BreastCheck
Data Quality Statement

Data Quality Statement to accompany data released by BreastCheck. It includes data quality assurance, contextual information, the methods used to compile the statistics and other background information that data users may find useful.

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

BreastCheck
The National Breast Screening Programme

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1. Introduction

BreastCheck provides a population-based breast screening programme. Its target population is women aged 50 to 69 years old and the screening interval for BreastCheck is biennial[1]. In order to identify the target population for the National Breast Screening Programme, BreastCheck requires maintenance of a population register[i] of women within the screening age range. This information is held by BreastCheck as a Population Register. BreastCheck also collects selected data pertaining to BreastCheck service users (Appendix A). The population registry data and the selected data are kept on the National Breast Screening Programme Database (known as 'NBSP').

2. Purpose

A Data Quality Statement (DQS) is a statement prepared to accompany data releases from national data collections that highlight the dimensions of data quality[ii], including strengths and weaknesses. The purpose of this DQS is to accompany data releases from the National Screening Service (NSS) regarding the National Breast Screening Programme. This document provides further information and/or context regarding the accompanying data release. This document details how BreastCheck uses data and specifically:

- Why the NSS can legally collect this data
- Where the NSS keeps the data
- How the NSS collects data and from whom it is collected
- Who the data in the data release refers to (the dataset cohort)
- How the NSS compiles the statistics for the data release
- How the NSS defines and assures data quality
- What caveats the NSS has applied to the data release for potential amendments

3. Legislative remit for Data Collection

BreastCheck has a legislative remit to acquire its population register 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*"[2][3].

This registry data is *personal data*[4]. In the provision of the national breast screening programme, BreastCheck processes this personal data. The law on protecting personal information, known as GDPR, allows BreastCheck to use personal information to invite women for screening[5]. As part of the National Screening Service (and part of the Health Service Executive), BreastCheck carries out this processing of personal data on the lawful basis that the processing is necessary for a task carried out in the public interest or in the exercise of official authority vested in the controller[iii]; for the HSE this official authority is vested in us through the Health Act 2004[6].

Upon accepting/uptake of a screening invitation, BreastCheck collects and processes selected *special category data*[7] pertaining to service users (specifically health records data) required to deliver the programme. The law on protecting personal information, known as GDPR, allows BreastCheck to process health data[8]. BreastCheck is a body of the National Screening Service (and part of the Health Service Executive). As such, BreastCheck carries out this processing of special category data on the basis that:

- It is necessary in the provision of healthcare or treatment
- It is necessary for medical diagnosis

[i] A population-based cancer screening register holds data on the target population in geographically defined area
[ii] *Data Quality Dimensions* are a set of data quality attributes that represent a single aspect or construct of data quality
[iii] *Data Controller* is any person, authority or agency that determines the purpose and manner of personal data processing

- It is utilised for the management of BreastCheck by the National Screening Service for the provision of a quality assured screening service
- It is processed by either a healthcare practitioner or a person who, in the circumstances, owes a duty of confidentiality to the data subject[iv] that is equivalent to that which would exist if that person were a health practitioner.
- The processing is necessary for a task carried out in the public interest or in the exercise of official authority vested in the controller

The law on protecting personal information, known as GDPR, allows BreastCheck to use personal information to ensure that a safe and effective screening programme is provided across Ireland[5][8][9].

4. National Breast Screening Programme Database (NBSP)

BreastCheck data is stored in an Oracle database known colloquially as 'NBSP'. Live and back-up versions of the database are kept on two physical servers. Security of the data kept on NBSP is detailed in section 9.3 (security) of this Data Quality Statement. NBSP is a bespoke client register, management, and clinical information system. All data collected and maintained on NBSP has a specific purpose in the provision of a quality assured screening service. The data collected is also linked to BreastCheck's Charter Aims and the Programme's Key Performance Indicators which are based on European Guidelines[10] and BreastCheck's Quality Assurance document[11]. The types of data kept on NBSP (and the utility of that data) have been categorised and documented. A summary of BreastCheck data variables (and their utility) is outlined in Appendix A.

5. Data Sources

The statistics in the data release are derived from information that is routinely collected by the National Screening Service for the operation of the National Breast Screening Programme, including for quality assurance and performance management purposes.

Information on the NBSP database regarding the population register is supplied from:

- The Department of Social Protection
- Online self-registration by eligible women

Data supplied to the National Screening Service for the BreastCheck population register is subject to data processing for the purpose of data cleansing/standardisation, duplicate identification, and electoral division (ED) assignment. This process involves; an external processing company, automated processing, and manual checks (Appendix B).

Client attendance, management and clinical data is provided from the National Breast Screening programme (NBSP) database.

To identify interval breast cancers, it is necessary to link[v] BreastCheck data with National Cancer Registry Ireland (NCRI) data. The resultant dataset is known as the '*agreed interval cancer file'* and is the data source for determining the interval cancer rate (ICR).

Validation and Quality Assurance checks are carried out by the Programme Evaluation Unit (PEU) as part of the publication process[9]. Each BreastCheck Unit is staffed with a Data Officer and an overall Data Quality Manager is employed to ensure the quality of the data collected.

[iv] *Data Subject* is any identified or identifiable living individual to whom personal data relates
[v] *Data linking* is the process of collating data from different sources to create a more valuable & helpful dataset

6. Data Cohort & Scope

Cohort selection for the data release is based on women aged 50 to 69 years old who were first invited for breast screening within the calendar year. Some of these women may have been screened or treated the following year.

The cohort selection for the interval cancer rate differs from above. The cohort selection criteria for the interval cancer rate are detailed within the data release.

7. Methods used to compile the statistics

The National Screening Service validates and analyses the data using Business Intelligence Reports developed in Business Objects as well as Microsoft Excel spreadsheets. The statistics in the accompanying data release are compiled by the NSS Programme Evaluation Unit (PEU). The PEU is staffed with a Consultant Epidemiologist (part time), the Head of the PEU, two research officers, three data analysts, a statistician, and a data quality manager.

The figures are published in downloadable PDF format and are available online. The figures presented in the data release are in the form of simple counts, percentages (rounded to one decimal place) or rates (e.g., number of women with cancer detected per 1,000 women screened). Definitions and formulae detailing how the statistics in the accompanying data release are calculated can be found in Appendix C and Appendix D of this publication.

8. Data Quality

Quality data is data which is *'fit for use'* or *'fit for purpose'*. The quality of data (fitness for purpose) is determined through assessment against internationally accepted dimensions. These dimensions need to be balanced against one another to meet users' needs. The data quality dimensions are relevance; accuracy & reliability; timeliness & punctuality; coherence & comparability; accessibility & clarity[12][13][14].

8.1 Relevance

Relevant data meets the current and potential future needs of the data users. Data is deemed relevant when it is **useful** and **valuable**[15].

The data users[vi] for the statistics within the data release include: the Department of Health (DoH); the National Cancer Control Programme (NCCP); the National Cancer Registry Ireland (NCRI); the Health Service Executive (HSE); clinicians, researchers, media, the public and other government organisations. The utility of BreastCheck data has been documented and categorised (Appendix A).

The statistics in the data release are relevant since they are **useful** for demonstrating compliance with Key Performance Indicators, provide accountability to the taxpayer and demonstrate the **value** of the programme. The data that is utilised to generate the statistics in the accompanying data release are structured according to those outlined in *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*[10].

The internationally recognised metric for programmatic assessment of interval cancers in breast cancer screening is the Interval Cancer Rate (ICR). In 2020 the Expert Reference Group (ERG) recommended that BreastCheck should continue to monitor interval cancers at the programmatic level through the assessment of the ICR. Calculation of the ICR allows measurement against predefined quality standards and comparison with other breast screening programmes internationally[16]. This means that interval cancer data is **relevant** for quality assurance and comparison purposes.

[vi] Data users are any stakeholders that use data held by a screening programme or use data outputs from that programme

8.2 Accuracy & Reliability

The accuracy of data refers to how closely the data correctly describes what it was designed to measure. Reliability refers to whether that data consistently measures, over time, the reality that it was designed to represent. The accuracy & reliability of the data in the accompanying data release is determined through its data **coverage, collection, completeness, processing, and revisions**[15].

Data **coverage** refers to the degree to which the data available covers the target population[15] (women aged 50 to 69 years old). The target population is further categorized by BreastCheck as *the Known Target Population*[vii] and *the Eligible Target Population*[viii]. Women fall outside the *Eligible Target Population* if they are excluded or suspended (Appendix E). The Programme Evaluation Unit (PEU) measures coverage by benchmarking a snapshot of the BreastCheck Population Register against Census Data from the Central Statistics Office (CSO) on the date of a Census.

'Collection' refers to the procedures that are in place to ensure that the data is captured in a usable format[15]. BreastCheck collects structured data as women progress through various designed care pathways. Where women progress to treatment as patients within secondary care providers (Hospitals), their data is collected and entered by the respective BreastCheck unit. Each BreastCheck Unit is staffed with a dedicated Data Officer for data collection and data entry. The National Screening Service provides BreastCheck Data Officers with Data Entry Standards of Practice[ix]. Service users/patients may receive neo-adjuvant treatment in one of the centres of excellence for breast cancer care. Some patients seek their treatment outside of BreastCheck's 'Host' Hospitals[x]. Where this occurs, the Data Officer makes every possible effort to obtain the relevant clinical data (with the client's permission). However, this is not always possible to obtain and may lead to incomplete clinical datasets for those who seek treatment elsewhere. Patients who seek treatment outside of the host hospitals are categorised as *'gone elsewhere'* on NBSP. Data collection processes for the population register are outlined in section 5 of this document. Data collection for determining interval breast cancers is a collaborative process between NSS and NCRI which is outlined in an agreed protocol.

'Completeness' refers to the degree to which individual variables are present within a dataset[15]. BreastCheck provides a self-registration service to women via web and freephone as part of efforts to attain 'completeness' regarding registry data. PEU measures and monitors the completeness of the BreastCheck Population Register through comparison with national Census data. Completeness of clinical data is monitored and achieved through mandatory fields, data entry protocols and various quality assurance reports. The NSS Data Quality Manager (DQM) monitors clinical dataset completeness.

'Processing' is the transformation of data from the form in which it is received into another form that facilitates analysis. Processing can include validation and/or correction of the data[15]. 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. PEU produces validation reports with predefined quality measures, on a monthly and annual basis, which allows the DQM to review practices and the quality of data across all four screening units[17]. Data processing of the interval cancer dataset, including validation, is outlined in an agreed protocol. Data processing for the population register dataset is outlined in section 5 of this document.

[vii] The *known target population* is all women of screening age that are known to the programme
[viii] The *eligible target population* is the known target population minus those women excluded or suspended
[ix] Data SOPs are accessible to NSS staff internally on the Q-Pulse document management system
[x] Mater Misericordiae Hospital, St Vincent's Healthcare Group, Cork University Hospital, Galway University Hospital

8.3 Timeliness & Punctuality

Good quality data should be both **timely** and **punctual**[15].

Timely data is collected within a reasonable agreed time period after the activity that it measures[15]. A memorandum of understanding (MOU) exists between the NSS and NCRI regarding ascertainment of interval breast cancers. BreastCheck data releases from The National Screening Service are published some months after the end of a calendar year. This is because:

- Cohort selection within the data release is based on client *"first invited"* date. As such, it can take some time after the end of the calendar year to gather a complete dataset for the cohort (particularly for those first invited in the final quarter of the calendar year and those who have been referred for treatment)
- Due to time required for an interval cancer to be diagnosed (24 months) and the processes whereby NCRI register and validate cancers, there is an inherent and expected time lag before an interval cancer rate can be validated[16]
- Trade-offs exist between data quality dimensions (timeliness & punctuality vs. accuracy & reliability)[12].

Punctual data is data delivered or reported on the dates promised, advertised, or announced[15]. As part of adherence to information management standards[xi], and as part of measuring punctuality, The National Screening Service is committed to developing a formal data release calendar for all its screening programmes.

8.4 Coherence & Comparability

Coherent and comparable data is consistent over time and across providers and can be easily combined with other sources. This data quality dimension is measured across **standardisation, coherence, historical comparability**, and **regional comparability**[15].

'Standardisation' refers to the degree to which data is collected using common definitions or standards. Standardisation is assisted through use of **standards** and **metadata**[15].
Standards: BreastCheck date data is stored in ISO 8601 standard format. However, BreastCheck date data is entered, extracted, and reported in the European IS/EN 28601 standard format. BreastCheck provides its Data Officers with policy documents on Data Classification[xii] which support data standardisation. BreastCheck use the messaging standard[xiii] Health Level 7 (HL7), which transfers clinical information between the Picture Archiving and Communication System (PACS) and Radiology Information System (RIS). BreastCheck does not currently utilise terminology/classification standards[xiv] such as SNOMED-CT or ICD-10. As part of adherence to information management standards[xv], the NSS is working with Ireland's National Release Centre (NRC) to create a SNOMED refset[xvi] for BreastCheck. The definitions and standards utilized by BreastCheck in recording data are those outlined in the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*[10].
Metadata: BreastCheck is working towards publishing a portion of its data dictionary. The structure of BreastCheck's data dictionary is outlined in Appendix H.

'Coherence' refers to the degree to which it is possible to combine and make use of related data from different sources[15]. There are future plans for the implementation and use of Individual Health Identifiers (IHI)[xvii]. The use of IHI by the National Screening Service is legislated for in the 2014 Health

[xi] Standard 7: *Data is disseminated appropriately & data users are provided with timely access to data*
[xii] Q-Pulse Document Reference: BC/DQ-050 *"Classification of Surgical Procedures"*
[xiii] *Messaging Standards* specify the structure & order of the elements that form a message exchanged between IT systems
[xiv] *Terminology Standards* assign a unique code or value to clinical concepts such as diseases, medications & procedures
[xv] Standard 5: *Health information standards & nationally agreed definitions are utilised to enable data sharing*
[xvi] A SNOMED refset is a set of SNOMED codes/concepts to be utilised within a health information system.
[xvii] IHI is a number that uniquely & safely identifies each person that has used, is using or may use Irish health services

Identifiers Act[18][19]. The use of IHI by both the NCRI and NSS will improve coherence of their respective datasets by improving the efficiency of data linkage[20][21][22][23].

'Comparability' refers to how the consistent use of definitions and standards facilitates comparison over time and across regions[15]. BreastCheck utilizes the definitions and standards outlined in the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*[10]. This allows for strong historical and regional comparability against other breast screening programmes within the EU. Data users should be aware of changes to the BreastCheck age range when carrying out historical comparisons (Appendix G). The interval cancer rate allows comparison with other breast screening programmes internationally[16]. BreastCheck interval cancer rates have been previously compared with other European countries[24].

8.5 Accessibility & Clarity

Good quality data is easily obtainable and clearly presented in a way that can be understood easily; it is **accessible** and **interpretable**[15].

Accessibility refers to the ease with which data can be identified, obtained and used[15]. Data users employed by the National Screening Service can request BreastCheck data through a data request process[xviii]. The data released is anonymous data (statistics) utilised for service evaluation and quality assurance. The accompanying data release is published online, in PDF[xix] format. It is freely accessible. A BreastCheck publication catalogue is available here.

Interpretability refers to the degree to which users are provided with the required documentation and metadata[xx] to assist them in understanding the data[15]. As part of adherence to information management standards[xxi], and as part of facilitating interpretation, BreastCheck metadata is documented in its data dictionary[xxii]. To assist interpretability, the appendices of this document contain a glossary of counts and an outline of the statistical calculations. BreastCheck is working towards publishing a portion of its data dictionary. BreastCheck shares metadata with the NCRI as part of the process in identifying interval cancers. Inclusion & Exclusion criteria for breast interval cancers are outlined in Appendix F.

[xviii] Q-Pulse Document Reference: BC/DQ-030 *'Release of Data'*
[xix] PDF is a digitally accessible, non-proprietary, non-machine-readable format
[xx] Metadata is 'data to explain data'. It provides structured information about the content of a dataset or database
[xxi] Standard 5: *Health information standards & nationally agreed definitions are utilised to enable data sharing*
[xxii] A data dictionary is a descriptive list of names, definitions & attributes of variables collected in a database or dataset

9. Confidentiality, Transparency & Security

9.1 Confidentiality

In order to maintain confidentiality and protect information from misuse, all members of staff within The National Screening Service have five main responsibilities:

- Storing & transferring information securely
- Restricting access to Information[xxiii]
- Maintaining internet and email security[xxiv]
- Improving data collection, quality, and reporting
- Reporting data breaches[xxv]

The National Screening Service utilises external organisation(s) to provide further data processing of the population register for the National Breast Screening Programme.

As part of adherence to information management standards[xxvi] and, to assure confidentiality is maintained in the provision of this data processing, a Privacy Impact Assessment (PIA) has been carried out on the process of processing/sharing data with Data Ireland and the NCRI. The PIA outlines the legal basis for processing the data, the legal basis for processing special category data, role of the data controller, any automated decision making, recipients of the personal data, identified risks & threats, technical security measures and controls in place.

9.2 Transparency

As part of adherence to information management standards[xxvi], a statement of information practices[xxvii] (SoIP) is in development within the National Screening Service. A link to the HSE *Privacy Notice* is provided here. The sharing or exchange of data between BreastCheck and the NCRI is facilitated through a Data Sharing Agreement (DSA).

As part of adherence to information management standards[xxviii], BreastCheck has a statement of purpose[xxix] which is publicly available here.

9.3 Security

The National Screening Service utilises specialised firewall software and hardware to protect the National Screening Service network and the data and equipment within it from security risks. National Screening Service laptops have encryption software that ensures the data-at-rest is protected from theft or loss. Various security applications are used to protect NSS systems and data in several ways including providing anti-virus protection, uncovering hidden malware, and scanning web traffic for infected websites that can install malware or be used as gateways for cyber-attacks. The sharing or exchange of data between the NSS and the NCRI is carried out securely through a cross-platform interface engine.

BreastCheck programme data is stored in an Oracle database. Live and back-up versions of the database are on two physical servers, securely located in two geographically separated offices. The servers are within the National Screening Service network and are protected from security vulnerabilities. Access to the data within the network is via a physical network connection or via a virtual private network (VPN) which provides enhanced security. The BreastCheck database is not internet facing and access to the data is provided on an as-needed basis via username and passwords which are issued based on manager approval.

[xxiii] *Fundamentals of GDPR* training and certification is mandatory for HSE staff

[xxiv] *Cyber Security Awareness* training and certification is mandatory for HSE staff

[xxv] Q-Pulse Document Reference: NSS/SOP-GDPR1 *"GDPR Data Breach Notification Escalation Process"*

[xxvi] Standard 1: *Arrangements are in place to protect the privacy of people about whom it holds information*

[xxvii] A *SoIP* is a publicly available document that sets out what information is collected; how it is used; with whom it is shared and for what purpose; the safeguards in place to protect it; and how service users can access data held about them

[xxviii] Standard 3: *The organisation documents and maintains a statement of purpose*

[xxix] A *Statement of Purpose* is a publicly available document outlining why the data collection exists & its stated objectives

10. Data Revisions

Statistics published in the accompanying data release are final statistics.

11. Strengths & Weaknesses

Strengths	Weaknesses
Coverage & Completeness: The population register is measured against census data.	**Processing:** Clinical data may be incomplete where patients seek treatment elsewhere
Standardisation (Standards): *EU Guidelines for Quality Assurance in Breast Cancer Screening*[10] used to standardise BreastCheck data. The NSS is working with the NRC to develop a SNOMED reset for BreastCheck.	**Transparency:** A statement of information practices is not currently available. The NSS is working towards a statement of information practices. A link to the HSE Privacy Notice is provided here.
Standardisation (Metadata): BreastCheck has developed a data dictionary for its information system. BreastCheck's data dictionary structure is outlined in Appendix H.	**Interpretability:** BreastCheck's data dictionary is not currently publicly available. BreastCheck is working towards publishing a portion of its data dictionary.
Relevance: Utility of BreastCheck data is documented here. The data presented in the data release is deemed relevant to data users because it measures quality parameters and Key Performance Indicators.	**Punctuality:** Punctuality is not currently measured due to lack of Data Release Calendar. The NSS is working towards the development of a data release calendar for all of its screening programmes.
Comparability: Legacy of consistent data collected over twenty-year period. Strong for historical comparability. Historical changes to data logged in BreastCheck Data Dictionary.	**Accessibility:** The accompanying data release is digitally accessible in PDF. This means that web-based tools are not applicable for manipulation[25].
Accuracy & Reliability: Accuracy & Reliability of data entry is supported through documented Standards of Practice.	
Processing: Data processing procedures are in place for data validation[17].	
Accessibility: BreastCheck data releases are freely accessible online and a publication catalogue is available to data users.	
Coherence: Preparations are underway to utilise IHI in the BreastCheck database to facilitate an integrated and coherent approach to the use of health data.	

References

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   BreastCheck Women's Charter (breastcheck.ie)

2. Health (Provision of Information) Act, 1997.
   Health (Provision of Information) Act 1997 (irishstatutebook.ie)

3. Data Protection Act, 2018
   Section 184; amendment to section 1 of Health (Provision of Information) Act 1997
   Data Protection Act 2018 (irishstatutebook.ie)

4. ***GDPR Article 4(1)*** *'personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*
   Art. 4 GDPR – Definitions (gdpr-info.eu)

5. **GDPR Article 6(1)(e)** *'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'*
   Art. 6 GDPR – Lawfulness of processing (gdpr-info.eu)

6. *Privacy Notice, section 3,* Health Service Executive, 2020
   HSE Privacy Notice (hse.ie)

7. ***GDPR Article 9(1)*** Special Category Data is personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation
   Art. 9 GDPR – Processing of special categories of personal data (gdpr-info.eu)

8. **GDPR Article 9(2)(h)** *'processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph three'*
   Art. 9 GDPR – Processing of special categories of personal data (gdpr-info.eu)

9. **GDPR Article 9(2)(i)** *'Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy'*
   Art. 9 GDPR – Processing of special categories of personal data (gdpr-info.eu)

10. *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, Fourth Edition,* European Commission, Belgium; 2006
    EU Guidelines for QA in Breast Cancer Screening & Diagnosis (screening.fr)

11. *Guidelines for Quality Assurance in Mammography Screening, Fourth Edition*, BreastCheck, Dublin; 2015.
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12. *Guidance for a Data Quality Framework for Health and Social Care*, Health Information & Quality Authority, 2018
    Guidance on a Data Quality Framework for Health & Social Care (hiqa.ie)

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Review of BreastCheck Information Management Practices (hiqa.ie)

18 *Health Identifiers Act 2014 (No. 15 of 2014).* 8th July 2014. Act of the Oireachtas. Irish Statute Book.
Health Identifiers Act 2014 (irishstatutebook.ie)

19 *Health Identifiers Act 2014 (No. 15 of 2014). Section 11: Use of individual health identifier and National Register of Individual Health Identifiers.* 8th July 2014. Act of the Oireachtas. Irish Statute Book.
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20 *Evidence Synthesis: Recommendations on a consent model for the collection, use and sharing of health information in Ireland*, Health Information & Quality Authority, 2021
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23 *Frequently Asked Questions about Health Identifiers*, Health Information & Quality Authority, 2015
FAQ on Health Identifiers (hiqa.ie)

24 *O'Brien KM, Dwane F, Kelleher T, Sharp L, Comber H. "Interval cancer rates in the Irish national breast screening programme"*. Journal of Medical Screening, 2015.
Interval Cancer Rates in the Irish National Breast Screening Programme (pubmed.gov)

25 *Open Data Publication Handbook,* Open Data Ireland, 2014
Open Data Publication Handbook (data.gov.ie)

Appendices

Appendix A – Data Utility, Organisational Aims & KPIs

Dataset	Data sub-set	Utility	Charter Aim / KPI / QA / Reporting
Person	Database key(s)[xxx]	Record Management, Communication, Decision-Making, Tracking Eligibility (age), Pathway Management, Charter Aim Measurement, KPI Metrics	●To send women information about screening before their appointment, ●Services will be arranged so that people with additional needs can access the service, ●To keep women informed of any delays regarding results ●KPI; Interval Cancer Rate
	Personal Details		
	Contact Details		
	Population Details		
	Service Use Details		
	Additional Time		
	Vital Status		
Episode	Database key(s)	Record Management, Decision-Making, Pathway Management	●To ensure women are invited for screening every two years ●To seek and measure the experience of clients & patients
	Episode Details		
Appointment & Session	Database keys	Record Management, Scheduling, Pathway Management	To see women as promptly as possible to their appointment time
	Appoint. Details		
	Session Details		
Screening	Database key(s)	Record Management, Scheduling, Pathway Management, Decision Making, Quality Assurance	Women will be screened using high quality modern equipment
	Background		
	Radiological Evaluation		
	Clinical Evaluation		
	Processing		
Screening Outcome	Imaging	Scheduling, KPI Metrics, Quality Assurance, Pathway Management	●To ensure women are offered an assessment appointment following an abnormal result ●KPI; Recall for Assessment rate
	Screening Outcome		
Assessment	Database key(s)	Record Management, Scheduling, KPI Metrics, Quality Assurance, Pathway Management	●KPI; Recall for Assessment Rate, ●KPI; Number of visits required to achieve diagnosis of malignancy
	Clinical Assessment		
	Radiological Assessment		
	Tissue Sampling		
Assessment Outcome	Database key(s)	Record Management, Scheduling, Pathway Management	●QA; Ensure women get their results from the assessment clinic within one week[3]
	Assessment Outcome		
Tissue Sample Pathology	Database key(s)	Record Management, Decision-Making, Pathway Management, Disease Classification	●QA; Ensure the accurate identification & characterisation of lesions[3] ●Promote consistency of diagnostic categorisation
	Core Biopsy		
	Cytopathology		
	Lymph Node		

[xxx] A database key is a variable (or a group of variables) that can uniquely identify each record in a table

Dataset	Data sub-set	Utility	Charter Aim / KPI / QA / Reporting
Surgery	Database key(s)	Record Management, Decision Making, KPI Metrics, Quality Assurance, Disease Classification	●KPI; Benign open biopsy rate ●KPI; Proportion of localised impalpable radiographic lesions excised at the first operation ●KPI; Time to Surgery post Diagnosis
	Surgery Details		
	Admission & Discharge Details		
	Diagnosis Summary		
Pathology	Database key(s)	Record Management, Disease Extent, Disease Classification, Decision Making, KPI Metrics, Quality Assurance	●QA; To standardise and enhance the quality and consistency of prognostic information in pathology reports[3] ●Reporting the number of women with invasive cancer <15mm ●KPI; Benign open biopsy rate ●KPI; Invasive cancer detection rate ●KPI; DCIS as proportion of all cancers detected
	Report Details		
	Benign Details		
	Atypia Details		
	in-situ Details		
	Invasive Details		
	Receptor Details		
	Node Details		
	Other Details		
Treatment Outcome	Database key(s)	Record Management, Decision Making, Pathway Management, Quality Assurance	
	Outcome		
Breast Care Nursing (BCN) Contact	Database key(s)	Record Management, Communication, Quality Assurance	To provide women with support from a Breast Care Nurse
	BC Nursing		
	Nursing Final Outcome		

Appendix B – Steps used to identify the Target Population

A file is received each month from the Department of Social Protection (DSP) containing a list of women identified by the DSP as eligible for screening. Eligibility is based on a woman's age. NSS instructs DSP to provide details of women aged between 48 and 70. The DSP list is composed of women who have just become eligible either as a result of turning 48 or they are a recent entrant to the country or have recently returned to the country after a period abroad. It also contains women who were already eligible and their details have been provided previously but have since had some change in their demographics, for example a change of address.

Every six weeks the population register update process is completed, refreshing the database that contains the eligible population. There are two primary inputs into this process:

1. the latest files from the DSP
2. an extract from the NSS database which contains every new client added to the database since the last extract was taken or any client that has had some demographic change, for example an address update.

The updates to the database in terms of existing clients or the addition of new clients are the result of client registrations via the BreastCheck website as well as details collected at the units by the radiographers and administrative staff when they speak with the clients upon them visiting or phoning BreastCheck.

The updates from the database along with the files from the external data providers are combined and sent to the external data processing company.

An external data processing company cleans and standardises the address information. The company also assigns Electoral Division (ED) codes based on the location of the address. These Electoral Division codes are an important part of screening operations as they allow the grouping and targeting of all eligible women in a particular geographical area maximising the efficiency of appointment scheduling.

The data processing company also performs duplicate identification and keeps a copy of our complete population register. They use this along with the extract of demographic changes to our database and the file from the DSP to identify any possible duplicate records. There are three different rules for duplicate identification. These rules use fields including PPSN, first name, surname, date of birth and address information to identify both exact and suspected duplicates.

The data processing company provides BreastCheck with two main files:

1. All new clients and any updates to existing clients
2. A list of duplicate and suspected duplicate clients.

Both of these files are uploaded to the database.

The records identified as new clients are added to the database. Where a record is provided to us as an update for an existing client, this update will only be applied to the client record if that client has not already attended a screening appointment. This is because if a client has attended a screening appointment this means her details were validated in person and so these details are given higher weight than updates that come in via DSP.

When the identified duplicates are uploaded to the database a software program is used to automatically merge positive duplicates.

Where there are duplicates which are not confirmed as suitable for automatic merging, a manual review of these cases is conducted by the population register team. This manual review is performed to ensure that true duplicates are identified and merged, with non-duplicates separated out and maintained.

The population register team also reviews those addresses for which the data processing company have been unable to assign an ED code and attempts to assign these both automatically using an internal HSE tool and manually where this tool is unable to do so.

Once the process is complete a copy of the database is then sent to the external data processor to ensure their version of the database is kept in sync with the live version.

Appendix C – Count Calculations Table

Category	Term	Definition	Extra explanatory Notes/NBSP
Open Biopsies	Total Open Biopsies	The sum total of Women that had either an Open Biopsy (Benign Findings) or an Open Biopsy (Malignant Findings). The definitions of Benign Open Biopsy and Malignant Open Biopsy are outlined below	This is the number of women with a Surgical Procedure(s) on the Surgical data sheet without a B5 result on any Core Biopsy data sheet or a C5 result on any Cytopathology data sheet in that episode. Note: The Final Diagnosis on the Pathology datasheet may be "Benign", "Atypia" or "Malignant"
	Open Biopsies (Benign Finding)	This is the number of women with a surgical biopsy(s) and where the only result(s) in that episode was benign. Benign results are those results with a final pathological diagnosis of either "Benign" or "Atypia".	●If the woman has a final pathological diagnosis of *"Malignant"* for the other side in that episode it takes precedence, and her case is not classified as a benign surgical biopsy. ●Where final diagnosis (on Pathology table) = Benign or Atypia
	Open Biopsies (Malignant Finding)	This is the number of women with a surgical biopsy(s) where the result was malignant. Malignant results are those results with a final pathological diagnosis of "Malignant".	If the woman has a Pre-op. Diagnosis for the other side in that episode this takes precedence and her case is not classified as a malignant open biopsy.
Cancers Detected	Cancers Detected	This is the number of women that have a final pathological diagnosis of "Malignant" for any lesion in that episode.	Cancers Detected = 'Invasive' + 'Pure DCIS' 'Invasive Cancer' and 'Ductal Carcinoma In-Situ (DCIS) only' are subsets of this cohort. The definitions of Invasive and DCIS calculations are outlined below.
	Invasive cancers detected	The number of women with a final diagnosis of "Malignant" and either "Invasive Carcinoma" chosen on any Pathology datasheet or "Invasive" on the Diagnosis Details under Core Biopsy Diagnosis on the Core Biopsy/Cytopathology sheet for that episode.	Where final diagnosis (on Pathology table) = Malignant And 'Invasive' is indicated on either Pathology or Core Biopsy
	DCIS cancers detected	Ductal Carcinoma in Situ (DCIS) a cancerous lesion which has not spread beyond the ducts within the breast. This is the number of women with a final diagnosis of "Malignant" and information under the heading Pure DCIS Cases Only.	A woman cannot belong in the Pure DCIS and the Invasive category. They are mutually exclusive in a single breast.
Cancer Size	Invasive cancers < 15mm	This is the number of women whose largest invasive cancer is < 15mm in size. The size of invasive cancers are taken from "Tumour Size (mms)" and field "Invasive" of pathology sheet.	• There may be two invasive cancers per woman – on right and left. • The size of the tumour on each side may be recorded on more than one sheet for that side (i.e. if the number of Surgical Procedures on that side > one). The size of the cancer is assessed on only one datasheet, not the total size of all the datasheets for that side. • The datasheet with the largest size for any particular side is usually the one with the earliest chronological date but all datasheets for that side should be checked for times when this is not the case. • This definition is suitable for determining the number of women only. If more detail is required on the size of individual tumours it must be noted if there is no entry for the "Invasive" size, do not take the" Invasive + In-situ" size: interpret as "Not Assessable" in this case even though it may not be ticked.

Category	Term	Definition	Extra explanatory Notes/NBSP
Women Invited	Total Invited	The number of women who have been issued their first invitation to screening within a specified time period	
	'Eligible' Women	The number of women whose first invitation to screening is within the specified dates. The episode in question for each woman is determined from this first invitation. It is irrelevant whether the appointment was cancelled, rescheduled, attended or did not attend. This invited figure excludes those women who were either 'excluded', or 'suspended' at the time of their last invitation – past or future - in the episode. It also excludes those people whose last appointment in the period was a session cancellation.	= Invited – (Excluded + Suspended + Opt-Out) 'Excluded', 'Suspended' & 'Opt-Out' are defined under the 'Ineligible Women' section of this table
	Initial Women	The number of women whose invitation for a first screening appointment is within the specified dates, irrespective of whether the appointment was attended, cancelled, rescheduled or did not attend. They are a highlighted sub-set of the 'eligible' cohort within the data release The 'Initial Women' cohort contains two sub-sets. These are; PNA's and 'New Initial'. PNA's are defined below	A person may have multiple invitations within the specified dates but these will amount to one count on reports (i.e. the first invitation) since numbers are for people rather than invitations. The first invitation may not be the earliest appointment date, therefore the **minimum appointment** number is used to get the first invitation offered.
	Subsequent Women	The number of women whose invitation to2nd (or greater) screening is within the specified dates, irrespective of whether the appointment was attended, cancelled, rescheduled or did not attend.	Subsequent women are a highlighted sub-set of the 'eligible' cohort within the data release
	PNA (previous non-attender)	This is the number of women that did not attend (DNA) any screening appointment in the previous screening round, have not de-consented (opted-out) of the programme & continue to be invited to screening.	Relates to client appointment history. PNA's are a highlighted sub-set of the 'initial Women' cohort within the data release
Invites: Ineligible Women	Ineligible Women	The sum total of women defined as either 'Excluded', or 'Suspended''.	= (Excluded + Suspended) The definition of 'Excluded', 'Suspended' calculations are outlined below.
	Excluded Women	This is the number of Women whose first invitation to screening is within the specified dates and who were 'excluded' at the time of their last invitation (past or future) in the episode.	Women in follow-up care for breast cancer; women who are not contactable by An Post; women who have a physical/mental disability (while BreastCheck attempts to screen all eligible women, certain forms of physical or mental disability may preclude screening); women with a terminal illness; or other reasons.
	Suspended Women	This is the number of women whose first invitation to screening is within the specified dates and who were 'suspended' at the time of their last invitation (past or future) in the episode.	Women on an extended holiday or working abroad; women who had a mammogram within the last year; women who opt to wait until the next round of screening; women who wished to defer their appointment; women who did not wish to reschedule their appointment; or other reasons.
	Opt-Out (De-Consented)	This is the number of women whose first invitation to screening is within the specified timeframe and who were 'de-consented' at the time of their last invitation (past or future) in the episode.	A woman can opt-out before or after receiving her invitation. A woman can opt back in at any time, provided they meet the age criteria for screening.
Screening Attendance	Attended for Screening	This is the number of women who are recorded as having had a complete screening visit within the specified date range.	This field is not based on the invited cohort of women selected in the report, instead its purpose is to show the level of screening activity in the time period. It excludes Technical Recalls.
	DNA (True)	DNA is where an appointment is not attended. This is the number of people whose 1st invitation to screening is within the specified dates and whose last past appointment within the episode was 'DNA', and **who also have another 'DNA' appointment within the episode.**	This figure excludes cancelled or rescheduled appointments, people who were sitting at either 'excluded', 'deconsented' or 'suspended' at the time of their last invitation – past or future - in the episode. It also excludes those who attended at any stage during the relevant episode.

Category	Term	Definition	Extra explanatory Notes/NBSP
Assessment	Re-Called to Assessment	This is the number of women who had a screening outcome of 'Recall to Assessment' (RA) or Clinical Recall (CR).	●The "Recall to Assessment (RA)" outcome is a radiological outcome at time of reading the mammograms. ●The "Clinical Recall (CR)"[xxxi] outcome originates at the time of screening with the radiographer observing appropriate physical attributes. If at the time of radiological evaluation, the reading radiologist agrees with the outcome of "Clinical Recall (CR)", it leads to the client being recalled to assessment also.
	Pre-Operative Diagnosis	This is the number of women with one or more pre-operative diagnosis. A pre-operative diagnosis is made where the woman has a B5 result for core biopsy or a C5 result for cytopathology for any lesion in that episode.	Core Biopsy/cytopathology where result is B5 and/or C5
Interval Breast Cancer	Number of Interval Cancers	This is the number of invasive cancers arising within 2 years of a woman having a negative screening examination	This number is derived from the "agreed interval cancer dataset" which is described in section 5
	Number Negatively Screened in matching time period	No. of women screened in the same period who did not have cancer detected	The number negatively screened is derived from the BreastCheck database

[xxxi] Only the *'Recall to Assessment'* outcome is applicable from 2022 onwards

Appendix D – Rates and Ratio Calculations Table

Term	Definition	Extra explanatory Notes
Standard Detection Ratio (SDR)	The SDR is defined as the observed number of screen detected invasive cancers divided by the expected number of invasive cancers (based on the underlying incidence).	The SDR allows an internationally comparative measure of programme performance.
Benign Open Biopsy rate (per 1000 women screened)	This is the number of women who have a benign surgical biopsy (as defined above) expressed per thousand women screened (based on parameters of report) = No. women with Benign Surgical Biopsies / No. women Screened (based on parameters of report) X 1000	
Open Biopsy Rate (%)	This is the number of women with Surgical Biopsies as a percentage of the number of women Screened (based on parameters of report). = No. women with Surgical Biopsy (ies) / No. Women screened (based on parameters of report) X 100%	
Pure DCIS only rate (%)	= No. of women with DCIS Cancers only / No. of Cancers Detected X 100%	
Invasive cancers < 15mm rate (%)	= No. "Invasive" OR "Invasive+Insitu" Cancers <15mm / No. "Invasive" Cancers X 100%	
Invasive cancer rate (per 1000 women screened)	This is the number of women with Invasive cancers per thousand women screened. = No of women with invasive cancers / No. women Screened (based on parameters of report) X 1000	
Cancers Detected (per 1000 women screened)	This is the number of women with a malignant result(s) per 1000 women screened. = Cancers Detected / No. women Screened (based on parameters of report) X 1000	
Pre-operative diagnosis rate (%)	This is the number of women with one or more pre-operative diagnosis as a percentage of the number of women with cancer(s). The number of women with cancer is the number of women with a final pathological diagnosis of "Malignant". = No. women with Pre-op Diagnoses / No. women with Malignant Tumour(s) X 100%	This can be expressed by woman or by lesion. In principle this can exceed 100% where the no. of cancers exceeds the no. of women (bilateral cases) or where women have had cancers diagnosed on core/cyto but have not had surgery for various reasons.
Recall rate (%)	This is the number of women recalled to assessment as a percentage of the number of women screened (to date) = No. women recalled [RA + CR] / No. women screened X 100%	Radiology evaluation ; Imaging outcome RA = Recall to Assessment CR = Clinical Recall[xxxii]
Screening uptake rate (on first invited population) (%)	This is the number of women screened based on the 1st invited population as a percentage of the number of Adjusted Invited women. = No. women screened (on 1st invited population.) / No. women adjusted Invited X 100%	
Interval Cancer Rate (per 10,000 women screened)	This is the number of interval cancers among women screened in a defined time-period per 10,000 women screened negatively within the same time period. = No. of interval cancers arising among women screened in a time-period / No. negatively screened in the same time period X 10,000	

[xxxii] Only the *'Recall to Assessment'* outcome is applicable from 2022 onwards

Appendix E – Details of ineligible categories

Ineligible Category	Details
Excluded	Women in follow-up care for breast cancer; women who are not contactable by An Post; women who have a physical/mental disability (while BreastCheck attempts to screen all eligible women, certain forms of physical or mental disability may preclude screening); women with a terminal illness; or other reasons.
Suspended	Women on an extended holiday or working abroad; women who had a mammogram within the last year; women who opt to wait until the next round of screening; women who wished to defer their appointment; women who did not wish to reschedule their appointment; or other reasons.

Appendix F – Criteria for Interval Cancers

Inclusion Criteria	Woman had a complete screening with BreastCheck Woman was aged 50-65[xxxiii] at time of complete screening. Invasive cancer Diagnosed within 2 years of previous complete screening date Cancer was diagnosed after BreastCheck screening Breast primary with histological evidence Confirmed primary breast cancer
Exclusion Criteria	Ductal carcinoma in situ (DCIS) Lobular carcinoma in situ (LCIS) Sarcoma Phyllodes Lymphomas Recurrence or second primary breast cancer[xxxiv] Unscreened women Women outside the age-limits for the screening years within the period of analysis[xxxv] Paget's disease without invasion/with DCIS Cancers in lapsed attenders are not included as interval cancers Cancer diagnosed before date of screening

[xxxiii] Note the historical changes to BreastCheck screening age range (documented in appendix G)
[xxxiv] Exclude any women who ever had a previous breast cancer, whether contralateral or ipsilateral or in situ
[xxxv] Breast cancer diagnosed greater than two years after complete screening

Appendix G – Historical Changes to BreastCheck Age-Range

Year of Operation	Lower Age	Upper Age	Age Range
2000 - 2014	50	64 (<65 years)	50 – 64 years old
2015	50	65 (<66 years)	50 – 65 years old
2016	50	65 (<66 years)	50 – 65 years old
2017	50	66 (<67 years)	50 – 66 years old
2018	50	67 (<68 years)	50 – 67 years old
2019	50	68 (<69 years)	50 – 68 years old
2020 onwards	50	69 (<70 years)	50 – 69 years old

Appendix H – Structure of BreastCheck Data Dictionary

BreastCheck's Data Dictionary Structure	
Variable ID number	A unique reference number assigned to the variable. Each variable has a unique number assigned to it. This allows for specificity when discussing a variable.
Actively Collected	Indicates if a variable is actively collected by BreastCheck. Where a variable has ceased to be collected, the date it ceased to be collected is indicated in the *"comments & guidelines"* section of the data dictionary. **Variables which are not collected are only available on the internal excel version of the data dictionary.**
Variable Name [1]	The column header name of the variable within the database. This the name of the variable in the back end of the database. This name may contain no spaces.
Variable Name [2]	The colloquial name for the variable within the database. This usually matches with the name given on the display screen (the font-end). This name may contain spaces.
Table	The table on which the variable is located. This indicates the variable's tabular dataset.
Data Type & Field Size	Refers to the type of data that is recorded for each variable. For BreastCheck these are: DATETIME, VARCHAR2, and NUMBER. The data type column of BreastCheck's data dictionary also includes the field size for each variable. For example: NUMBER*(7,0)* or *VARCHAR2(20BYTE)*
Codes & Values	Indicates the codes and values that are captured as part of the variable. This indicates whether a variable is Boolean, date, integer, decimal or string. Where the value is numeric with a link to a *"look-up table"* for the meaning of that value, then this section of the data dictionary will specify both the value and its associated meaning.
Definition	Definition which clearly explains what is meant by the variable & associated values.
Context	Explains the context in which the variable is collected
Related variables	Any other variables that are linked to or closely related to the variable. This section does not contain details of primary, foreign, or composite keys.
Comments & Guidelines	This section contains relevant comments or guidelines related to the variable. It may contain a broad range of information. Examples include dates new values were introduced, further detail about the variable, changes to the variable over time, etc.
Verification Rules	This section outlines the ways in which the accuracy of the variable can be verified. Where language such as "should" is used, this indicates that the system does not enforce the rule. Definitive terms like "will" indicate enforcement within the system.
Look-up Table (where applicable)	The name of the *"look-up table"* which is used to view numeric data with its associated meaning. This does not apply to all variables (e.g., date or Boolean variables will not have an associated *"look-up table"*). **This is only available on the internal excel version of the data dictionary.**
Column ID number	A reference number for the column assigned to a variable within a table. It is an ordered number assigned to the variable as it appears on its table from left to right. This is sometimes referred to as the *"ordinal position"*. **This is only available on the internal excel version of the data dictionary.**

Appendix I – List of Abbreviations

Abbreviations	
ED	Electoral Division
CR	Clinical Recall
CSO	Central Statistics Office
DCIS	Ductal Carcinoma in-situ
DNA	Did Not Attend
DOH	Department of Health
DQM	Data Quality Manager
DQS	Data Quality Statement
DSA	Data Sharing Agreement
DSP	Department of Social Protection
ERG	Expert Reference Group
EU	European Union
GDPR	General Data Protection Regulations
GP	General Practitioner
HIQA	Health Information & Quality Authority
HSE	Health Service Executive
ICD-10	International Classification of Diseases (10th Revision)
ICR	Interval Cancer Rate
IHI	Individual Health Identifier
ISO	International Standards Organisation
LCIS	Lobular Carcinoma in-situ
KPI	Key Performance Indicator
MDM	Multidisciplinary Meeting
MOU	Memorandum of Understanding
NBSP	National Breast Screening Programme (NBSP is also colloquial name for BreastCheck database)
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry Ireland
NHS	National Health Service
NRC	National Release Centre
NSS	National Screening Service
PACS	Picture Archiving & Communication System
PEU	Programme Evaluation Unit
PIA	Privacy Impact Assessment
PNA	Previous Non-Attender
QA	Quality Assurance
RA	Recall to Assessment
Refset	Reference Set
RIS	Radiology Information System
SDR	Standard Detection Ratio
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms
VPN	Virtual Private Network