list of the policies and procedures that they adhere to in the area of information governance. These included a list of the HSE policies and standards as detailed in Table 3 below.

Table 3. HSE Policies and Standards in relation to information governance

HSE ICT policies and standards
Information Security Policy
I.T. Acceptable Use Policy
Electronic Communications Policy
Mobile Phone Device Policy
Password Standard Policy
Encryption Policy
Access Control Policy
Remote Access Policy
Information Classification
Data Protection Breach Management Policy
Internet Content Filter Standard
Service Provider Confidentiality Agreement
Third Party Network Access Agreement
HSE Standard Terms for ICT Services and Supplies
HSE Vendor Participation Framework Agreement for ICT Services and Supplies
HSE ICT Infrastructural and Operational Technical Standards for the Deployment of Computer Based Systems Version 2.04

In interview, management highlighted that the HSE policies were sufficient for the needs of the organisation and that additional policies were developed as required. For example, a data security for USB flash drives policy, a systems continuity strategy, a standby invocation procedure and a release of data policy had been developed by the programme. Furthermore, at the time of the second site visit, a records retention policy was being developed.

In respect to information security arrangements, in interview HIQA were informed that BreastCheck ensures that access to the NBSP is based on need. All staff members are provided with role-based access, which is specified and approved by line managers. Furthermore, the IT department can track access to information and amendments to files containing personal identifiable information. BreastCheck provided evidence that a network security audit is carried out annually which focuses on the networks under the management of an external company. However, BreastCheck did not provide evidence of audits to assess compliance against any of the policies and procedures listed above.

As outlined in Chapter 4, BreastCheck has many processes and procedures in place to evaluate, monitor and improve the quality of data. However, a data quality policy was not in place to incorporate all of the data quality dimensions for each of the data processing activities.

HIQA also identified that the organisation has a consent form for patients to enable the sharing of personal health information for the purposes of providing screening. All service users provide consent on arrival in the screening unit prior to commencing the screening process. This consent enables BreastCheck to share personal health information for the purposes of providing the screening service and to assist BreastCheck in examining the impact of screening on reducing mortality. HIQA did not identify a policy to outline the process of obtaining consent for purposes other than that outlined in the standard consent form. This policy should clearly outline the circumstances in which it is necessary to seek specific consent for using data beyond the purposes for which service users have consented.

Furthermore, as outlined in Section 3.3, currently BreastCheck does not have KPIs or a specific audit schedule to review compliance with relevant legislation and policies in the area of information governance.

5.2.2 Training and education

BreastCheck has a very thorough data quality training schedule for the Data Officers. Other than this formal training, information governance education is delivered by means of an online information governance module through HSeLanD.(38) The review team were informed that an email had been sent to all employees highlighting that it was a mandatory requirement to complete this training; however, figures on how many employees had completed the training were not available.

5.2.3 A culture of information governance

HIQA identified that there was an awareness of information governance within BreastCheck, particularly in the areas of maintaining an individual's privacy and ensuring and improving the quality of data in the BreastCheck units. The review team recognised that employees in the screening units were acutely aware of the importance of maintaining the privacy and confidentiality of individuals. Staff at all levels also recognised the importance of high-quality data and knew their responsibility in respect to collecting and storing data that was accurate and complete. There was also a general awareness of information security issues, particularly in relation to the appropriate use of computers and laptops and access to areas storing information within the screening units. In reviewing the management of data breaches, HIQA identified a lack of consistency and awareness about the definition of a breach of information among staff. However, senior staff recognised the actions to take if a breach was to occur. BreastCheck provided HIQA with documentation to demonstrate the action taken for two instances that occurred in the latter stages of the review, one breach and one near-miss. The reports outline the implementation of remedial and preventative changes.

HIQA recognised areas which would further enhance privacy controls and mitigate potential risks. For example, at the time of the review BreastCheck had not completed a review to identify if a privacy impact assessment (PIA) was required to manage potential risks and implement necessary controls to help maintain individual's privacy. Furthermore, as discussed in Chapter 3 the use of formalised data sharing agreements when sharing data would improve quality and reduce potential risks. HIQA also recognised that further education and training in the area of information governance would create a better balance between maintaining privacy and security while effectively using information, both internally and externally.

Finally, the review team found that BreastCheck do not publish a Statement of Information Practices to describe how personal information is used or to detail the submission process for a freedom of information request. These arrangements would enhance a patient-centred and transparent approach to the processing of health information, which will be a requirement under the forthcoming GDPR.(39)

5.3 Significance of findings — Information governance

Information governance arrangements

- HIQA found that there is a general awareness of the significance and importance of information governance in BreastCheck. While there are identified individuals with responsibility for some aspects of information governance, there is a need to delegate executive responsibility for information governance. These arrangements should include assigning specific roles and responsibilities for the four aspects of information governance including data quality, privacy and confidentiality, information security and the use of information throughout BreastCheck. Furthermore, the governance structures, including reporting structures, need to be clear for the many teams with responsibility for information management to identify, report and manage risks appropriately.

- Management within the organisation acknowledged that the BreastCheck programme lacks a strategic and coordinated approach to managing information governance. A well-governed and managed organisation needs an assurance framework to routinely review adherence to information governance policies and procedures and current and forthcoming legislation. A robust process to monitor information governance performance at a senior management level is essential. This should include the use of KPIs, audit and risk management. These measures are required to regularly provide assurance to the Head of Screening and senior management that the programme is managing information governance appropriately.

Information Security

- BreastCheck provided evidence that a network security audit is carried out annually. However, currently there is no audit schedule in place to assess compliance against ICT policies and procedures. Information security is necessary to protect personal and sensitive health information from a wide array of threats such as unauthorised access to data, as well as unauthorised amendment, destruction or disclosure of data. This can only be achieved by implementing appropriate policies and procedures. Information security controls need to be continuously monitored, reviewed and improved to maintain the highest level of protection.(36) BreastCheck would benefit from an audit plan to assess compliance against the relevant information security policies and procedures.

Privacy and confidentiality

- Service users provide consent on arrival in the BreastCheck screening unit prior to commencing the screening processes, which enables BreastCheck to share personal health information for the purposes of providing the screening service and to assist BreastCheck in examining the impact of screening on reducing mortality. HIQA did not identify a policy to outline the process of obtaining consent for purposes other than that outlined in the standard consent form. This policy should clearly outline the circumstances in which it is necessary to seek specific consent for using data beyond the purposes for which service users have consented. An organisation with robust information governance practices provides assurances to service users that their personal health information will not be disclosed inappropriately.

- BreastCheck provided HIQA with documentation to demonstrate the action taken for two instances of data breaches, including a near-miss. Routinely reporting near-misses is important as this practice will create learning opportunities and will help to avoid a similar event or incident from occurring in the future. BreastCheck has defined reporting structures and investigation procedures for information breaches; however, it is important to enhance communication and education with staff so they have the appropriate knowledge and awareness to routinely report both incidences and near-misses.

- Necessary preparations for the GDPR should be agreed and implemented in order to meet forthcoming legal obligations.

- BreastCheck currently does not publically report a statement of information practices. A simple method employed by organisations to comply with the principle of transparency is to publish a statement of information practices which outlines what information the service collects, how it is used, whom it is shared and for what purpose, the safeguards that are in place to protect it and how people can assess information held about them.(40) Service users have a right to control when, where and with whom to share their personal health information, and these rights are enshrined in the current data protection legislation.(39) The rights of the individual about whom data is held will be further enhanced through GDPR.(39,41,42)

- Furthermore, as stated in section 3.4, under GDPR there will be a mandatory obligation for organisations to conduct a privacy impact assessment where a processing is 'likely to result in a high risk'. Organisations should undertake a review to assess the need for a PIA.(29)

Training

- BreastCheck has a very thorough data quality training schedule for the Data Officers. Other than this formal training, information governance education is delivered by means of an online information governance module through HSeLanD; however, currently the completion of this course is not monitored by management. A comprehensive training plan is necessary to embed a culture of information governance within the organisation.

5.4 Recommendations — Information governance and workforce

Information governance	
10.	**Effective arrangements in place for information governance**
	As part of an information management strategy and annual business plan for the National Screening Service, effective arrangements should be put in place for information governance within BreastCheck. This includes: ▪ assigning an individual with responsibility for information governance within the National Screening Service ▪ providing assurance in relation to adherence to policies and procedures, and current and forthcoming legislation for information governance through reporting of KPIs, audit and risk management ▪ developing and implementing a training plan for staff to embed a culture of information governance within BreastCheck.
Workforce	
11.	**Skilled workforce in relation to information management**
	BreastCheck should conduct a workforce planning exercise in relation to information management to ensure that the appropriate skilled workforce is in place, to include the following areas: ▪ data quality ▪ information governance, including the impact of legislative changes ▪ data analytics and the use of information.

6. Conclusion

The aim of this review was to assess the compliance of BreastCheck with the Information Management Standards. Ultimately, the overall review programme of national data collections in Ireland aims to drive improvements by identifying areas of good practice and areas where improvements are necessary across national data collections.

BreastCheck was established with the remit of providing a population-based breast screening programme for women aged 50 to 64. The service is currently being extended to women aged 50 to 69, and, by the end of 2021, all women within this age group will be invited for routine screening. BreastCheck currently provides screening through a network of four static units and 19 mobile units throughout the country. In the context of screening, information management is crucial as a comprehensive screening service can only be delivered if the programme has a complete and accurate population register. Furthermore, to provide a high quality and safe screening service it is necessary for clinical information to be handled and processed efficiently. The process of screening generates large volumes of personal health information and relies heavily on accurate documentation and communication of information about health status, processes of care and outcomes of care. Service users want to be assured that their information will be managed correctly so that they will receive timely, efficient and effective care if a cancer is detected.(5) Furthermore, good information management practices are necessary to provide assurances that the organisation is achieving its objectives through careful strategic and business planning, and monitoring performance against these targets.

Effective information management leads to enhanced knowledge and understanding for all involved in providing and using the service as it instils confidence in service users, clinicians and all other stakeholders that decisions are made based on high-quality information, the availability of which will ultimately improve outcomes from screening.(2) Furthermore, good information management promotes assurance that information will be held securely, it puts in place the necessary precautions to maintain individuals' privacy and confidentiality, it facilitates greater empowerment and involvement by communicating effectively with the public and, ultimately, it creates a culture in which information will be used more effectively.(7)

The 11 recommendations outlined in this report should be considered in conjunction with the findings of this review in order to improve information management practices in BreastCheck. The National Screening Service is responsible for preparing and implementing quality improvement plans to ensure that the areas for improvement are prioritised and implemented in order to comply with the Information Management Standards. National data collections should continue to assess their adherence to the standards in between reviews by HIQA to assure that they are meeting the requirements of the Information Management Standards.

References

1. Health Act 2007. Available from: http://www.irishstatutebook.ie/eli/2007/act/23/enacted/en/print, (2007).
2. Health Information and Quality Authority. *Information management standards for national health and social care data collections*. Dublin: 2017.
3. Health Information and Quality Authority. *Guide to the Health Information and Quality Authority's review of information management practices in national health and social care data collections*. Dublin: 2017.
4. Anttila A, Lonnberg S, Ponti A, Suonio E, Villain P, Coebergh JW, et al. Towards better implementation of cancer screening in Europe through improved monitoring and evaluation and greater engagement of cancer registries. European journal of cancer (Oxford, England:1990). 2015;51(2):241-51.
5. CervicalCheck. *Guidelines for Quality Assurance in Cervical Screening*. Dublin: 2014.
6. Health Information and Quality Authority. *Guidance on Developing Key Performance Indicators and Minimum Data Sets to Monitor Healthcare Quality*. Dublin: 2013.
7. Health Chief Information Officer Council. *Information for Health. A Strategic Plan for Health Information Management in British Columbia 2002/03 – 2006/07*. British Columbia: 2002.
8. Health Service Executive. *Knowledge & Information Strategy*. Office of the Chief Information Officer. 2015.
9. Department of Health. *eHealth Strategy for Ireland*. Dublin: 2013.
10. Health Information and Quality Authority. *National Standards for Safer Better Healthcare*. Dublin: 2012.
11. Department of Health. *Strategy for Cancer Control in Ireland*. Dublin: 2007.
12. National Screening Service. *About the National Screening Service*. 2017. Available from: http://www.screeningservice.ie/about/index.html. Accessed on: 24/10/17.
13. BreastCheck. *BreastCheck Programme Report 2015/16*. Dublin: 2017.
14. BreastCheck. *BreastCheck- Breast Screening*. 2017. Available from: https://www.breastcheck.ie/. Accessed on: 24/10/17.
15. BreastCheck. *Guidelines for Quality Assurance in Mammography Screening*. Dublin: 2015.
16. Health (Provision of Information) Act, 1997. Available from: http://www.irishstatutebook.ie/eli/1997/act/9/enacted/en/html, (1997).
17. National Screening Unit. *Strategic Plan 2010-2015*. New Zealand: 2010.

18. Health Information and Quality Authority. *Corporate Plan 2016-2018*. Dublin: 2016.
19. Department of Health. *Quality and Fairness – A Health System for You*. Dublin: 2001.
20. Department of Health. *National cancer strategy 2017 - 2026*. Dublin: 2017.
21. Health Service Executive. *HSE Transformation Programme….to enable people live healthier and more fulfilled lives. The Health Service Executive Population Health Strategy.* Dublin: 2008.
22. Health Service Executive. *National Service Plan*. Dublin: 2016.
23. Health Service Executive. *Health & Wellbeing Division Operational Plan 2016*. Dublin: 2016.
24. National Screening Service. *National Screening Service Business Plan*. Dublin: 2017.
25. National Health Service. *Information Management & Communications Technology Strategy*. Wales: Conway & Denbighshire NHS Trust. 2007.
26. National Health Service. *IM&T Strategy 2012-2017*. England: North Tees and Hartlepool. 2012.
27. Health Service Executive. *Performance Profile- July – September 2017 Quarterly Report*. Dublin: 2017.
28. Health Service Executive. *HSE Integrated Risk Management Policy Incorporating an overview of the Risk Management process*. 2017.
29. Health Information and Quality Authority. *Privacy Impact Assessment toolkit for health and social care*. Dublin: 2017.
30. REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), (2016).
31. Department of Public Expenditure and Reform. *Open Data Strategy.* Dublin: 2017
32. National Data Guardian. *Information: To Share Or Not To Share? The Information Governance Review*. England: 2013.
33. Irish Government. *Ireland's open data portal*. 2017. Available from: https://data.gov.ie/data. Accessed on: 24/10/17.
34. NHS Digital. *Breast Screening Programme, England - 2014-15* 2017. Available from: https://digital.nhs.uk/catalogue/PUB20018. Accessed on: 24/10/17.
35. Health and Social Care Information Centre. *Information and technology for better care- Health and Social Care Information Centre Strategy 2015–2020*. England: 2015.
36. Health Information and Quality Authority. *Guidance on information governance for health and social care services in Ireland*. Dublin: 2010.

37. Health Information and Quality Authority. *What you should know about Information Governance- A Guide for health and social care staff.* Dublin: 2011.
38. Health Service Executive. *HSeLanD - the Health Services e-Learning and Development service*. 2017. Available from: http://www.hseland.ie/dash/Account/Login. Accessed.
39. Data Protection Act 1988 (Ireland). Available from: http://www.irishstatutebook.ie/eli/1988/act/25/enacted/en/html, (1988).
40. Health Information and Quality Authority. *Five quality improvement tools for national data collections*. Dublin: 2017.
41. EU Directive 95/46/EC. The Data Protection Directive 1995. Available from: http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf, (1995).
42. Data Protection Commission. *The GDPR and You- General Data Protection Regulation. Preparing for 2018.* Dublin: 2017.
43. Health Information and Quality Authority. *Catalogue of National Health and Social Care Data Collections in Ireland*. Dublin: 2017.
44. Health Information and Quality Authority. *Guiding Principles for National Health and Social Care Data Collections*. Dublin: 2013.
45. Health Information and Quality Authority. *Recommendations on a More Integrated Approach for National Health and Social Care Data Collections*. Dublin: 2014.
46. Health Information and Quality Authority. *What you should know about data quality- A guide for health and social care staff*. Dublin: 2012.
47. Health Information and Quality Authority. Guidance on Privacy Impact Assessment (PIA) in Health and Social Care. 2017.
48. Information Commissioner's Office. *Data sharing code of practice*. England: 2011.

Appendices

Appendix 1 — Key publications by HIQA in relation to national health and social care data collections

- A catalogue of all national health and social care data collections in Ireland was first published in 2010 and was most recently updated in 2017 — *Catalogue of National Health and Social Care Data Collections in Ireland.*(43) The current catalogue features 120 data collections. National health and social care data collections vary in size from large data repositories, such as the National Perinatal Reporting System (NPRS), to smaller patient registries, such as the Alpha-1 Research Registry.
- In 2013, HIQA published *Guiding Principles for National Health and Social Care Data Collections,*(44) which provide current and new national health and social care data collections with advice and guidance on best practice.
- In 2014, HIQA published and submitted to the Minister for Health *Recommendations on a More Integrated Approach for National Health and Social Care Data Collections.*(45) These recommendations emphasise the need for a strategic framework to inform policy development in this area. The implementation of these recommendations has the potential to reduce fragmentation and duplication and ensure a more consistent approach to improving the quality of data collected.
- HIQA has published a number of detailed guidance documents on best practice for information management:
    - *What you should know about information governance: a guide for health and social care staff*(37)
    - *Guidance on information governance for health and social care services in Ireland*(36)
    - *What you should know about data quality- a guide for health and social care staff*(46)
    - *Five quality improvement tools for national data collections, 2017*(40)
    - *Guidance on privacy impact assessment (PIA) in health and social care*(47)
    - *Privacy impact assessment (PIA) toolkit for health and social care*(29)

Appendix 2 — Steps used to identify the target population for the National Breast Screening Programme

- Files are received from data providers which contain new and updated information.
- Change information is downloaded from the information system, NBSP, into a file.
- The files are sent to the data processing company.
- The data processing company cleans the address information and assigns ED codes.
- The data processing company sends the amended information back to BreastCheck and the database is updated accordingly.
- The data processing company sends information about possible duplicates.
- A program is used to automatically merge positive duplicates.
- The registration team reviews additional duplicates and amend the relevant records manually.

Appendix 3 — BreastCheck key performance indicators (15)

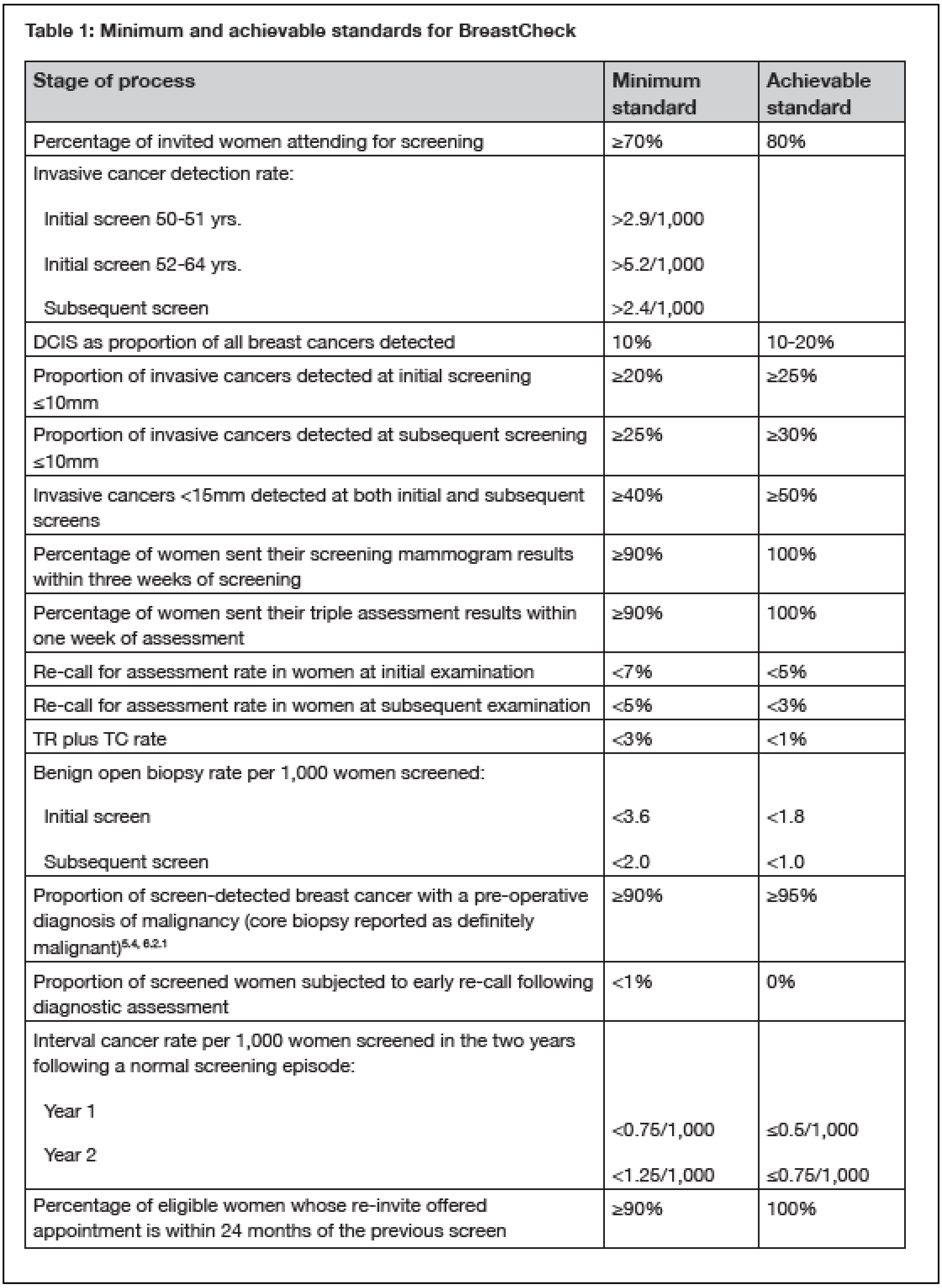

Table 1: Minimum and achievable standards for BreastCheck

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.	>2.9/1,000	
Initial screen 52-64 yrs.	>5.2/1,000	
Subsequent screen	>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	<3.6	<1.8
Subsequent screen	<2.0	<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	<0.75/1,000	≤0.5/1,000
Year 2	<1.25/1,000	≤0.75/1,000
Percentage of eligible women whose re-invite offered appointment is within 24 months of the previous screen	≥90%	100%

Appendix 4 — Data sharing agreements

Data sharing agreements should document, at a minimum, the following:

- the purpose(s) of sharing
- legal basis for sharing (if applicable)
- the potential recipients or types of recipients and the circumstances in which they will have access
- the data to be shared
- data quality — relevant data quality dimensions
- data security
- retention of shared data
- individuals' rights — procedures for dealing with access requests, queries and complaints
- review of effectiveness/termination of the sharing agreement
- sanctions for failure to comply with the agreement or breaches by individual staff.(48)

Appendix 5 — Committees with information management responsibilities

Committee	Membership	Function
QA Committee	-Head of Screening -Clinical Directors x4 -Operations Manager -National Radiology Services Manager -QA coordinator -QA pathologist -QA Surgeon -Director of Evaluation -Head of PEU -Eccles Unit Manager -Chief Physicist -Clinical Nurse -PA to Clinical Director	The function of the QA Committee is to: oversee the implementation of the QA document; advise the National Screening Service senior management of QA issues; ensure that all professionals participating in the screening programme are fully trained and comply with performance guidelines; formulate QA policy; and to ensure that results at local and national levels are produced in a complete and timely manner.
QA Imaging Committee	-Chief Physicist; -Merrion QA Radiology -Eccles QA Radiology -South QA Radiology -Physicist x2 -Senior Physicist -National Radiology Services Manager -Radiology Services Manager, Merrion Unit -Radiology Services Manager, South Unit -Radiology Services Manager, West Unit -Radiology Services Manager, Eccles Unit -PACS manager	The function of the QA imaging committee is to: advise and inform B-EMT of any ongoing QA issues with service delivery; audit and discuss clinical quality and safety issues associated with equipment and client care; physics QA; and NBSP data input.
Risk Assessment Committee	-QA Co-ordinator (Chair) -Clinical Director, West Unit -Unit Manager, Eccles -Unit Manager, West -Unit Manager, South -Unit Manager, Merrion -National Radiology Services Manager -Radiology Services Manager, Merrion Unit -Radiology Services Manager, South Unit -Radiology Services Manager, West Unit -Radiology Services Manager, Eccles Unit	The function of the Risk Assessment Committee is to: assess risk with a view to proceeding to a paper light situation; present any issues that may require change to B-EMT; perform a risk analysis on BreastCheck operations; provide an overview of the monthly database; update of database duplicates carried out in units; provide an overview of attendance for digital mammogram; digital mammogram process; administration procedures for recall to assessment clinic; and an overview of assessment.

Committee	Membership	Function
	-PACS Manager -Head of ICT -Database Administrator -Data Quality Manager -Scheduler	
Radiation Safety Committee	-Clinical Director (Chair) -Chief physicist -National Radiology Services Manager -Radiation safety Officer	The function of the Radiation Safety Committee is to: establish and review policies; receive reports of radiation safety incidents; review, update and approve the radiation safety manual; ensure that the manual is read by all members of staff who will be using ionising radiation; carry out audits on identification procedures and safety compliance.
PACS Oversight Committee	-PACS Manager -Chief Physicist -PACS administrator -Radiologist -Database Manager -QA Coordinator -National Radiology Services Manager	The function of the PACS Oversight Committee is to: advise the National Screening Service and B-EMT in relation to: clinical and technical issues associated with PACS; clinical quality and safety issues associated with utilization of digital imaging and PACs; identify and lead ongoing development and change controls in respect to technical and clinical issues, digital imaging processes and clinical and administrative workflow; identify and lead the development of processes and SOPs associated with digital imaging and PACs; identify and prioritise ongoing development of interfaces and integration with the NBSP; coordinate clinical and admin training in PACS; develop necessary linkages with host hospital PACS system and future national PACS to enable efficient and secure sharing of clinical information between BreastCheck and other host hospitals; in conjunction with PEU, co-ordinate the collection, analysis and reporting of clinical data associated with the transition to digital imaging.
RSM Group	-Radiology Services Manager, Merrion Unit -Radiology Services Manager, South Unit -Radiology Services Manager, West Unit -Radiology Services Manager, Eccles Unit -National Radiology Services Manager	The function of the RSM Group is to: manage radiographers in each of the four units. This includes data management and training of radiographers in safe accurate data input and analysis; ensure privacy when confirming patient information/identification; ensure data protection manual is read and adhered to; oversight of uploading and PACS super users; and liaising with National RSM and PACS manager on all imaging issues.

Committee	Membership	Function
Record Retention	-Data Protection Officer -Chief physicist -QA Co-ordinator -Data administrator -PACS administrator -PACS Manager	The function of this group is to: review image retention and develop a management system for retention or deletion of imaging; and any data going forward in accordance with national guidelines.
GDPR Group	Newly established — not documented	Newly established — not documented

Appendix 6 —Glossary of abbreviations

Abbreviation	**Explanation**
AMA	Authority Monitoring Approach
B-EMT	BreastCheck – Executive Management Team
CIDR	Computerised Infectious Disease Reporting
CSR	Cervical Screening Register
DSP	Department of Social Protection
ED	Electoral Division
GDPR	General Data Protection Regulation
GMS	General Medical Services
GP	General Practitioner
HIQA	Health Information and Quality Authority
HIPE	Hospital In-Patient Enquiry
HL7	Health Level 7
HSE	Health Service Executive
ICT	Information and Communications Technology
IHFD	Irish Hip Fracture Database
IHI	Individual Health Identifier
IT	Information Technology
KPI	Key Performance Indicator
NBSP	National Breast Screening Programme
NCRI	National Cancer Registry of Ireland
NPRS	National Perinatal Reporting System
NSS	National Screening Service
PACS	Picture Archiving and Communications System
PIA	Privacy Impact Assessment
QA	Quality Assurance
RIS	Radiology Information System
RSM	Radiology Services Manager
SMT	Senior Management Team
SOP	Standard Operating Procedure

Appendix 7 —Glossary of terms

Classification systems: these provide a uniform, meaningful and relevant framework that is used as a common language. An example is the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10).

Clinical terminologies: a structured collection of descriptive terms for use in clinical practice, used by clinicians to describe the assessment of and care given to patients during a consultation. An example is SNOMED CT (Systematised Nomenclature Of Medicine-Clinical Terms).

Computerised Infectious Disease Reporting (CIDR): an information system developed to manage the surveillance and control of infectious diseases in Ireland. It also monitors organisms' ability to resist antibiotic drugs (antimicrobial resistance).

Data: the building blocks for information. It has been described as numbers, symbols, words, images and graphics that have been validated but yet to be organised or analysed.

Database: a collection of data that is organised so that its contents can easily be accessed, managed and updated.

Data dictionary: a descriptive list of names (also called representations or —displays), definitions and attributes of data elements to be collected in an information system or database. The purpose of the data dictionary is to standardise definitions and ensure consistency of use. It is a tool to aid in the standardisation of data definitions.

Data quality: data that are complete, valid, accurate, reliable, relevant, legible and available in a timely manner.

Data quality framework: a document which outlines the approaches to systematically assess, document and improve data quality and includes data quality policies and procedures; key performance indicators and metrics; audits; and improvement initiatives.

Data quality statement: a statement prepared to accompany all published outputs from the national health and social care data collection which highlights the dimensions of data quality, including strengths and weaknesses, so that potential data users can make informed judgments about fitness for use.

Data provider: any person, organisation, or part of an organisation contributing data to the national health or social care data collection, for example, a hospital, general practitioner or laboratory.

Data user: any user of data or information produced by the national health and social care data collection.

Formalised agreements: agreements between the national health and social care data collection and data providers that outline the responsibilities and deliverables of both parties and the associated timelines. This could take the form of, for example, a service level agreement.

Information and communication technology (ICT): the tools and resources used to communicate, create, disseminate, store, and manage information electronically.

Information governance: the arrangements that are in place to manage information to support national health and social care data collections' immediate and future regulatory, legal, risk, environmental and operational requirements.

Information: information is data that has been processed or analysed to produce something useful.

Interoperability: the ability of National Health and Social Care Data Collection to work together within and across organisational boundaries in order to advance the effective delivery of healthcare for individuals and communities.

Irish Hip Fracture Database (IHFD): a web-based system that uses the Hospital In-patient Enquiry (HIPE) portal infrastructure. It audits care standards and outcomes for patients with hip fractures.

Key performance indicators (KPIs): specific and measurable elements of practice that are designed to assess key aspects of structures, processes and outcomes.

Management committee: this committee is responsible for focusing on the operational functions of the national health and social care data collection.

Managing organisation of the national health and social care data collection: the organisation, agency, responsible managing unit, institution or group with overall responsibility for the national health and social care data collection.

National health and social care data collection: National repositories of routinely collected health and social care data, including administrative sources, censuses, surveys and national patient registries in the Republic of Ireland.

National Cancer Registry of Ireland (NCRI): the body that maintains a national registry of cancer cases and deaths for the whole population in the Republic of Ireland.

Personal health information: data relating to an individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller. The term personal health information is broad and includes such matters as personal information relating to the physical or mental health of the individual as well as any genetic data or human tissue data that could be predictive of the health of the individual or his or her relatives or descendants. In essence, it covers any information relating to an individual that is collected for or in connection with the provision of a health service.

Privacy impact assessment (PIA): a process designed to identify and address the privacy issues of a particular initiative. It considers the future consequences of a current or proposed action by identifying any potential privacy risks and then examining ways to mitigate or avoid those risks that have been identified.

Risk assessment: the overall process of risk analysis and risk evaluation.

Service provider: any person, organisation or part of an organisation delivering health or social care services and contributing data to the national health and social care data collection, for example, a hospital, pharmacy, general practitioner, optician, screening services, residential care for older people or children's residential centres.

Service user: any person who uses or is a potential user of a health or social care service. For example, a patient, client or resident.

Stakeholder: a group/person/expert who is significantly involved with/affected by the work of the national health and social care data collections.

Statement of information practices: a document made available to service users that sets out what information the service collects; how it is used; with whom it is shared and for what purpose; the safeguards that are in place to protect it; and how service users can access information held about them.

Statement of purpose: a publically available document which succinctly captures why the national health and social care data collection exists and clearly outlines its stated objectives.

Health Information and Standards Directorate
Health Information and Quality Authority
Unit 1301, City Gate,
Mahon,
Cork
T12 Y2XT