NHS SCOTLAND

Scottish Cancer Taskforce
National Cancer Quality Steering Group

Breast Cancer Clinical Quality Performance Indicators

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1. National Cancer Quality Programme

Better Cancer Care[1] states that a wide ranging approach to quality improvement is required to ensure that services improve performance across all dimensions of quality. The NHS Scotland Healthcare Quality Strategy[2] (launched in May 2010) further expands upon this by articulating three quality ambitions:

- Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision-making.

- No avoidable injury or harm from the healthcare they receive, and that they are cared for in an appropriate, clean and safe environment at all times.

- The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, with no wasteful or harmful variation.

The quality strategy aims to put quality at the very heart of the NHS, building upon the excellent foundations already in place. A quality measurement framework has been developed which sets out measures and targets which will be used to monitor, challenge, manage and report progress towards the three quality ambitions. This framework also allows for supplementary national indicators that will underpin progress towards the quality ambitions[2].

Under the auspices of the Scottish Cancer Taskforce, National Cancer Quality Performance Indicators (QPIs) have been developed to drive continuous quality improvement in cancer care across NHSScotland. The QPIs are small sets of cancer-specific outcome focussed, evidence based indicators. These are underpinned by Patient Experience QPIs that are applicable to all, irrespective of cancer type. QPI implementation ensures that activity is focussed on those areas that are most important in terms of improving survival and patient experience whilst reducing variance and ensuring the most effective and efficient delivery of care.

A QPI is defined as a proxy measure of quality care. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of, continuous quality improvement, whereby real time data is reviewed regularly at an individual Multi Disciplinary Team/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This is underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards are required to report against QPIs as part of a mandatory, publicly reported, programme at a national level. A rolling programme of reporting is in place, with approximately three national tumour specific reports published annually. National reports include comparative reporting of performance against QPIs at Board/Multi Disciplinary Team level across NHSScotland, trend analysis and survival. This approach helps to overcome existing issues relating to the reporting of small volumes in any one year.

In the intervening years tumour specific QPIs are monitored on an annual basis through established Regional Cancer Network and local governance processes, with analysed data submitted to Information Services Division (ISD) for inclusion in subsequent national reports. This approach ensures that timely action is taken in response to any issues that may be identified through comparative reporting and systematic review.

2. Quality Performance Indicator Development Process

The QPI development process was designed to ensure that indicators are developed in an open, transparent and timely way. The development process can be found in appendix 1.

The Breast Cancer QPI Development Group was convened in December 2010, chaired by Dr Jennifer Armstrong (Senior Medical Officer, Scottish Government). Membership of this group included clinical representatives drawn from the three regional cancer networks, Healthcare Improvement Scotland (formerly NHS Quality Improvement Scotland), Information Services Division (ISD) and patient/carer representatives.
Membership of the development group can be found in appendix 2.

3. QPI Formal Review Process

As part of the National Cancer Quality Programme a systematic national review process has been developed, whereby all tumour specific QPIs published are subject to formal review following 3 years analysis of comparative QPI data.

Formal review of the Breast Cancer QPIs was undertaken in December 2015. A formal review group was convened, chaired by Dr Hilary Dobson (Chair, National Cancer Quality Steering Group). Membership of this group included Clinical Leads from the three Regional Cancer Networks. Membership of this group can be found in appendix 3.

The formal review process is clinically driven with comments sought from specialty specific representatives in each of the Regional Cancer Networks for discussion at the initial meeting. This review builds on existing evidence using expert clinical opinion to identify where new evidence is available.

During formal review QPIs may be removed and replaced with new QPIs. Triggers for doing so include significant change to clinical practice, targets being consistently met by all Boards, and publication of new evidence.

Any new QPIs have been developed in line with the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

4. Format of the Quality Performance Indicators

QPIs are designed to be clear and measurable, based on sound clinical evidence whilst also taking into account other recognised standards and guidelines.

- Each QPI has a **short title** which will be utilised in reports as well as a fuller **description** which explains exactly what the indicator is measuring.

- This is followed by a brief overview of the **evidence base and rationale** which explains why the development of this indicator was important.

- The measurability **specifications** are then detailed; these highlight how the indicator will actually be measured in practice to allow for comparison across NHSScotland.

- Finally a **target** is indicated, this dictates the level which each unit should be aiming to achieve against each indicator.

In order to ensure that the chosen target levels are the most appropriate and drive continuous quality improvement as intended they will be kept under review and revised as necessary, if further evidence or data becomes available.

Rather than utilising multiple exclusions, a tolerance level has been built into the QPIs. It is very difficult to accurately measure patient choice, co-morbidities and patient fitness therefore target levels have been set to account for these factors. Further detail is noted within QPIs where there are other factors which influenced the target level.

Where 'less than' (<) target levels have been set the rationale has been detailed within the relevant QPI. All other target levels should be interpreted as 'greater than' (>) levels.

5. Supporting Documentation

A national minimum core dataset and a measurability specification document have been developed in parallel with the indicators to support the monitoring and reporting of Breast Cancer QPIs. These were implemented for all patients diagnosed with breast cancer on, or after, 1st January 2012. All relevant updates have been made to the supporting documentation following formal review of the QPIs.

6. Quality Performance Indicators for Breast Cancer

QPI 1: Multidisciplinary Team Meeting (MDT)

QPI Title:	Patients with newly diagnosed breast cancer should be discussed by a multidisciplinary team prior to definitive treatment.
Description:	Proportion of patients with breast cancer who are discussed at MDT meeting before definitive treatment.
Rationale and Evidence:	Evidence suggests that patients with cancer managed by a multidisciplinary team have a better outcome. There is also evidence that the multidisciplinary management of patients increases their overall satisfaction with their care[3]. Discussion prior to definitive treatment decisions being made provides reassurance that patients are being managed appropriately.
Specifications:	**Numerator:** Number of patients with breast cancer discussed at the MDT before definitive treatment. **Denominator:** All patients with breast cancer. **Exclusions:** • Patients who died before first treatment.
Target:	95% The tolerance within this target is designed to account for situations where cancer is not suspected pre-operatively or where patients receive endocrine treatment prior to MDT meeting.

QPI 2: Non-Operative Diagnosis

QPI Title:	Patients with breast cancer should have a non-operative histological diagnosis.	
Description:	Proportion of patients with invasive or in-situ breast cancer who have a non-operative diagnosis (core biopsy / large volume biopsy).	
Rationale and Evidence:	Diagnosis of patients non-operatively allows them to have only one definitive procedure, where possible. A lesion considered malignant should have histopathological confirmation of malignancy before any definitive surgical procedure takes place[4].	
Specifications:	**Numerator:**	Number of patients with a non-operative diagnosis of breast cancer (core biopsy / large volume biopsy).
	Denominator:	All patients with invasive or in-situ breast cancer.
	Exclusions:	• All breast cancer patients with lobular carcinoma in situ (LCIS).
Target:	95% The tolerance within this target accounts for the fact that it may not always be technically possible to undertake a biopsy and factors of patient choice.	

QPI 3: Pre-Operative Assessment of Axilla

QPI Title:	Patients with breast cancer should have pre-operative assessment of the axilla.
Description:	Proportion of patients with invasive breast cancer who undergo assessment of the axilla: (i) ultrasound (ii) +/- FNA/core biopsy if suspicious morphology is reported on ultrasound, before surgery. **Please note:** This QPI measures 2 distinct elements: (i) All patients with invasive breast cancer should undergo ultrasound assessment of the axilla; and (ii) If findings of ultrasound are suspicious of cancer spread to nodes all patients should undergo FNA/core biopsy. The specifications are therefore separated to ensure clear measurement of both these factors.
Rationale and Evidence:	"A preoperative diagnosis of nodal disease enables definitive treatment of the axilla at the time of initial breast surgery[5]. Patients with invasive breast cancer should undergo pre-treatment ultrasound assessment of the axilla. If morphologically suspicious nodes are identified these should be sampled, using FNA or core biopsy[5 6].
Specifications (i) :	**Numerator:** Number of patients with invasive breast cancer who undergo assessment of the axilla by ultrasound before surgery. **Denominator:** All patients with invasive breast cancer undergoing surgery. **Exclusions:** • No exclusions.
Target:	95% The tolerance within this target accounts for the fact that some patients may refuse investigation and/or treatment.
Specifications (ii):	**Numerator:** Number of patients with invasive breast cancer with suspicious morphology reported on ultrasounds who undergo a FNA/core biopsy of the axilla before surgery. **Denominator:** All patients with invasive breast cancer undergoing surgery with suspicious morphology reported on ultrasound. **Exclusions:** • No exclusions.
Target:	85% The tolerance within this target accounts for the fact that FNA/core biopsy of the axilla it is not always technically possible.

QPI 4: Conservation Rate

QPI Title:	Patients with small breast cancers should undergo breast conservation whenever appropriate*.
Description:	Proportion of surgically treated patients with breast cancer less than 20mm whole tumour size on histology who achieve breast conservation.
Rationale and Evidence:	Breast conservation is appropriate for small breast cancers. Randomised trials have shown no difference in survival for tumours treated by conservation surgery followed by radiotherapy to mastectomy[4]. *Breast conservation may not be appropriate for all patients for a variety of reasons including patient choice, genetic risk and small breast size[7].
Specifications:	**Numerator:** Number of surgically treated patients with breast cancer less than 20mm whole tumour size on histology (invasive plus in situ disease) treated by breast conservation surgery. **Denominator:** All surgically treated patients with breast cancer less than 20mm whole tumour size on histology (invasive plus in situ disease). **Exclusions:** • Patients with multifocal breast cancer. • Patients with breast cancer who have received neoadjuvant systemic therapy for ≥6 weeks (hormonal therapy or chemotherapy). • High risk patients. • Patients who have had previous ipsilateral breast cancer. • Male patients.
Target:	90% The tolerance within this target accounts for the fact that breast conservation may not always be an appropriate treatment option for a variety of reasons, primarily patient choice.

QPI 5: Surgical Margins

QPI Title:	Breast cancers which are surgically treated should be adequately excised.	
Description:	Proportion of surgically treated patients with breast cancer (invasive or ductal carcinoma in situ) with final radial excision margins of less than 1mm.	
Rationale and Evidence:	There is an increased risk of local recurrence if radial surgical excision margins are less than 1mm after breast cancer surgery[4].	
Specifications:	**Numerator:**	Number of patients with breast cancer (invasive or ductal carcinoma in situ) having breast conservation surgery with final radial (i.e. superior, inferior, medial or lateral) excision margins less than 1mm (on pathology report).
	Denominator:	All patients with breast (invasive or ductal carcinoma in situ) cancer having breast conservation surgery.
	Exclusions:	• LCIS alone
Target:	<5% This QPI is measuring the proportion of patients who undergo surgery where the tumour has not been completely excised, a 'less than' target level has therefore been set.	

QPI 6: Re-excision Rates

QPI Title:	Patients undergoing surgery for breast cancer should only undergo one definitive operation where possible.
Description:	Proportion of surgically treated patients with breast cancer (invasive or in situ) who undergo re-excision or mastectomy following their initial surgery.
Rationale and Evidence:	It is important to minimise treatment related morbidity. Patients undergoing additional surgical procedures can be subject to unnecessary stress, as well as potential complications and delays in recovery[8]. Re-operation is also a factor related to poorer cosmetic outcomes for patients [9].
Specifications:	**Numerator:** Number of patients with breast cancer (invasive or in situ) having breast conservation surgery who undergo re-excision or mastectomy following initial surgery. **Denominator:** All patients with breast (invasive or in situ) cancer having breast conservation surgery. **Exclusions:** • LCIS alone
Target:	<20% This QPI is measuring the proportion of patients who undergo more than one surgical procedure to achieve clear margins, a 'less than' target level has therefore been set.

QPI 7: Immediate Reconstruction Rate

QPI Title:	Patients undergoing mastectomy for breast cancer should have access to immediate breast reconstruction.
Description:	Proportion of patients who undergo immediate breast reconstruction at the time of mastectomy for breast cancer.
Rationale and Evidence:	Evidence suggests that breast reconstruction is not associated with an increase in the rate of local recurrence, nor does it affect the ability to detect recurrence, and it can yield psychological benefit. There may be good reasons for individual patients not to undergo immediate breast reconstruction but this indicator is intended to demonstrate that mastectomy patients have access to a reconstructive service[4 7]. Access to immediate breast reconstruction is very difficult to measure accurately therefore uptake is utilised within this QPI as a proxy for access. Although it will not provide an absolute measure of patient access to this procedure it will give an indication of access across NHS Boards and highlight any areas of variance which can then be further examined.
Specifications:	**Numerator:** Number of patients with breast cancer undergoing immediate breast reconstruction at the time of mastectomy. **Denominator:** All patients with breast cancer undergoing mastectomy. **Exclusions:** • All patients with M1 disease*. • All male patients.
Target:	25% The tolerance within this target accounts for patient choice and fitness for treatment. Patient choice is a key factor in the number of patients who undergo immediate breast reconstruction at the time of mastectomy.

Please note:
Additional information on the time from diagnosis to reconstructive surgery will be reported across NHS Boards. This information should be reviewed to ensure there is no impact on quality of care for patients undergoing this treatment option.

* The exclusion of patients with M1 disease is not intended to imply that mastectomy and immediate reconstruction is not a valid treatment option for patients with metastatic disease. The development group recommend that all patients are discussed on an individual basis to determine the most appropriate treatment.

QPI 8: Referral for Genetics Testing

QPI Title:	Patients with breast cancer should be offered referral to a specialist genetics clinic within 6 months of diagnosis where appropriate	
Description:	Proportion of patients with breast cancer who meet the following criteria for gene testing and are referred to a specialist genetics clinic: (i) Patients who are <30 years of age diagnosed with breast cancer (ii) Patients who are <40 years of age diagnosed with triple negative† breast cancer **Please note:** The specifications of this QPI are separated to ensure clear measurement of both.	
Rationale and Evidence:	Where patients have breast cancer, genetic testing should be offered if their combined BRCA1 and BRCA2 mutation carrier probability is ≥10%[10]. Various predictions models exist to assess the likelihood of a BRCA1 or BRCA2 mutation in a family. All patients with TNBC <40 would be predicted to have ≥10% of a BRCA1 or BRCA2 mutation. Breast cancer <30 also increases the likelihood of a BRCA1/BRCA2 or p53 mutation. It is difficult to accurately capture data for all eligibility criteria for gene testing within current systems, therefore measurement of this QPI will focus on patients <30 years of age and patients <40 years of age with triple negative breast cancer in the first instance. This will be kept under review and revised as necessary when further data becomes available.	
Specification (i):	**Numerator:**	Number of patients <30 years of age with breast cancer referred to a specialist clinic for genetic testing within 6 months of diagnosis
	Denominator:	All patients <30 years of age with breast cancer
	Exclusions:	• None
Specification (ii):	**Numerator:**	Number of patients <40 years of age with triple negative breast cancer* referred to a specialist clinic for genetics testing within 6 months of diagnosis
	Denominator:	All patients <40 years of age with triple negative breast cancer*
	Exclusions:	• None
Target:	90% The target tolerance level accounts for factors of patient choice. **Please note:** varying evidence exists regarding the most appropriate target level therefore this may need redefined in the future, to take account of new evidence or as further data becomes available.	

† Triple negative breast cancers are cancers that have tested negative for oestrogen receptors (ER-), progesterone receptors (PR-) and HER2 (HER2-) receptors.

QPI 9: Minimising Hospital Stay -"23 Hour" Surgery

QPI Title:	Patients should have the opportunity for "23 hour" surgery (no overnight stay) wherever appropriate.	
Description:	Proportion of patients undergoing wide excision and/or an axillary sampling procedure for breast cancer with no overnight stay following their procedure.	
Rationale and Evidence:	It is safe to perform wide excision and axillary staging as a short stay procedure in the majority of patients and clinical quality has been shown to be improved utilising this model, resulting in better patient outcomes. Benefits of short stay following surgery include: reduction in re-admissions, reduction in complications, improved patient mobility and enhanced recovery [11].	
Specifications:	**Numerator:**	Number of patients with breast cancer undergoing wide excision and/or axillary sampling procedure (sentinel node biopsy or node sample (≥4 nodes) with no overnight stay following their procedure.
	Denominator:	All patients with breast cancer undergoing wide excision and/or axillary sampling procedure (sentinel node biopsy or node sample (≥4 nodes).
	Exclusions:	• All patients with breast cancer undergoing partial breast reconstruction.
Target:	20% The tolerance within this target takes account of the fact that "23 hour" surgery may not be appropriate for all patients due to social circumstances, co-morbidities and/or the geographical area in which they live. It may not always be safe or practical for patients to go home immediately after surgery; this may therefore affect short-stay surgery rates across NHS Scotland.	

Please note:
SMR01 data will be utilised to support reporting and monitoring of this QPI rather than clinical audit. This will maximise the use of data which are already collected and remove the need for any duplication of data collection. Standard reports are currently being specified and direct access for each Board to run these reports is being investigated to ensure nationally consistent analysis and reporting.

QPI 10: HER2 Status for Decision Making

QPI Title:	HER2 status should be available to inform treatment decision making.
Description:	Proportion of patients with HER2 positive cancer, as defined by ImmunoHistoChemistry (IHC), where HER2 result is available prior to commencing treatment.
Rationale and Evidence:	HER2 status has a significant impact on survival and so has a significant influence on decisions on neoadjuvant and adjuvant treatment[5]. Delay in the availability of a HER2 result may lead to a delay in appropriate neoadjuvant or adjuvant therapy and make communication of a clear plan to the patient more difficult. At present HER2 testing is undertaken in all relevant cases; however the point of the patient pathway at which this takes place varies across NHS Scotland. The purpose of this indicator is to synchronise practice across Scotland by ensuring the availability of HER2 status to inform treatment decision making.
Specifications:	**Numerator:** Number of patients with HER2 positive (by 3+ on IHC &/or FISH +ve) breast cancer for whom the HER2 result is available prior to definitive treatment. **Denominator:** All patients with HER2 positive (by 3+ on IHC &/or FISH +ve) breast cancer. **Exclusions:** • No exclusions.
Target:	90% The tolerance within this target is designed to account for situations where patients require treatment urgently.

QPI 11: Radiotherapy for Breast Conservation

QPI Title:	After wide local excision patients with breast cancer should receive radiotherapy.	
Description:	Proportion of patients with breast cancer who receive radiotherapy to the breast after conservation for invasive cancer.	
Rationale and Evidence:	Trials have demonstrated a significant reduction in local recurrence with the use of radiotherapy after breast conservation[12]. Clinical trials of radiotherapy have shown it can produce a reduction in local recurrence would produce an absolute increase in 20-year survival of about 2-4%[13 14 15].	
Specifications:	**Numerator:**	Number of patients with invasive breast cancer having conservation surgery receiving radiotherapy to the breast.
	Denominator:	All patients with invasive breast cancer having conservation surgery.
	Exclusions:	• All patients with breast cancer taking part in clinical trials of radiotherapy treatment. • All patients with M1 disease.
Target:	95% The tolerance within this target accounts for factors of patient choice and fitness for treatment.	

QPI 12: Adjuvant Chemotherapy

QPI Title:	Patients with higher risk breast cancer should receive chemotherapy post operatively where it will provide a survival benefit for patients.
Description:	Proportion of patients with surgically proven node positive (or at least G3 >20mm breast cancer) and a ≥5% benefit predicted* who receive adjuvant chemotherapy.
Rationale and Evidence:	Large randomised trials have confirmed that adjuvant systemic therapy improves relapse-free survival and overall survival[12]. Clinical trials have demonstrated that adjuvant drug treatments substantially reduce 5-year recurrence rates and 15-year mortality rates[16]. Success of treatment is based on a number of different factors including tumour size, grade and involvement of lymph nodes. Prognostic tools such as PREDICT assist clinicians and patients to make informed decisions on appropriate treatment by predicting survival and determining those patients likely to benefit from adjuvant treatment.[17, 18]
Specifications:	**Numerator:** Number of patients with surgically proven node positive (or at least G3 >20mm breast cancer), with a ≥5% benefit predicted who receive adjuvant chemotherapy. **Denominator:** All patients with surgically proven node positive (or at least G3 >20mm breast cancer), with a ≥5% benefit predicted. **Exclusions:** • All patients with breast cancer taking part in trials of chemotherapy treatment. • All patients with breast cancer who have had neo-adjuvant chemotherapy. • All patients with M1 disease.
Target:	85% The tolerance within this target accounts for factors of patient choice, co-morbidities and fitness for treatment.

*The validated tool PREDICT should be used to calculate predicted benefit

QPI 13: 30 Day Mortality following Chemotherapy

QPI Title:	30 day mortality following chemotherapy treatment with curative intent for breast cancer.	
Description:	Proportion of patients with breast cancer who die within 30 days of chemotherapy with curative intent. .	
Rationale and Evidence:	Treatment related mortality is a marker of the quality and safety of the whole service provided by the Multi Disciplinary Team (MDT)[12] Outcomes of treatment, including treatment related morbidity and mortality should be regularly assessed. Treatment should only be undertaken in individuals that may benefit from that treatment, that is, treatments should not be undertaken in futile situations. This QPI is intended to ensure treatment is given appropriately, and the outcome reported on and reviewed.	
Specifications:	**Numerator:**	Number of patients with breast cancer who undergo neoadjuvant or adjuvant chemotherapy with curative intent that die within 30 days of treatment.
	Denominator:	All patients with breast cancer who undergo neoadjuvant or adjuvant chemotherapy with curative intent.
	Exclusions:	• No exclusions
	Please note:	This indicator will be reported separately for neoadjuvant and adjuvant chemotherapy, as opposed to one single figure.
Target:	<2%	

7. Survival

Improving survival forms an integral part of the national cancer quality improvement programme. The Breast Cancer QPI Development Group has therefore identified issues which should be addressed within breast cancer survival analysis (see survival QPIs 1 and 2 below).

To ensure consistent application of survival analysis, it has been agreed that a single analyst on behalf of all three regional cancer networks undertakes this work. Survival analysis is scheduled as per the national survival analysis and reporting timetable, agreed with the National Cancer Quality Steering Group and Scottish Cancer Taskforce. This reflects the requirement for record linkage and the more technical requirements of survival analyses which makes it difficult for individual Boards to undertake routinely and in a nationally consistent manner.

Survival QPI 1: Overall 5 year Survival

QPI Title:	Overall 5 year survival for Breast Cancer.
Description:	5 year observed (Kaplan Meier) survival estimates for all breast cancer patients in Scotland diagnosed in the relevant year(s).
Rationale and Evidence:	Previous studies suggest that population-based survival from breast cancer was lower in Scotland than in some other European countries. Survival from breast cancer has been improving and it is expected that better clinical management will result in better outcomes for patients[19 20].
Specifications:	5 year observed (Kaplan Meier) survival estimates for all breast cancer patients in Scotland diagnosed in the relevant year(s). Time to event measured: days between date of diagnosis and date of death. Patients with no date of death are censored at the latest available confirmed date of death (from GRO(S) linked file). Ideally, requires case ascertainment in excess of 90%. Further analysis may be provided depending on clinical relevance e.g. • Prognostic indicators e.g. Deprivation • Age-standardised estimates • Cause-specific analysis • Relative survival **Exclusions:** • Patients with breast lymphoma, sarcoma/phyllodes or in situ disease only. • Patients diagnosed at autopsy.
Target:	85%

Survival QPI 2: Overall 5 year survival for patients presenting symptomatically

QPI Title:	Overall 5 year survival for Breast Cancer for patients presenting symptomatically.
Description:	5 year observed (Kaplan Meier) survival estimates for all symptomatic breast cancer patients in Scotland diagnosed in the relevant year(s).
Rationale and Evidence:	Previous studies suggest that population-based survival from breast cancer was lower in Scotland than in some other European countries. Survival from breast cancer has been improving and it is expected that better clinical management will result in better outcomes for patients. It is likely that screening has contributed to these improvements but it is important that those presenting symptomatically are managed appropriately to ensure the optimum outcome and that units not dealing with screening patients are able to compare their results with those across the country[19 20].
Specifications:	5 year observed (Kaplan Meier) survival estimates for all symptomatic breast cancer patients in Scotland diagnosed in the relevant year(s). Time to event measured: The number of days between date of diagnosis and date of death. Patients with no date of death are censored at the latest available confirmed date of death (from GRO(S) linked file). Ideally, requires case ascertainment in excess of 90%. Further analysis may be provided depending on clinical relevance e.g. • Prognostic indicators e.g. Deprivation • Age-standardised estimates • Cause-specific analysis • Relative survival **Exclusions:** • All screen-detected breast cancer patients. • Patients with breast lymphoma, sarcoma/phyllodes or in situ disease only. • Patients diagnosed at autopsy.
Target:	75%

8. Governance and Scrutiny

A national and regional governance framework to assure the quality of cancer services in NHSScotland has been developed; key roles and responsibilities within this are set out below. Appendices 4 and 5 provide an overview of these governance arrangements diagrammatically. The importance of ensuring robust local governance processes are in place are recognised and it is essential that NHS Boards ensure that cancer clinical audit is fully embedded within established processes.

8.1 National

- Scottish Cancer Taskforce
  - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHS Scotland.

- Healthcare Improvement Scotland
  - Proportionate scrutiny of performance.
  - Support performance improvement.
  - Quality assurance: ensure robust action plans are in place and being progressed via regions/Boards to address any issues identified.

- Information Services Division (ISD)
  - Publish national comparative report on tumour-specific QPIs and survival for approximately 3 tumour types per annum as part of the rolling programme of reporting.

8.2 Regional – Regional Cancer Networks

- Annual regional comparative analysis and reporting against tumour-specific QPIs.
- Support national comparative reporting of specified generic QPIs.
- Identification of regional and local actions required and development of an action plan to address regional issues identified.
- Performance review and monitoring of progress against agreed actions.
- Provide assurance to Board Chief Executive Officers that any issues identified have been adequately and timeously progressed.

8.3 Local – NHS Boards

- Collect and submit data for regional comparative analysis and reporting in line with agreed measurability and reporting schedule (generic and tumour-specific QPIs).
- Utilise local governance structures to review performance, develop local action plans and monitor delivery.
- Demonstrate continual improvements in quality of care through on-going review, analysis and feedback of clinical audit data at an individual MDT or unit level.

9. Areas for Future Consideration

The Breast Cancer QPI Groups have not been able to identify sufficient evidence, or determine appropriate measurability specifications, to address all areas felt to be of key importance in the treatment of breast cancer, and therefore in improving the quality of care for patients affected by breast cancer.

The following areas for future consideration have been raised across the lifetime of the Breast Cancer QPIs:

- Conservation rates for more extensive cancers
- Optimum number of nodes for accurate axillary staging
- Management of the Axilla
- Cardiac Sparing Radiotherapy

10. How to participate in the engagement process

In order to ensure wide inclusiveness of clinical and management colleagues from across NHS Scotland, patients affected by breast cancer and the wider public, several different methods of engagement are being pursued:

Professional groups, health service staff, voluntary organisations and individuals:

- Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

- Organised patient focus group sessions to be held.

10.1 Submitting your comments

You can submit your comments on the breast cancer QPIs via the Scottish Government Consultation Hub (website link below):

https://consult.scotland.gov.uk/nhs/breast-cancer-qpi

All responses should be submitted by **Friday 3rd June 2016**.

If you require any further information regarding the engagement process please use the email address below.

Email: BreastQPIPublicEngagement@gov.scot

10.2 Engagement feedback

At the end of the engagement period, all comments and responses will be collated for review by the Breast Cancer QPI Formal Review Group. Those who have participated in the engagement process will receive an overview of the changes made and a copy of the final Breast Cancer QPI document.

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12. Appendices

Appendix 1: QPI Development Process

Preparatory Work and Scoping

NHS Quality Improvement Scotland (formerly Clinical Standards Board for Scotland) Clinical Standards for Breast Cancer have been utilised nationally since 2001. It was therefore agreed that rather than undertake a lengthy QPI development process the extensive literature search and clinical discussion undertaken in the review of NHS Quality Improvement Scotland (NHSQIS) breast standards (in 2008) was used as the basis for QPI development.

The preparatory work involved the development group members independently reviewing and assessing the existing NHS QIS Breast Cancer Standards against agreed criteria and identifying any potential gaps where they considered a need to develop new outcome focussed quality indicators. Responses were then collated and the output of this exercise used to inform development group discussions.

Indicator Development

The Breast Cancer QPI Development Group defined evidence based, measurable indicators with a clear focus on improving the quality and outcome of care provided.

The Group developed QPIs using the existing NHS QIS clinical standards as a base. Draft QPIs were then assessed by the Breast Cancer QPI Development Group against three criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Engagement Process

A wide clinical and public engagement exercise was undertaken as part of development in 2011 where the Breast Cancer QPIs, along with accompanying draft minimum core dataset and measurability specifications, were made available on the Scottish Government website.

During the engagement period clinical and management colleagues from across NHSScotland, patients affected by breast cancer and the wider public were given the opportunity to influence the development of Breast Cancer QPIs. Several different methods of engagement were utilised:

Professional groups, health service staff, voluntary organisations and individuals:

- Wide circulation of the draft documentation for comment and feedback.

Patient representative groups:

- Organised patient focus group sessions were held in conjunction with Cancer Support Scotland (Tak Tent) and Breakthrough Breast Cancer.

Following the engagement period all comments and responses received were reviewed by the Breast Cancer QPI Development Group and used to produce and refine the final indicators.

Appendix 2: Breast Cancer QPI Development Group Membership

Name	Designation	Cancer Network/Base
Jennifer Armstrong	Senior Medical Officer (CHAIR)	Scottish Government
Ruth Adamson	Consultant Pathologist (Clinical Lead – Subgroup 1)	WoSCAN (Crosshouse Hospital, Kilmarnock)
Matthew Barber	Consultant Surgeon (Clinical Lead – Subgroup 2)	SCAN (Western General Hospital, Edinburgh)
Sophie Barrett	Consultant Oncologist	WoSCAN (Beatson West of Scotland Cancer Centre)
Carolyn Bedi	Consultant Oncologist	SCAN (Western General Hospital, Edinburgh)
Emma Bennett	Lead Breast Care Nurse Specialist	SCAN (Western General Hospital, Edinburgh)
Janet Clarke	Consultant Radiographer	SCAN (Western General Hospital, Edinburgh)
John Dewar	Consultant Oncologist (Clinical Lead – Subgroup 3)	NOSCAN (Ninewells Hospital, Dundee)
Heather Deans	Consultant Radiologist	NOSCAN (Aberdeen Royal Infirmary, Aberdeen)
Hilary Dobson	Clinical Director (Clinical Lead – Subgroup 1)	WoSCAN (WoS Breast Screening Service, Glasgow)
Christine Dodds	Senior Cancer Audit Facilitator	SCAN (Western General Hospital, Edinburgh)
Clare Echlin	Acting Head of Standards Development	Healthcare Improvement Scotland
Steven Heys	Consultant Breast Surgeon	NOSCAN (Aberdeen Royal Infirmary, Aberdeen)
Alison Lannigan	Consultant Breast Surgeon (Clinical Lead – Subgroup 2)	WoSCAN (Wishaw General Hospital, Lanarkshire)
Joseph Loane	Consultant Pathologist	SCAN (Western General Hospital, Edinburgh)
Evelyn Macdonald	Clinical Nurse Specialist	NOSCAN (Raigmore Hospital, Inverness)
Stella MacPherson	Patient Representative	
Carol Marshall	Information Manager	WoSCAN
Andy Maylon	Consultant Plastic Surgeon	WoSCAN (Royal Infirmary, Glasgow)
Pauline McIlroy	Clinical Nurse Specialist	WoSCAN (Beatson West of Scotland Cancer Centre)
Brian Murray	National Cancer Information Coordinator	Information Services Division

Name	Designation	Cancer Network/Base
Colin Purdie	Consultant Pathologist	NOSCAN (Ninewells Hospital, Dundee)
Iona Scott	Project Manager	
Carole Smith	Patient Representative	
Evelyn Thomson	Regional Manager (Cancer)	WoSCAN
Eva Weiler-Mithoff	Consultant Plastic Surgeon	WoSCAN (Royal Infirmary, Glasgow)
Philippa Whitford	Consultant Surgeon	WoSCAN (Crosshouse Hospital, Kilmarnock)

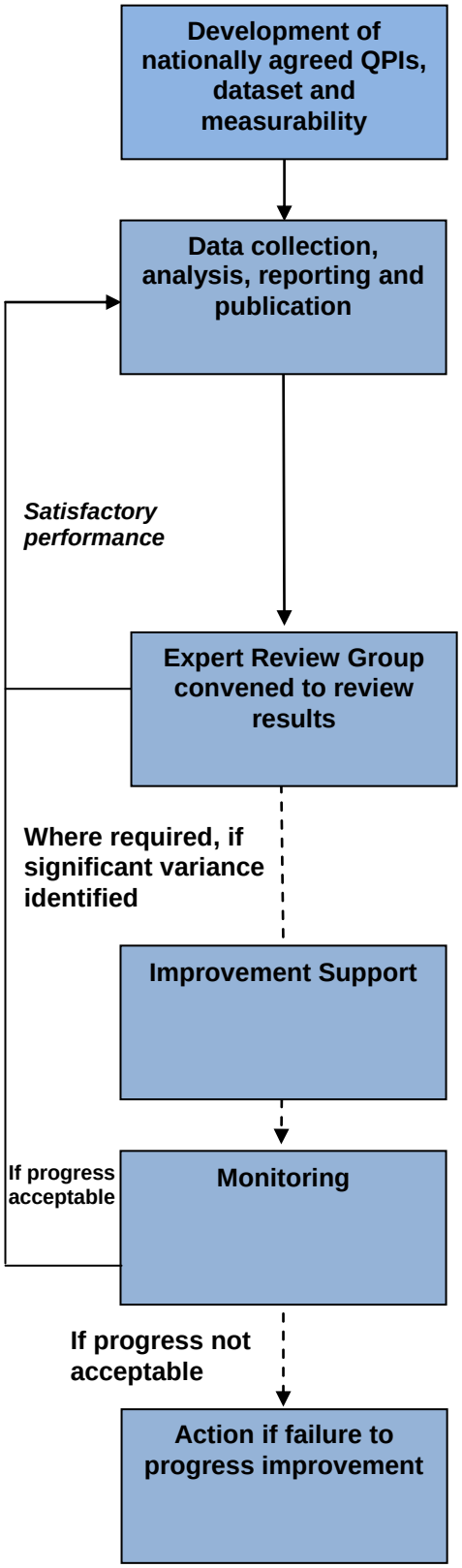
NOSCAN - North of Scotland Cancer Network
SCAN – South East Scotland Cancer Network
WoSCAN – West of Scotland Cancer Network

Appendix 3: Breast Cancer QPI Formal Review Group Membership

Name	Designation	Cancer Network/Base
Hilary Dobson	Chair, National Cancer Quality Steering Group	WoSCAN
Evelyn Thomson	Regional Cancer Manager	WoSCAN
Iona Reid	Clinical Lead Breast Cancer MCN	WoSCAN / NHS Greater Glasgow & Clyde
Glyn Neades	Clinical Lead Breast Cancer MCN	SCAN / NHS Lothian
Douglas Brown	Clinical Lead Breast Cancer MCN	NOSCAN / NHS Tayside
Wilma Jack	Senior Clinical Research Fellow	SCAN / NHS Lothian
Christine Urquhart	Cancer Audit Manager	NOSCAN
Iona Scott	Quality & Service Improvement Manager	WoSCAN
Jen Doherty	Project Co-ordinator	National Cancer Quality Programme

Appendix 4: 3-Yearly National Governance Process and Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 5).



1. National QPI Development Stage

- QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, ISD, patient representatives and the Cancer Coalition.

2. Data Analysis Stage:

- NHS Boards and Regional Cancer Advisory Groups (RCAGs)* collect data and analyse on yearly basis using nationally agreed measurability criteria and produce action plans to address areas of variance, see section 2.
- Submit yearly reports to ISD for collation and publication every 3 years.
- ISD produce comparative, publicly available, national report consisting of trend analysis of 3 years data and survival analysis.
- National comparative report approved by NHS Boards and RCAGs.

3. Expert Review Group Stage (for 3 tumour types per year):

- Expert group, hosted by Healthcare Improvement Scotland, review comparative national results.
- Write to RCAGs highlighting areas of good practice and variances.
- Where required NHS Boards requested to submit improvement plans for any outstanding unresolved issues with timescales for improvement to expert group.
- Improvement plans ratified by expert group and Scottish Cancer Taskforce.

4. Improvement Support Stage:

- Where required Healthcare Improvement Scotland provide expertise on improvement methodologies and support.

5. Monitoring Stage:

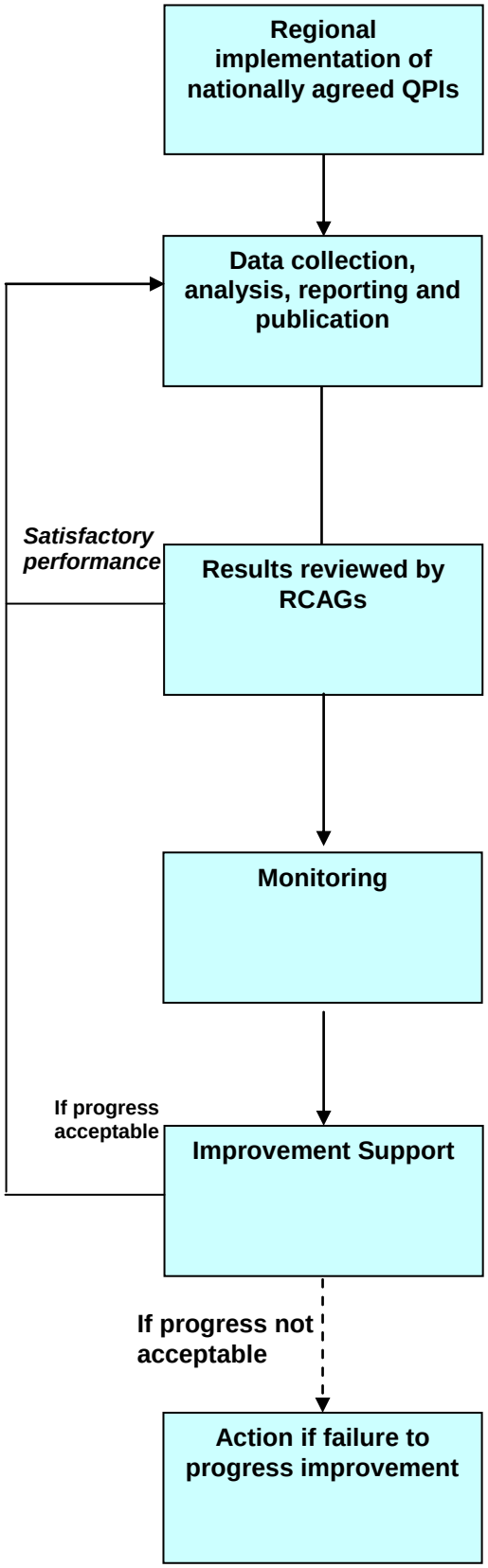
- RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
- Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable.

6. Escalation Stage:

- If progress not acceptable, Healthcare Improvement Scotland will visit the service concerned and work with the RCAG and Board to address issues.
- Report submitted to Scottish Cancer Taskforce and escalation with a proposal to take forward to Scottish Government Health Department.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 5: Regional Annual Governance Process and Improvement Framework for Cancer Care



1. Regional QPI Implementation Stage:

- National cancer QPIs and associated national minimum core dataset and measurability specifications, developed by QPI development groups.
- Regional implementation of nationally agreed dataset to enable reporting of QPIs.

2. Data Analysis Stage:

- NHS Boards collect data and data is analysed on a yearly basis using nationally agreed measurability criteria at local/ regional level.
- Data/results validated by Boards and annual regional comparative report produced by Regional Networks.
- Areas of best practice and variance across the region highlighted.
- Yearly regional reports submitted to ISD for collation and presentation in national report every 3 years.

3. Regional Performance Review Stage:

- RCAGs* review regional comparative report.
- Regional or local NHS Board action plans to address areas of variance developed.
- Appropriate leads identified to progress each action.
- Action plans ratified by RCAGs.

4. Monitoring Stage:

- Where required, NHS Boards monitor progress with action plans and submit progress reports to RCAGs.
- RCAGs review and monitor regional improvement.

5. Improvement Support Stage:

- Where required Healthcare Improvement Scotland maybe requested to provide expertise to NHS Boards/RCAGs on improvement methodologies and support.

6. Escalation Stage:

- If progress not acceptable, RCAGs will escalate any issues to relevant Board Chief Executives. If progress remains unacceptable RCAGs will escalate any relevant issues to Healthcare Improvement Scotland.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).

Appendix 6: Glossary of Terms

23-hour surgery	23-hour surgery is the admission of patients to hospital for a planned surgical procedure where they return home within 24 hours, i.e. involves 1 overnight stay.
Adjuvant therapy / treatment	Treatment given in addition to the primary therapy, or a secondary remedy assisting the action of another.
Age-standardised	Age-standardisation facilitates comparisons across geographical areas by controlling for differences in the age structure of local populations.
Axilla	The armpit.
Axillary clearance	Operation to remove all the lymph glands from under the arm.
Biopsy	Removal of a sample of tissue from the body to assist in diagnosis of a disease.
Breast	Glandular organ located on the chest. The breast is made up of connective tissue, fat, and breast tissue that contains the glands that can make milk. Also called mammary gland.
Cause-specific survival	A method of estimating net survival. Only deaths attributable to the cancer of diagnosis are counted as deaths, giving the probability of survival in the absence of other causes of death.
Chemotherapy	The use of drugs that kill cancer cells, or prevent or slow their growth.
Co-morbidity	The condition of having two or more diseases at the same time.
Conservation surgery	An operation to remove the breast cancer but not the breast itself. Types of breast-conserving surgery include lumpectomy (removal of the lump), quadrantectomy (removal of one quarter, or quadrant, of the breast), and segmental mastectomy (removal of the cancer as well as some of the breast tissue around the tumour and the lining over the chest muscles below the tumour).
Core biopsy	Removal (using a needle) of a piece of a breast tissue for diagnosis.
Day case	Day surgery is the admission of selected patients to hospital for a planned surgical procedure, returning home on the same day.
Definitive procedure/ treatment	The treatment plan for a disease or disorder that has been chosen as the best one for a patient after all other choices have been considered.
Deprivation	Currently, the Scottish Index of Multiple Deprivation (SIMD) is used to estimate an individual's level of affluence. This is based on seven domains (income, employment, education, housing, health, crime, and geographical access) combined into an overall index.
Ductal Carcinoma In Situ (DCIS)	When the breast cancer cells are completely contained within the ducts (the channels in the breast that carry milk to the nipple) and have not spread into the surrounding breast tissue.
Excision Margins	The edge or border of the tissue removed in surgery.
Fine Needle Aspiration (FNA)	The withdrawal of fluid, containing cells, from the body by means of suction using a fine needle. The samples obtained are used to provide information on the cells of tumours or cysts.

Fluorescence In Situ Hybridization (FISH)	This is a lab test that measures the amount of a certain gene in cells. It can be used to see if an invasive cancer has too many HER2 genes.
Genetic	Inherited; having to do with information that is passed from parents to offspring through genes in sperm and egg cells.
Histological / Histopathogical	The study of the structure, composition and function of tissues under the microscope, and their abnormalities.
Hormonal therapy	Treating a disease with hormones, or by blocking the action of hormones.
Human Epidermal growth factor Receptor (HER) 2	One of many receptors on the surface of certain cells which can protect the cell from damage or stimulate it to grow. This is the target, present on some breast cancer cells, which is hit by Herceptin (trastuzumab).
Immediate Breast Reconstruction	Breast reconstruction carried out at the same time as the operation to remove the breast.
Immunohistochemistry (IHC)	A technique used to identify specific molecules in different kinds of tissue. The tissue is treated with antibodies that bind the specific molecule. These are made visible under a microscope by using a colour reaction, a radioisotope, colloidal gold, or a fluorescent dye. Immunohistochemistry is used to help diagnose diseases, such as cancer, and to detect the presence of micro organisms. It is also used in basic research to understand how cells grow and differentiate (become more specialized).
In situ	A cancer that is 'in place', is non-invasive, has not spread beyond the initial location.
Invasive	Cancer that can or has spread from its histological original site.
Kaplan Meier	A widely used technique for estimating observed (crude) survival.
Lesion	Tumour, mass, or other abnormality.
Lobular Carcinoma In Situ (LCIS)	A condition in which abnormal cells are found in the lobules of the breast. Lobular carcinoma in situ seldom becomes invasive cancer; however, having it in one breast increases the risk of developing breast cancer in either breast.
Lymph Nodes	Small bean shaped organs located along the lymphatic system. Nodes filter bacteria or cancer cells that might travel through the lymphatic system.
Malignant/Malignancy	Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.
Mastectomy	Surgical removal of a breast.
Metastases/Metastatic	Spread of cancer away from the primary site to somewhere else via the bloodstream or the lymphatic system.
Morbidity	How much ill health a particular condition causes.
Morphology / Morphologically	The science of the form and structure of organisms (plants, animals, and other forms of life).
Multidisciplinary team meeting	A meeting which is held on a regular basis, which is made up of participants from various disciplines appropriate to the disease area, where diagnosis, management, and appropriate treatment of patients is discussed and decided.
Multifocal disease	Occurring in more than one location in the breast.

Neoadjuvant therapy / treatment	Drug treatment which is given before the treatment of a primary tumour with the aim of improving the results of surgery or chemotherapy and preventing the development of metastases.
Observed survival	A method of estimating the actual survival prospects of patients following diagnosis. Includes deaths from all causes and does not adjust for underlying differences in patient populations.
Pathological	The study of disease processes with the aim of understanding their nature and causes. This is achieved by observing samples of fluid and tissues obtained from the living patient by various methods, or at post mortem.
Prognostic indicators	Factors, such as staging, tumour type or deprivation that may influence treatment effectiveness and outcomes.
Psychological	Having to do with how the mind works and how thoughts and feelings affect behaviour.
Radiotherapy	The use of radiation, usually X-rays or gamma rays, to kill tumour cells.
Randomised Clinical Trials	A study to test a specific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study.)
Recurrence	When new cancer cells are detected at the site of the original tumour, following treatment.
Relative survival	A method of estimating net survival. The ratio of observed survival divided by expected survival, where the expected survival is based on the life expectancy of the population (from lifetables). This can be thought of as a measure of the survival expectation after developing cancer, or the probability of survival from cancer in the absence of other causes of death.
Sentinel node biopsy	The lymph node near a body organ or part of an organ which is thought to be the first reached by tissue fluid draining from that organ, this lymph node may be the one most likely to contain cancer cells if the cancer has begun to spread.
Staging	Process of describing to what degree cancer has spread from its original site to another part of the body. Staging involves clinical, surgical and pathology assessments.
Surgery/Surgically	Surgical removal of the tumour/lesion.
Surgical margins	See *Excision Margins*
Survival	The percentage of people in a study or treatment group who are alive for a certain period of time after they were diagnosed with or treated for a disease, such as cancer.
Trastuzumab	A manufactured antibody (a small part of out immune defences) which is attracted to the HER2 receptor on some breast cancers. It signals to the immune system to destroy these cells.

Tumour/s	A lump or mass of cells which can be either benign (not cancerous) or malignant.
Ultrasound	An imaging test that bounces sound waves off tissues and converts the echoes into pictures.
Wide excision	The removal of the breast lump together with some surrounding tissue.

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