NHS
Quality Improvement Scotland

Clinical Standards ~ July 2008 (new edition)

Management of breast cancer services

NHS Quality Improvement Scotland is committed to equality and diversity. We have assessed this area of work for likely impact on the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation. An equality and diversity impact assessment report has been published along with these standards and is available online or in hardcopy upon request.

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1 Introduction

Cancer services are provided by a wide range of individuals and organisations (statutory and voluntary), throughout Scotland: from primary care, through secondary and tertiary care, regional centres such as the Beatson Oncology Centre in Glasgow and local hospices/specialist palliative care units. Cancer treatment and care is highly dependent on other core NHS services, such as diagnostics and imaging, and therefore cannot be planned or managed in isolation. The role and importance of others in the delivery of cancer care and the provision of cancer services should also be noted, for example, community pharmacists and dentists.

In July 2001, the then Scottish Executive Health Department (SEHD), now the Scottish Government Health Directorates (SGHD), published its cancer strategy, Cancer in Scotland: Action for Change[1]. This document sets the context in which NHSScotland should plan activity to improve the services for people across Scotland. The commitment of the then SEHD to tackle cancer in Scotland was emphasised by the new resources that accompanied the cancer strategy, and were allocated specifically to improve cancer services. These funds were distributed through Regional Cancer Advisory Groups (RCAGs), supported by Regional Cancer Networks. Each Regional Cancer Network reports to the Scottish Cancer Group (SCG) via its RCAG.

Objective

In May 2004, Cancer in Scotland: Sustaining Change[2] was published by the SEHD to highlight progress made since the original strategy was published in 2001, and to identify new challenges facing the service. To support NHSScotland in the continuous improvement of cancer services, NHS Quality Improvement Scotland (NHS QIS) agreed to revise and update four tumour specific cancer standards: breast, colorectal (bowel), lung and gynaecological (ovarian) cancer, first developed in 2001.

2 Development of the clinical standards for management of breast cancer services

In 2001, the Clinical Standards Board for Scotland (CSBS, one of the organisations drawn together to form NHS QIS) produced standards for breast, colorectal, gynaecological (ovarian) and lung cancer. Peer review visits to assess performance against the four cancer standards were carried out throughout Scotland during 2001. Findings from these reviews were published by CSBS in 2002, in the form of local NHS board reports and a national overview.

The standards for core cancer services draw together common elements of service provision covered by the original standards, and these have been updated in light of developments in the service. NHS QIS began revisions of the four original tumour-site specific cancer standards in 2006, and the clinical standards for breast cancer services form part of this work.

The revision of clinical standards for breast cancer services has been the responsibility of NHS QIS, taking into account advice from SGHD and in consultation with NHS organisations.

Under the direction of the core cancer services working group established by NHS QIS, a clinical adviser was appointed to oversee the revision of the breast cancer standards. A small working group was then convened to re-examine the evidence base on which the 2001 breast cancer standards were developed, and to revise the standards in light of changes in current best practice and clinical advancements.

Evidence base

During the revision of the clinical standards for breast cancer services, the working group considered a wide range of evidence, which is fully referenced in Chapter 4 (References).

The following standards, local reports and national overview formed the core evidence reviewed by the working group.

- **Clinical standards: breast cancer**[3]
- **Local reports: breast cancer services**[4]
- **National overview: breast cancer**[5]
- **National Standards: Clinical Governance and Risk Management: Achieving Safe, Effective, Patient-Focused Care and Services**[6]
- **Draft core standards for cancer services**[7]

Relevance to standards development: A review of these documents determined the scope of the clinical standards, to establish equity of care and the best possible condition management for patients, no matter where they live. The group considered how these standards should be applied at an operational level, and ensured that duplication would not occur across the above standards.

- **NHS HDL(2007)21: Strengthening the role of managed clinical networks**[8]
- **Quality assurance frameworks for north of Scotland cancer network (NOSCAN)**[9], **south east Scotland cancer network (SCAN)**[10] **and west of Scotland cancer network (WOSCAN)**[11]

Relevance to standards development: The frameworks provide quality assurance measures for all staff involved in the delivery of care in cancer services and are tailored on a regional basis. The frameworks for the three regional cancer networks were reviewed to prevent duplication within the standards.

- **Cancer Scenarios: An aid to planning cancer services in Scotland in the next decade**[12]
- **Cancer in Scotland: Action for Change**[1]
- **Cancer in Scotland: Sustaining Change**[2]
- **Cancer waiting times: National delivery plan**[13]

Relevance to standards development: These documents guide operating divisions and clinicians to implement the measures necessary to improve cancer services. Awareness of the recognised processes across NHSScotland is important when developing standards. It helped the working group to develop a practical tool for supporting continuous quality improvement, taking into account how services are delivered and monitored. Further guidance to support the introduction of Cancer in Scotland: Action for Change is available in two Health Department Letters, HDL(2001)54[14] and HDL(2001)71[15].

Standards development

To take forward the revision of the standards, NHS QIS appointed a working group to review the evidence and use it to inform the revision of the clinical standards. The group was chaired by Ms Philippa Whitford, Consultant Breast Surgeon, NHS Ayrshire & Arran. Full membership of the group can be found in Appendix 3.

Consultation

Following publication of the Draft Clinical Standards for Breast Cancer Services[16] in August 2007, consultation was undertaken. During this period professional groups, health service staff, voluntary organisations and individuals were given the opportunity to influence the development of the standards.

Finalising the standards

Following consultation each written comment and all feedback on the draft standards were used by the working group to produce final standards.

3 Clinical standards for management of breast cancer services

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Section 1: Unit structure

Standard 1: Referral and diagnosis of breast cancer

Standard Statement 1a
All breast clinics have facilities to provide a rapid access breast cancer service.

Rationale

There is evidence that rapid access to a symptomatic breast clinic provides an accurate and effective means of establishing a correct diagnosis in women referred with symptoms.

'One-stop' clinics have significantly improved patients' experiences of rapid access to investigation and diagnosis across the country. However, to increase capacity, or in a rural setting, other strategies may be utilised.

References: 1, 17, 18, 19, 20

Essential Criterion

1a.1 All main diagnostic modalities are available to the breast clinic:

- mammography (with immediate reporting)
- ultrasound (with immediate reporting)
- fine needle aspiration (FNA) (if this modality is used) (with immediate reporting), and
- core biopsy (not reported immediately).

Section 1: Unit structure

Standard 1: Referral and diagnosis of breast cancer

Standard Statement 1b
All breast imaging departments are equipped and staffed to deliver a high quality service and accurate imaging.

Rationale

High quality mammographic equipment and trained specialist breast imaging staff are essential for breast cancer diagnosis.

References: 21, 22, 23, 24, 25

Essential Criteria

1b.1 All mammographic equipment, processors, ultrasound units and dedicated mammographic viewers are subject to regular quality assurance (QA) and performance testing in line with NHS Breast Screening Programme (NHSBSP) guidelines.

1b.2 Breast magnetic resonance imaging (MRI) is available within the NHS board area as part of the local breast imaging network.

1b.3 There are local imaging protocols in place in the NHS board area.

1b.4 Breast radiologists and film readers:

- read a minimum of 500 mammogram cases per year
- double report all 'screening' mammograms such as family history patients, and
- have a protocol in place for resolving discrepancies between first and second reader.

1b.5 Diagnostic mammography reports include:

- assessment of breast density, and
- radiological grading.

Desirable Criteria

1b.6 All categories of mammograms are double-read as part of standard practice.

1b.7 Breast radiologists and film readers:

- report more than 1,000 mammogram cases per year
- are involved in both symptomatic and screening breast imaging, and
- have access to Personal Performance in Mammographic Screening (PERFORMS) external radiology QA.

Section 1: Unit structure

Standard 2: Multidisciplinary working

Standard Statement 2a
Patients with breast cancer are managed within a structured multidisciplinary network of care locally, and in the region.

Rationale

Evidence suggests patients with breast cancer managed by a multidisciplinary team have a better outcome.

To ensure co-ordination and appropriate management of a patient within a multidisciplinary team, it is essential for patients that there is a named lead consultant.

Rural units who do not have specialist surgeons or breast clinical nurse specialists, are recommended to link with the multidisciplinary team and multidisciplinary team meetings in their nearest breast unit in order to discuss patients, allowing for some aspects of care to be delivered locally.

References: 8, 17, 18, 23, 26, 27, 28, 29

Essential Criteria

2a.1 There is a named lead consultant for breast cancer services within the NHS board.

2a.2 The following core constitution of a breast cancer multidisciplinary team (MDT) is represented at each weekly MDT meeting:

- specialist breast surgeon/s
- specialist oncologist/s
- breast pathologist on a rotational basis
- breast radiologist on a rotational basis
- breast clinical nurse specialist (CNS), and
- mammographer.

With access to:

- plastic surgeon (with special interest)
- orthopaedic surgeon (with special interest)
- palliative care specialist
- physiotherapist, and
- psychologist/psychiatrist.

2a.3 Representatives of the core breast cancer MDT actively participate in the regional breast cancer managed clinical network (MCN).

2a.4 Members of the core breast cancer MDT demonstrate ongoing professional development in breast cancer management by obtaining more than 12 hours per year externally registered continuing professional development (CPD) points.

2a.5 All breast clinical nurse specialists, radiographers and sonographers have appropriate accreditation to conform to the knowledge and skills framework (KSF).

2a.6 All laboratories undertaking immunoassays of hormone and human epidermal growth factor receptor 2 (HER2) status participate in a recognised external QA scheme.

Desirable Criteria

2a.7 All pathologists undertaking breast work participate in the UK breast histopathology National External Quality Assessment Scheme or equivalent.

2a.8 Members of the core breast cancer MDT demonstrate ongoing professional development in breast cancer management by obtaining more than 20 hours per year externally registered CPD points.

N.B. Rural units must describe how they access the MDT and MDT meetings within their area or region.

Section 1: Unit Structure

Standard 2: Multidisciplinary working

Standard Statement 2b
Prior to performing any definitive treatment the patient is fully discussed by a breast cancer multidisciplinary team.

Rationale

The Clinico Pathological Conference is at the core of the multidisciplinary team, allowing input from all team members to treatment planning.

Reference: 17

Essential Criteria

2b.1 There is a weekly meeting of the core breast cancer MDT where treatment planning is carried out (this may be physical or by a variety of forms of communication such as video conferencing but must allow discussion).

2b.2 The following is discussed at the weekly core breast cancer MDT meeting:

- newly diagnosed cancers preoperatively, and
- full postoperative pathology and adjuvant treatment.

2b.3 There are detailed records of the weekly core breast cancer MDT meetings kept including attendance register and a record of decisions.

2b.4 There is discussion of patients with new recurrence or metastatic disease by the core breast cancer MDT.

2b.5 There is review of equivocal or discordant diagnostic results (pathology, imaging and clinical correlation) to allow further investigation if required.

Section 1: Unit structure

Standard 3: Support and communication

Standard Statement 3a
Patients are fully informed of the different options for treatment and involved in decision-making to the extent they wish. Clear lines of communication are maintained between the staff in the breast unit and the primary care team.

Rationale

Specialist nurses are an integral part of the multidisciplinary team and provide patient support and care at critical times in the patient journey. Studies have shown a reduction in psychological morbidity in patients receiving emotional support and information from a breast CNS.

Women have complex needs at diagnosis and throughout their experience of the disease, requiring the input from many members of the team. Although there is limited research in this field, supporting women from diagnosis is acknowledged as an important intervention valued by women.

To participate in decision making women need adequate information. With few exceptions, patients are informed of the diagnosis of cancer and the options for treatment are discussed with them.

References: 17, 28, 29, 30, 31, 32, 33

Essential Criteria

3a.1 Patients with a suspected or known diagnosis of breast cancer have access to a named breast CNS, or alternative in rural units, for information and support throughout their treatment.

3a.2 Patients have access to support services to deal with commonly encountered morbidity associated with the treatment of breast cancer including lymphoedema and limitation of shoulder movement.

3a.3 Written information leaflets (including information about local support groups) are available for all patients (including those with disabilities and those requiring translation services).

3a.4 There is a written plan of treatment and follow-up provided to the patient and the patient's general practitioner (GP).

3a.5 There are systems in place for giving patients follow-up investigation results (eg annual check mammogram or symptomatic investigation) directly.

Desirable Criterion

3a.6 Breast CNSs have access to administrative support to allow written communication within the breast cancer MDT and with the primary care team.

Section 1: Unit structure

Standard 4: Audit

Standard Statement 4a
Prospective audit is an integral part of breast cancer services.

Rationale

Clinical audit is a continuing process that helps to identify clinically important variations in practice and encourages examination of the reasons for these. It identifies the changes required to effect improvements. It is, therefore, integral to the process of implementing guidelines and standards.

References: 17, 34, 35

Essential Criteria

4a.1 There is a continuous collection of breast cancer core dataset to facilitate audit of clinical management and outcomes (National Breast Cancer dataset is minimum standard).

4a.2 Breast units participate in regional and national network audit comparisons.

4a.3 The breast cancer MDT have audit meetings at least every 6 months to review cases with suboptimal pathways or outcomes such as delayed diagnosis, radiological 'misses', technical failure and failure of excision.

Desirable Criterion

4a.4 There is an expansion of the core dataset to include diagnostic accuracy (radiology, cytology, and pathology) and treatment morbidity.

Section 2: Service delivery

Standard 5: GP referral to breast clinic

Standard Statement 5a
Breast units collaborate with GPs to achieve appropriate and rapid referral of patients suspected of having breast cancer.

Rationale

Delay in being seen at a breast clinic is associated with marked anxiety, although delays in onset of treatment of less than 3 months have not been shown to affect survival.

References: 1, 17, 36, 37

Essential Criterion

5a.1 A minimum of 80% of patients referred to a symptomatic breast clinic, who are diagnosed with breast cancer, are seen within 28 days from the date of GP referral.

Numerator: All patients diagnosed with breast cancer, referred by their GP to a symptomatic breast clinic who are seen within 28 days from date of GP referral.

Denominator: All patients diagnosed with breast cancer, referred to a symptomatic clinic by a GP.

Exclusions: All patients referred by a source other than their GP.

All patients with an incidental diagnosis in follow-up (ie previous cancer or family history).

Desirable Criteria

5a.2 A minimum of 80% of patients referred to a symptomatic breast clinic, who are diagnosed with breast cancer, are seen within 14 days from the date of GP referral.

Numerator: All patients diagnosed with breast cancer, referred by their GP to a symptomatic breast clinic who are seen within 14 days from date of GP referral.

Denominator/Exclusions: refer to criterion 5a.1.

5a.3 A minimum of 95% of patients referred to a symptomatic breast clinic, who are diagnosed with breast cancer, are seen within 28 days from the date of GP referral.

Numerator/Denominator/Exclusions: refer to criterion 5a.1.

Section 2: Service delivery

Standard 6: Waiting time to diagnosis

Standard Statement 6a
Where a localised breast abnormality is present, the time between triple assessment to accurate diagnosis is minimised.

Rationale

Where a localised abnormality is present, patients should have imaging usually followed by fine needle aspiration or core biopsy (triple assessment).

References: 17, 36

Essential Criterion

6a.1 A minimum of 85% of breast cancer patients have a diagnosis within 14 days of first clinic visit (including image-guided needle biopsy).

Numerator: All breast cancer patients receiving a diagnosis within 14 days of first clinic visit.

Denominator: All patients referred directly to a symptomatic breast clinic by a GP, who are diagnosed with breast cancer.

Exclusions: All patients referred by a source other than their GP.

All patients with an incidental diagnosis in follow-up (ie previous cancer or family history).

Desirable Criterion

6a.2 A minimum of 95% of breast cancer patients have a diagnosis within 14 days of first clinic visit (including image-guided needle biopsy).

Numerator/Denominator/Exclusions: refer to criterion 6a.1.

Section 2: Service delivery

Standard 7: Waiting time for treatment

Standard Statement 7a
Waiting times for treatment are within acceptable limits.

Rationale

Protracted waiting times cause distress for patients and their families.

References: 36, 38

Essential Criteria

7a.1 A minimum of 80% of breast cancer patients who require surgery as their first treatment, undergo surgery within 31 days of diagnosis.

Numerator: All breast cancer patients having surgery as their first treatment within 31 days of diagnosis.

Denominator: All breast cancer patients having surgery as their first treatment.

Exclusions: All breast cancer patients diagnosed only at terminal stage of disease for whom no active treatment is felt to be appropriate.

All breast cancer patients who are diagnosed by open biopsy/excision biopsy only.

7a.2 A minimum of 80% of breast cancer patients start primary or neoadjuvant chemotherapy within 31 days of diagnosis.

Numerator: All breast cancer patients starting primary or neoadjuvant chemotherapy within 31 days of diagnosis.

Denominator: All breast cancer patients receiving primary or neoadjuvant chemotherapy.

Exclusions: All breast cancer patients diagnosed only at terminal stage of disease for whom no active treatment is felt to be appropriate.

7a.3 A minimum of 80% of breast cancer patients start primary or neoadjuvant hormonal therapy within 31 days of diagnosis.

Numerator: All breast cancer patients starting primary or neoadjuvant hormonal therapy within 31 days of diagnosis

Denominator: All breast cancer patients receiving primary or neoadjuvant hormonal therapy.

Exclusions: All breast cancer patients diagnosed only at terminal stage of disease for whom no active treatment is felt to be appropriate.

7a.4 A minimum of 70% of breast cancer patients start radiotherapy (adjuvant) within 42 days of final therapeutic operation/chemotherapy dose.

Numerator: All breast cancer patients starting adjuvant treatment in the form of radiotherapy within 42 days of final therapeutic operation/chemotherapy dose. This refers to the treatment plan at the time of diagnosis and treatment of primary breast cancer and not to the management of later disease progression/recurrence.

Denominator: All breast cancer patients receiving adjuvant treatment in the form of radiotherapy.

Exclusions: All breast cancer patients receiving radiotherapy, which is given during the course of chemotherapy.

7a.5 A minimum of 80% of breast cancer patients start chemotherapy (adjuvant) within 42 days of final therapeutic operation.

Numerator: All breast cancer patients starting adjuvant treatment in the form of chemotherapy within 42 days of final therapeutic operation. This refers to treatment plan at the time of diagnosis and not to the management of later disease progression.

Denominator: All breast cancer patients receiving adjuvant treatment in the form of chemotherapy.

Exclusions: None.

Note: *previously read as "…within 28 days of final therapeutic operation."*

7a.6 A minimum of 80% of all breast cancer patients receive first treatment within 62 days of GP referral.

Numerator: All breast cancer patients receiving first treatment within 62 days of GP referral.

Denominator: All breast cancer patients referred by their GP receiving first treatment.

Exclusions: All breast cancer patients diagnosed only at terminal stage of disease for whom no active treatment is felt to be appropriate.

Desirable Criteria

7a.7 A minimum of 95% of breast cancer patients who require surgery as first treatment, undergo surgery within 31 days of diagnosis.

Numerator/Denominator/Exclusions: refer to criterion 7a.1.

7a.8 A minimum of 95% of breast cancer patients start primary or neoadjuvant chemotherapy within 31 days of diagnosis.

Numerator/Denominator/Exclusions: refer to criterion 7a.2.

7a.9 A minimum of 95% of breast cancer patients start primary or neoadjuvant hormonal therapy within 31 days of diagnosis.

Numerator/Denominator/Exclusions: refer to criterion 7a.3.

7a.10 A minimum of 85% of breast cancer patients start radiotherapy (adjuvant) within 42 days of final therapeutic operation/chemotherapy dose.

Numerator/Denominator/Exclusions: refer to criterion7a.4.

7a.11 A minimum of 95% of breast cancer patients start chemotherapy (adjuvant) within 42 days of final therapeutic operation.

Numerator/Denominator/Exclusions: refer to criterion 7a.5.

Note: *previously read as "…within 28 days of final therapeutic operation."*

7a.12 A minimum of 95% of all breast cancer patients receive first treatment within 62 days of GP referral.

Numerator/Denominator/Exclusions: refer to criterion 7a.6.

Section 3: Clinical management

Standard 8: Diagnosis

Standard Statement 8a
All efforts are made to diagnose patients non-operatively, allowing them to have only one definitive procedure, where possible.

Rationale

Triple assessment of a discrete abnormality provides more accurate diagnosis than a smaller number of tests. A lesion considered malignant following triple assessment should, where possible, have histopathological confirmation of malignancy before any definitive surgical procedure takes place.

References: 17, 36

Essential Criteria

8a.1 A minimum of 85% of breast cancer patients have a non-operative diagnosis (FNA/core biopsy/large volume biopsy).

Numerator: All breast cancer patients with a non-operative diagnosis of breast cancer (FNA/core biopsy/large volume biopsy).

Denominator: All breast cancer patients.

Exclusions: Lobular carcinoma in situ (LCIS).

8a.2 A minimum of 70% of breast cancer patients are classified as R3, R4 or R5 on mammography or U3, U4 or U5 on ultrasound during the diagnostic work-up.

Numerator: All breast cancer patients who were classified as R3, R4 or R5 on mammography or U3, U4 or U5 on ultrasound.

Denominator: All breast cancer patients who underwent mammography or ultrasound as part of diagnostic work-up.

Exclusions: Lesions so locally advanced that mammography is impossible.

Desirable Criteria

8a.3 A minimum of 95% of breast cancer patients have a non-operative diagnosis (FNA/core biopsy/large volume biopsy).

Numerator/Denominator/Exclusions: refer to criterion 8a.1.

8a.4 A minimum of 85% of breast cancer patients are classified as R3, R4 or R5 on mammography or U3, U4 or R5 on ultrasound during the diagnostic work-up.

Numerator/Denominator/Exclusions: refer to criterion 8a.2.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9a
All patients who do not have metastatic disease are considered for surgery (+/-neoadjuvant treatment).

Rationale

Breast cancer requires multi-modality treatment of which surgery is a major component. Older patients benefit from the same management as younger patients, excluding only those who are medically unfit.

Reference: 17

Essential Criterion

9a.1 A minimum of 70% of all symptomatic breast cancers are surgically treated.

Numerator: All breast cancer patients (including neoadjuvant) receiving surgical treatment within one year of diagnosis.

Denominator: All breast cancer patients.

Exclusions: All breast cancer patients found to have metastatic disease during initial investigations.

All breast cancer patients diagnosed through screening service.

Desirable Criterion

9a.2 A minimum of 80% of all symptomatic breast cancers are surgically treated.

Numerator/Denominator/Exclusions: refer to criterion 9a.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9b
Breast conservation is appropriate for small focal breast tumours.

Rationale

Randomised trials have shown no difference in survival for tumours treated by conservation or mastectomy.

References: 17, 36

Essential Criterion

9b.1 There is a minimum of 75% conservation rate of surgically-treated small cancers less than 15mm whole tumour size (pathological diameter/invasive and in situ disease). (Excluding patients with multifocal disease and patients who have undergone neoadjuvant treatment).

Numerator: All breast cancer patients with tumour less than 15mm whole tumour size (invasive and in situ disease) treated with breast conservation surgery.

Denominator: All surgically-treated cancers less than 15mm whole tumour size (pathological diameter/invasive and in situ disease).

Exclusions: All breast cancer patients with multifocal disease.

All breast cancer patients who have undergone neoadjuvant treatment (either hormonal or chemotherapy).

Desirable Criterion

9b.2 There is a minimum of 85% conservation rate of surgically-treated small cancers less than 15mm whole tumour size (pathological diameter/invasive and in situ disease). (Excluding patients with multifocal disease and patients who have undergone neoadjuvant treatment).

Numerator/Denominator/Exclusions: refer to criterion 9b.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9c
Mastectomy patients have access to immediate breast reconstruction.

Rationale

Breast reconstruction does not appear to be associated with an increase in the rate of local cancer recurrence, nor to impede the ability to detect recurrence if it develops and can yield psychological benefit.

Reference: 17

Essential Criterion

9c.1 A minimum of 5% of mastectomy patients have immediate breast reconstruction.

Numerator: All breast cancer patients who underwent immediate breast reconstruction at time of mastectomy.

Denominator: All breast cancer patients who underwent mastectomy.

Exclusions: None.

Desirable Criterion

9c.2 A minimum of 10% of mastectomy patients have immediate breast reconstruction.

Numerator/Denominator/Exclusions: refer to criterion 9c.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9d
Tumours are adequately excised.

Rationale

There is an increased risk of local recurrence if margins are less than 1mm.

Reference: 17

Essential Criterion

9d.1 A maximum of 10% of breast cancer patients with breast conservation have final excision margins of less than 1mm.

Numerator: All breast cancer patients undergoing breast conservation with final excision margins of less than 1mm (pathological distance).

Denominator: All breast cancer patients having breast conservation surgery (including invasive or ductal carcinoma in situ (DCIS).

Exclusions: LCIS only.

Where the only margin <1mm is to an area of LCIS.

Desirable Criterion

9d.2 A maximum of 5% of breast cancer patients with breast conservation have final excision margins of less than 1mm.

Numerator/Denominator/Exclusions: refer to criterion 9d.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9e
Surgical staging of the axilla is performed in all newly diagnosed patients with operable invasive breast cancer.

Rationale

Lymph node status is one of the most important prognostic indicators and hence is a major determinant of appropriate adjuvant therapy.

Reference: 17

Essential Criterion

9e.1 A minimum of 90% of breast cancer patients having surgery for invasive tumours, undergo surgical staging of the axilla.

Numerator: All breast cancer patients with invasive tumours receiving surgical staging of the axilla.

Denominator: All breast cancer patients with invasive tumours, having surgery.

Exclusions: None.

Desirable Criterion

9e.2 A minimum of 95% of breast cancer patients having surgery for invasive tumours, undergo surgical staging of the axilla.

Numerator/Denominator/Exclusions: refer to criterion 9e.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9f
To minimise arm morbidity, the extent of surgical staging of the axilla is minimised in patients with a low likelihood of nodal spread.

Rationale

Extensive surgical staging of the axilla is associated with increased arm morbidity.

References: 17, 39

Essential Criterion

9f.1 A minimum of 75% of breast cancer patients undergoing surgical staging of the axilla for invasive tumours less than 15mm whole tumour size (pathological diameter) have node sampling or a sentinel lymph node biopsy (SLNB) rather than axillary clearance. (Excluding patients who have undergone neoadjuvant treatment).

Numerator: All breast cancer patients undergoing axillary sampling or SLNB for an invasive tumour less than 15mm whole tumour size.

Denominator: All breast cancer patients undergoing surgical staging of the axilla for invasive tumours less than 15mm whole tumour size.

Exclusions: All breast cancer patients with pre-operative diagnosis (FNA or core biopsy) of nodal involvement.

Patients who have undergone neoadjuvant treatment.

Desirable Criterion

9f.2 A minimum of 85% of breast cancer patients undergoing surgical staging of the axilla for invasive tumours less than 15mm whole tumour size (pathological diameter) have node sampling or a SLNB rather than axillary clearance. (Excluding patients who have undergone neoadjuvant treatment).

Numerator/Denominator/Exclusions: refer to criterion 9f.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9g
In an axillary sample (excluding dual dye SLNB technique) a minimum of four nodes are removed to predict the pathological node status. This also applies in the case of failed SLNB (failure of any axillary nodes to take up either radioactive colloid or blue dye).

Rationale

A sample of four or more lymph nodes adequately predicts node status when non-guided.

Reference: 17

Essential Criterion

9g.1 A maximum of 10% of breast cancer patients undergoing unguided surgical staging or blue dye only guided sampling of the axilla have less than four lymph nodes removed.

Numerator: All breast cancer patients with invasive tumours undergoing surgical axillary staging with fewer than four lymph nodes removed.

Denominator: All breast cancer patients with invasive tumours undergoing surgical axillary staging, including axillary node clearance, sampling or failed SLNB.

Exclusions: All breast cancer patients with a successful SLNB.

Desirable Criterion

9g.2 A maximum of 5% of breast cancer patients undergoing unguided surgical staging or blue dye only guided sampling of the axilla have less than four lymph nodes removed.

Numerator/Denominator/Exclusions: refer to criterion 9g.1.

Section 3: Clinical management

Standard 9: Surgical management

Standard Statement 9h
In a SLNB using blue dye and radioactive colloid (after the start up phase) the failed localisation rate is kept to a minimum.

Rationale

Due to the importance of lymph node status as a prognostic indicator and determinant of adjuvant treatment, accuracy of nodal staging must be maintained after the introduction of SLNB.

Reference: 17

Essential Criterion

9h.1 A maximum of 10% of breast cancer patients undergoing SLNB have a failed SLNB localisation.

Numerator: All breast cancer patients with invasive tumours undergoing surgical axillary node staging using blue dye and radioactive colloid in whom the sentinel nodes cannot be identified.

Denominator: All breast cancer patients with invasive tumours undergoing surgical axillary node staging using blue dye and radioactive colloid.

Exclusions: Patients not undergoing SNLB staging of axilla.

Desirable Criterion

9h.2 A maximum of 5% of breast cancer patients undergoing SLNB have a failed SLNB localisation.

Numerator/Denominator/Exclusions: refer to criterion 9h.1.

Section 3: Clinical management

Standard 10: Pathology

Standard Statement 10a
Pathology reports of surgically-treated breast cancers include the minimum details recommended by the Scottish Intercollegiate Guidelines Network (SIGN) and the NHSBSP.

Rationale

Detailed and adequate reporting of pathology is required to allow appropriate treatment planning.

References: 17, 36

Essential Criteria

10a.1 A minimum of 90% of surgically-treated invasive breast cancers have the tumour grade known and reported.

Numerator: Percentage of invasive breast cancer specimens with the tumour grade reported.

Denominator: All breast cancer patients with invasive tumours who undergo definitive surgery.

Exclusions: None.

10a.2 A minimum of 90% of surgically-treated breast cancers have the closest margin reported in millimetres (mm) from invasive tumour and in situ disease, where present.

Numerator: Percentage of breast cancer specimens with the closest margin from invasive tumour and in situ disease reported separately, where present.

Denominator: All breast cancers which are surgically treated.

Exclusions: All breast cancer patients who have had neoadjuvant chemotherapy.

10a.3 A minimum of 90% of surgically-treated breast cancers have the whole tumour size reported in mm including invasive tumour and in situ disease, where present.

Numerator: Percentage of breast cancer specimens with the whole tumour size as well as invasive component reported.

Denominator: All breast cancers which are surgically treated.

Exclusions: All breast cancer patients who have had neoadjuvant chemotherapy.

Desirable Criteria

10a.4 A minimum of 95% of surgically-treated invasive breast cancers have the tumour grade known and reported.

Numerator/Denominator/Exclusions: refer to criterion 10a.1.

10a.5 A minimum of 95% of surgically-treated breast cancers have the closest margin reported in mm from invasive tumour and in situ disease, where present.

Numerator/Denominator/Exclusions: refer to criterion 10a.2.

10a.6 A minimum of 95% of surgically-treated breast cancers have the whole tumour size reported in mm including invasive tumour and in situ disease, where present.

Numerator/Denominator/Exclusions: refer to criterion 10a.3.

Section 3: Clinical management

Standard 10: Pathology

Standard Statement 10b
Pathology reports of invasive breast cancer receptor status include the minimum details recommended by SIGN and the NHSBSP.

Rationale

Detailed reporting of receptor status is an important guide to adjuvant treatment planning.

References: 17, 36

Essential Criteria

10b.1 A minimum of 90% of invasive breast cancers have the oestrogen receptor (ER) status measured and reported.

Numerator: Percentage of invasive breast cancer specimens with the appropriate receptor status reported.

Denominator: All breast cancer patients with invasive tumours.

Exclusions: None.

10b.2 A minimum of 90% of invasive cancers have human epidermal growth factor receptor 2 (HER2) tested and reported.

Numerator/Denominator/Exclusions: refer to criterion 10b.1.

Desirable Criteria

10b.3 A minimum of 95% of invasive breast cancers have the ER status measured and reported.

Numerator/Denominator/Exclusions: refer to criterion 10b.1.

10b.4 A minimum of 95% of invasive cancers have HER2 tested and reported.

Numerator/Denominator/Exclusions: refer to criterion 10b.1.

Section 3: Clinical management

Standard 11: Oncological management

Standard Statement 11a
Radiotherapy is normally given to the breast after wide local excision.

Rationale

Trials have demonstrated a significant reduction in local recurrence with the use of radiotherapy after breast conservation.

Reference: 17

Essential Criterion

11a.1 A minimum of 85% of breast cancer patients receive radiotherapy to the breast after conservation for invasive cancer (excluding breast cancer patients taking part in trials of radiotherapy treatment).

Numerator: All breast cancer patients with invasive tumours having conservation surgery receiving radiotherapy to the breast.

Denominator: All breast cancer patients with invasive tumours having conservation surgery.

Exclusions: All breast cancer patients taking part in trials of radiotherapy treatment.

Desirable Criterion

11a.2 A minimum of 95% of breast cancer patients receive radiotherapy to the breast after conservation for invasive cancer (excluding breast cancer patients taking part in trials of radiotherapy treatment).

Numerator/Denominator/Exclusions: refer to criterion 11a.1.

Section 3: Clinical management

Standard 11: Oncological management

Standard Statement 11b
Breast cancer patients undergoing staging of the axilla (FNA, SLNB or axillary sample), which shows nodal involvement, are treated by radiotherapy or axillary node clearance.

Rationale

After undergoing staging of the axilla (FNA, SLNB or axillary node sample), radiotherapy will significantly reduce the risk of axillary recurrence if there is nodal involvement. Patients with axillary nodal involvement may equally be treated by axillary node clearance.

Reference: 17

Essential Criterion

11b.1 A minimum of 85% of breast cancer patients receive axillary radiotherapy or axillary clearance with nodal involvement (diagnosed by ultrasound/FNA, SLNB or sample).

Numerator: All breast cancer patients with invasive tumours, proven to be node-positive, having surgery, and axillary node clearance.

All breast cancer patients with invasive tumours, proven to be node-positive, having axillary radiotherapy.

Denominator: All breast cancer patients with invasive tumours, proven to be node-positive by whichever diagnostic measurement (ultrasound/FNA, axillary node sample, axillary node clearance, SLNB), having surgery.

Exclusions: None.

Desirable Criterion

11b.2 A minimum of 95% of breast cancer patients with nodal involvement receive axillary radiotherapy or axillary clearance.

Numerator/Denominator/Exclusions: refer to criterion 11b.1.

Section 3: Clinical management

Standard 11: Oncological management

Standard Statement 11c
All women with invasive breast cancer are considered for adjuvant systemic therapy.

Rationale

Large randomised trials have confirmed that adjuvant systemic endocrine therapy improves relapse-free survival and overall survival.

Reference: 17

Essential Criterion

11c.1 A minimum of 90% of invasive breast cancer patients who are ER-positive or progesterone receptor (PR)-positive, receive adjuvant treatment which includes hormonal therapy or ovarian ablation.

Numerator: All breast cancer patients who have undergone surgery for invasive tumours, who are ER-positive or PR-positive, receiving adjuvant treatment including hormonal therapy or ovarian ablation.

Denominator: All breast cancer patients with invasive tumours, who are ER-positive or PR-positive, undergoing surgical treatment.

Exclusions: None.

Desirable Criterion

11c.2 A minimum of 95% of invasive breast cancer patients who are ER-positive or PR-positive, receive adjuvant treatment which includes hormonal therapy or ovarian ablation.

Numerator/Denominator/Exclusions: refer to criterion 11c.1.

Section 3: Clinical management

Standard 11: Oncological management

Standard Statement 11d
All women with intermediate or high-risk disease are considered for chemotherapy.

Rationale

Women who are node-positive show the greatest survival benefit from chemotherapy.

Reference: 17

Essential Criteria

11d.1 A minimum of 85% of breast cancer patients less than 50 years of age at diagnosis who are node-positive, receive chemotherapy as part of the initial plan of treatment.

Numerator: All breast cancer patients less than 50 years of age with invasive tumours undergoing surgery who are node-positive, receiving neoadjuvant and/or adjuvant chemotherapy as part of the initial plan of treatment.

Denominator: All breast cancer patients less than 50 years of age with invasive tumours undergoing surgery who are node-positive.

Exclusions: All breast cancer patients found to be metastatic at time of initial treatment.

11d.2 A minimum of 80% of breast cancer patients less than 70 years of age at diagnosis who are ER and PR-negative, node-positive, receive chemotherapy as part of the initial plan of treatment.

Numerator: All breast cancer patients less than 70 years of age with invasive tumours undergoing surgery who are ER/PR-negative, node-positive, receiving neoadjuvant and/or adjuvant chemotherapy.

Denominator: All breast cancer patients less than 70 years of age with invasive tumours undergoing surgery who are ER/PR-negative, node-positive.

Exclusions: All breast cancer patients found to be metastatic at time of initial treatment.

Desirable Criteria

11d.3 A minimum of 95% of breast cancer patients less than 50 years of age at diagnosis who are node-positive, receive chemotherapy as part of the initial plan of treatment.

Numerator/Denominator/Exclusions: refer to criterion 11d.1.

11d.4 A minimum of 90% of breast cancer patients less than 70 years of age at diagnosis who are ER and PR negative, node-positive, receive chemotherapy as part of the initial plan of treatment.

Numerator/Denominator/Exclusions: refer to criterion 11d.2.

Section 3: Clinical management

Standard 11: Oncological management

Standard Statement 11e
All women with HER2 positive intermediate or high-risk disease who have received chemotherapy are considered for trastuzumab.

Rationale

Women with intermediate or high risk-disease who are HER2 positive show benefit when they receive trastuzumab in addition to chemotherapy.

References: 17, 40, 41, 42, 43

Essential Criterion

11e.1 A minimum of 70% of breast cancer patients with HER2 positive or fluorescence in situ hybridisation (FISH) positive invasive cancer greater than 10 mm or node-positive, excluding T4 or inflammatory cancers, who have received chemotherapy, receive trastuzumab.

Numerator: All breast cancer patients with HER2 positive or FISH positive disease which is greater than 10mm or node-positive, excluding T4 or inflammatory cancers, undergoing surgery, receiving chemotherapy who received trastuzumab.

Denominator: All breast cancer patients with HER2 positive or FISH positive disease which is greater than 10mm or node-positive, excluding T4 or inflammatory cancers, undergoing surgery, receiving chemotherapy.

Exclusions: All breast cancer patients who are non-HER2 over-expressing.

All HER2 over-expressing breast cancer patients who have tumours which are T4 or inflammatory cancers or node negative less than 10mm.

Desirable Criterion

11e.2 A minimum of 80% of breast cancer patients with HER2 positive or FISH positive invasive cancer greater than 10mm or node-positive, excluding T4 or inflammatory cancers, who have received chemotherapy, receive trastuzumab.

Numerator/Denominator/Exclusions: refer to criterion 11e.1.

Section 3: Clinical management

Standard 12: Clinical trials

Standard Statement 12a
Newly diagnosed breast cancer patients are entered into well-designed, peer reviewed clinical trials.

Rationale

Randomised clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions. It has been shown that patients recruited to clinical trials tend to have a more favourable prognosis, regardless of the arm of the trial to which they are assigned.

References: 17, 44, 45

Essential Criterion

12a.1 A minimum of 5% of newly diagnosed breast cancer patients enter into peer reviewed clinical trials as part of their initial management.

Numerator: All newly diagnosed breast cancer patients entering into peer reviewed clinical trials.

Denominator: All newly diagnosed breast cancer patients.

Exclusions: None.

Desirable Criterion

12a.2 A minimum of 10% of newly diagnosed breast cancer patients enter into peer reviewed clinical trials as part of their initial management.

Numerator/Denominator/Exclusions: refer to criterion 12a.1.

Section 4: Outcomes

Standard 13: Long-term outcome of treatment

Standard Statement 13a
The aim of improving the breast service is to improve the outcome from breast cancer.

Rationale

Previous studies suggest that population-based survival from breast cancer was lower in Scotland than in some other European countries, even those comparable in terms of national coverage of cancer registration, data quality, and completeness of follow-up. A previous breast cancer audit in Scotland demonstrated improvements in clinical management between 1987 and 1993, perhaps in part resulting from the introduction of a well-organised national breast-screening programme. Observed survival at five years has increased in Scotland from 54% among women diagnosed during 1980–1984 to 72% among those diagnosed during 2000–2004. There seems to be little doubt that better outcomes for patients can be achieved with better clinical management.

References: 27, 46, 47

Essential Criteria

13a.1 A minimum of 75% 5-year overall survival for all breast cancer patients

Numerator: All breast cancer patients who received treatment at the unit in the relevant year, who are alive 5 years after diagnosis.

Denominator: All breast cancer patients who received treatment at the unit for the year under analysis.

Inclusions: All patients with primary invasive breast cancer receiving active treatment.

All screen-detected breast cancer patients.

Exclusions: Breast cancer patients receiving no active treatment.

Patients with lymphoma, sarcoma/phylloides, or *in situ* disease only.

All breast cancer patients who are terminally ill at the time of diagnosis.

Patients diagnosed for the first time after death at autopsy (by definition, such patients should not have received any breast cancer-related treatment).

13a.2 A minimum of 70% 5-year overall survival for patients presenting symptomatically (ie not screen-detected).

Numerator: All symptomatic breast cancer patients who received treatment at the unit in the relevant year, who are alive 5 years after diagnosis.

Denominator: All symptomatic breast cancer patients who received treatment at the unit for the year under analysis.

Inclusions: All patients with primary invasive breast cancer receiving active treatment.

Exclusions: All screen-detected breast cancer patients.

Breast cancer patients receiving no active treatment.

Patients with lymphoma, sarcoma/phylloides, or *in situ* disease only.

All breast cancer patients who are terminally ill at the time of diagnosis.

Patients diagnosed for the first time after death at autopsy (by definition, such patients should not have received any breast cancer-related treatment).

13a.3 Not more than 10% 5-year local recurrence for patients who have been treated surgically.

Numerator: All patients for the relevant year, who underwent surgical excision of the primary cancer and have developed recurrence in the breast or chest wall less than 5 years after diagnosis.

Denominator: All patients from the relevant year, who underwent surgical excision of the primary cancer.

Inclusions: All patients with primary invasive breast cancer receiving surgery (with surgery defined as excision biopsy, conservation including wide local excision, re-excision, segmentectomy, quadrantectomy), or mastectomy.

Exclusions: All non-surgical breast cancer patients (as defined above).

All breast cancer patients undergoing incision biopsy as their only surgical procedure (with no attempt at complete excision of the primary lesion).

Patients with lymphoma, sarcoma/phylloides, or *in situ* disease only.

All breast cancer patients with distant metastases at the time of diagnosis.

All breast cancer patients who are terminally ill at the time of diagnosis.

Patients diagnosed for the first time after death at autopsy (by definition, such patients should not have received any breast cancer-related treatment).

13a.4 A minimum of 60% 5-year disease-free survival for patients who have been treated surgically.

Numerator: All patients from the relevant year, who underwent surgical excision of the primary cancer who are free of recurrence at any site (local, regional nodes or distant metastases) less then 5 years after diagnosis.

Denominator: All patients from the relevant year, who underwent surgical excision of the primary cancer.

Inclusions: All patients with primary invasive breast cancer receiving surgery (with surgery defined as excision biopsy, conservation (including wide local excision, re-excision, segmentectomy, quadrantectomy) or mastectomy).

Exclusions: All non-surgical breast cancer patients (as defined above).

All breast cancer patients undergoing incision biopsy as their only surgical procedure (with no attempt at complete excision of the primary lesion).

Patients with lymphoma, sarcoma/phylloides, or *in situ* disease only.

All breast cancer patients with distant metastases at the time of diagnosis.

All breast cancer patients who are terminally ill at the time of diagnosis.

Patients diagnosed for the first time after death at autopsy (by definition, such patients should not have received any breast cancer-related treatment).

Desirable Criteria

13a.5 A minimum of 85% 5-year overall survival for all breast cancer patients.

Numerator/Denominator/Inclusions/Exclusions: refer to criterion 13a.1.

13a.6 A minimum of 75% 5-year overall survival for patients presenting symptomatically (ie not screen-detected).

Numerator/Denominator/Inclusions/Exclusions: refer to criterion 13a.2.

13a.7 Not more than 5% 5-year local recurrence for patients who have been treated surgically.

Numerator/Denominator/Inclusions/Exclusions: refer to criterion 13a.3.

13a.8 A minimum of 70% 5-year disease-free survival for patients who have been treated surgically.

Numerator/Denominator/Inclusions/Exclusions: refer to criterion 13a.4.

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5 Appendices

Appendix 1: About NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

We achieve our objectives through five key functions that link together:

- providing clear advice and guidance on effective clinical practice
- setting clinical and non-clinical standards of care
- reviewing and monitoring the performance of NHS services
- supporting NHS staff in improving services, and
- promoting patient safety and implementation of clinical governance.

We deliver our commitments to the public and to NHSScotland by following an approach that is:

- **independent** – we reach our own conclusions and report on what we find
- **open and transparent** – we explain what we do, how and why we do it, and what we find, using language and formats that are easy to understand and to access
- **sensitive and professional** – we recognise needs, beliefs and opinions and respect and encourage diversity.

Our work is:

- **partnership-focused** – we work with patients and the public, NHSScotland and many organisations to improve the quality of care and avoid duplication
- **evidence-based** – we base our conclusions and recommendations on the best evidence available as indicated in Chapter 2 (Development of the clinical standards for management of breast cancer services : evidence base).
- **quality-driven** – we make sure our own work is monitored and evaluated, internally and externally.

Appendix 2: NHS Quality Improvement Scotland standards development methodology

Basic principles

A major part of our remit is to develop and run a national system of quality assurance of clinical services. Working in partnership with healthcare professionals and members of the public, we set standards for clinical services, assess performance throughout NHSScotland against these standards, and publish the findings. The standards are based on the patient's journey as he or she moves through different parts of the health service. A wide range of conditions and services have already been addressed, including asthma services for children and young people and bowel screening programme.

In fulfilling our responsibility to develop and run a system of quality assurance, we take account of the principles set out in Fair for All[48] and Partnership for Care[49], to ensure that 'our health services recognise and respond sensitively to the individual needs, background and circumstances of people's lives'.

We will ensure that consideration of equality and diversity issues feature prominently in the design, development and delivery of all our functions and policies.

The standards are developed in accordance with the commitments of the National Health Service Reform (Scotland) Act 2004[50] which state that 'individual patients receive the service they need in the way most appropriate to their personal circumstances and all policy and service developments are shown not to disadvantage any of the people they serve'.

Process

For each set of standards we develop, we appoint a group representing a range of stakeholders, including healthcare professionals and members of the public, to:

- oversee the development of, and consultation on, the standards and self-assessment framework, and
- recommend an external peer review process.

The way in which standards are developed is a key element of the quality assurance process. Project groups working on our behalf are expected to:

- adopt an open and inclusive process involving members of the public, voluntary organisations and healthcare professionals
- work within NHS QIS policies and procedures, and
- test the measurability of draft standards by undertaking pilot reviews.

The standards are clear and measurable, based on appropriate evidence, and written to take into account other recognised standards and clinical guidelines. The standards are:

- written in simple language and available in a variety of formats
- focused on clinical issues and include non-clinical factors that impact on the quality of care
- developed by healthcare professionals and members of the public, and consulted on widely
- regularly reviewed and revised to make sure they remain relevant and up to date, and
- achievable but stretching.

Format of standards and definition of terminology

All our standards follow the same format.

- Each standard has a **title**, which summarises the area on which that standard focuses.
- This is followed by the **standard statement**, which explains the level of performance to be achieved.
- The **rationale** section provides the reasons why the standard is considered to be important.
- The standard statement is expanded in the section headed **criteria**, which states exactly what must be achieved for the standard to be reached. Criteria are **essential**, in that it is expected that they will be met wherever a service is provided. Other criteria are **desirable**, in that they are being met in some parts of the service and demonstrate levels of quality, which other providers of a similar service should strive to achieve. The criteria are numbered for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority.

Clinical governance and risk management standards

Every patient using healthcare services should expect these to be safe and effective. The NHS QIS standards for Clinical Governance and Risk Management[6] will ensure NHS boards can provide assurance that clinical governance and risk management arrangements are in place, and are supporting the delivery of safe, effective, patient-focused care and services.

These standards underpin all care and services delivered by NHSScotland and provide the context within which NHS QIS service and condition-specific standards apply. They should be read in conjunction with all our standards.

The clinical governance and risk management standards are available on request from NHS QIS or can be downloaded from the website (www.nhshealthquality.org).

Assessment of performance against the standards

The framework for the NHS QIS review process is as follows.

- Once the current cancer standards have been finalised, these will link into the accreditation of regional managed clinical networks for cancer.
- With the need for a cohesive and comprehensive approach to continual improvement based on these standards, the subsequent measurement, and assessment and reporting of the standards from a local, regional and nationwide perspective will be adopted, with support provided by Information Services Division, NHS National Services Scotland.
- Ongoing monitoring of the standards will be a function of the networks with NHS QIS intervening if there were concerns regarding data. Occasional visits may be undertaken by NHS QIS on a regional basis to test the system.

Our processes are subject to internal and external evaluation, to help improve the quality assurance system.

Revision of the standards

NHS QIS standards are considered for revision and updating every 3 years. If a revision of a set of standards is undertaken the original standards will be withdrawn and the revised standards would be considered for further updating every 3 years thereafter. Please check the status of these standards with the Standards Development Unit if they are past the 3 years revision date.

Appendix 3: Membership of the clinical standards for management of breast cancer services working group

Name	Title	NHS board area/ organisation
Ms Philippa Whitford (Chair)	Consultant Breast Surgeon	NHS Ayrshire & Arran
Mr Matthew Barber	Consultant Breast Surgeon	NHS Lothian
Dr Angela Bowman	Consultant Medical Oncologist	NHS Lothian
Dr Marzi Davies	Consultant Radiologist	NHS Greater Glasgow and Clyde
Dr Wilma Jack	Senior Clinical Research Fellow	NHS Lothian
Ms Pauline McIlroy	Breast Clinical Nurse Specialist	NHS Greater Glasgow and Clyde
Mrs Yvonne McIntosh	Breast Care Nurse Specialist	NHS Lothian
Ms Elsbeth McLatchie	Breast Care Sister	NHS Greater Glasgow and Clyde
Ms Ann Mumby	National Training Co-ordinator Scottish Breast Screening Programme	NHS Greater Glasgow and Clyde

Support from NHS QIS in developing these draft standards was provided by the Standards Development Unit: Mrs Anne Coote (Project Administrator), Ms Hilary Davison (Head of Standards Development Unit), Ms Clare Echlin (Senior Project Officer), Miss Ali McAllister (Project Officer) from January 2008 and Mrs Stacey Moffat (Project Officer) until January 2008.

NHS QIS would like to thank the following for his input and support during the development of the clinical standards for management of breast cancer services:

- Dr David Brewster (Consultant in Public Health Medicine, NHS National Services Scotland).

Appendix 4: Glossary

abnormality	A finding requiring further investigation/treatment.
acute care	Refers to either a pattern of healthcare in which a patient is treated for an acute (immediate and severe) episode of illness, or to the subsequent treatment of injuries related to an accident or other trauma, or care during recovery from surgery. Acute care is usually given in a hospital by specialised personnel using complex and sophisticated technical equipment and materials, and is often necessary for only a short time.
adjuvant chemotherapy	The use of chemotherapy after initial treatment by surgery and/or radiotherapy. The aim of adjuvant therapy is to destroy any cancer that has spread.
adjuvant radiotherapy	The use of radiotherapy in association with treatment by surgery.
adjuvant treatment	Treatment given in addition to the primary therapy, or a secondary remedy assisting the action of another.
audit	The measuring and evaluation of care against best practice with a view to improving current practice and care delivery.
axilla	The armpit.
axillary clearance	Operation to remove all the lymph glands from under the arm.
biopsy	The removal of a small piece of tissue from an organ or part of the body for laboratory examination. It is an important means of confirming or excluding a diagnosis from analysis of a fragment of the tissue sample.
breast clinical nurse specialist	A registered nurse with a qualification or specialist knowledge in breast care.
breast conservation	The removal of a breast lump together with some surrounding tissue. This may be for diagnosis or treatment.
breast reconstruction	An operation to replace breast tissue lost during mastectomy or lumpectomy, restoring the breast shape.
cancer centres	Cancer services are based in cancer centres. Such centres provide the entire spectrum of cancer care - both on-site and to associated cancer units.
chemotherapy	The use of drugs that kill cancer cells, or prevent or slow their growth.
clinical governance	Ensures that patients receive the highest quality of care possible, putting each patient at the centre of his or her care. This is achieved by making certain that those providing services work in an environment that supports them and places the safety and quality of care at the top of the organisation's agenda. Management of clinical risk at an organisational level is an important aspect of clinical governance. Clinical risk management recognises that risk can arise at many points in a patient's journey, and that aspects of how organisations are managed can systematically influence the degree of risk.
Clinical Standards Board for Scotland (CSBS)	The Clinical Standards Board for Scotland was a statutory body, established as a Special Health Board in April 1999. Its role was to develop and run a system of quality control of clinical services designed to promote public confidence that the services provided by the NHS met nationally agreed standards, and to demonstrate that, within the resources available, the NHS was delivering the highest possible standards of care. On 1 January 2003, CSBS was merged, along with four other clinical effectiveness bodies, to form NHS Quality Improvement Scotland (NHS QIS).

clinical trial	Research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease.
continuing professional development (CPD)	An ongoing commitment to learning in various forms, which maintains and enhances professional standards of work, and develops the ability to recognise good practice.
core biopsy	Removal (using a needle) of a piece of a breast tissue for diagnosis.
cytology	The study of the structure and function of cells under the microscope, and of their abnormalities (cytopathology).
dataset	A list of required and specific information relating to a single disease.
diagnostic	The process of determining the nature of a disorder by considering signs and symptoms.
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.
endocrine	Glandular tissues that secrete (make and release) hormones directly into the blood stream.
excision biopsy	Surgical biopsy that removes entire lesion.
film reader	A healthcare professional trained to interpret, or 'read', screening mammography films.
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 hybridisation (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.
Health Department Letter (HDL)	A formal communication from the former Scottish Executive Health Department (SEHD) to NHSScotland, previously known as a Management Executive Letter - MEL.
Herceptin	See trastuzumab.
histology/ histopathology	The study of the structure, composition and function of tissues under the microscope, and of their abnormalities (histopathology).
hormone therapy	Treating a disease with hormones, or by blocking the action of hormones.
human epidermal growth factor receptor 2 (HER2)	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 reconstruction	Breast reconstruction carried out at the same time as the operation to remove the breast.
immunoassay	A technique of identifying a substance by its ability to bind to an antibody.
Information Services Division (ISD)	Part of NHS National Services Scotland. Health service activity, manpower and finance data are collected, validated, interpreted and distributed by ISD. These data are received from NHS boards and general practices. Website address: www.isdscotland.org
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.
knowledge and skills framework (KSF)	Defines and describes the knowledge and skills which NHS staff need to apply in their work in order to deliver quality services. It provides a single, consistent, comprehensive and explicit framework on which to base review and development for all staff.

lesion	Tumour, mass, or other abnormality.
lymph	Almost colourless fluid that travels through the lymphatic system, bathing body tissues and carrying cells that help fight infection.
lymph nodes	Small bean-shaped organs located along the lymphatic system. Nodes filter bacteria or cancer cells that might travel through the lymphatic system.
lymphoedema	The swelling of an arm, leg or another part of the body which sometimes happens when lymph nodes and vessels in the armpit or groin have been removed or damaged by surgery or radiotherapy, or have been blocked by a tumour.
lymphoma	A neoplasm (new and abnormal growth of tissue, which may be benign or cancerous) of lymph tissue that is usually malignant.
magnetic resonance imaging (MRI)	An imaging technique used to image the internal structures of the body. The technique uses a large magnet to excite and then monitor atoms within cells, and is particularly useful for detecting some cancers and monitoring their progress
mammogram	An X-ray film of the breast.
mammography	X-ray examination of the breast. Using low-energy X-rays, fine details of breast tissue can be visualised, particularly the presence of calcification or soft tissue masses, enabling the early diagnosis of breast cancer.
managed clinical network (MCN)	A formally organised network of clinicians. The main function is to audit performance on the basis of standards and guidelines, with the aim of improving healthcare across a wide geographic area, or for specific conditions.
mastectomy	Surgical removal of a breast.
mean glandular dose	The average radiation dose received by the glandular tissues in the breast during a mammogram.
metastasis	Spread of cancer from one part of the body to another.
modality	One form of therapy as opposed to another, such as the modality of physiotherapy contrasted with that of radiotherapy.
morbidity (in a disease)	How much ill health a particular condition causes.
multidisciplinary team (MDT)	A multiprofessional group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These include: the specific condition; the scale of the service being provided; and geographical/socio-economic factors in the local area.
multifocal disease	Occurring in more than one location in the breast.
neoadjuvant chemotherapy	Chemotherapy that 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.
NHS board	There are 21 NHS boards of two types: 14 territorial boards responsible for healthcare in their areas and seven special health boards which offer supporting services nationally.
NHS Breast Screening Programme (NHSBSP)	The UK-wide programme of free population-based screening for breast cancer. Website address: www.cancerscreening.nhs.uk/breastscreen/index.html
oestrogen receptor (ER)	A specific site on the surface of a cell that binds to the hormone oestrogen. Anti-oestrogens used for treating breast cancer act by preventing the binding of oestrogen to these receptors.

oncologist	A doctor who specialises in the treatment of cancer patients. A clinical oncologist, or radiotherapist, specialises in treating cancer with radiation or drugs, and a medical oncologist specialises in treating cancer with drugs.
oncology	The branch of medicine devoted to the study of cancer and its diagnosis and treatment.
outcome	The end result of care and treatment and/or rehabilitation. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care and treatment, and/or rehabilitation.
ovarian ablation	Removal of the ovaries.
palliative care	Palliative care is the active total care of patients and their families by a multiprofessional team when the patient's disease is no longer responsive to curative treatment.
pathologist	A qualified medical practitioner trained in the study of disease processes.
pathology	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.
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS QIS approach, all members of a review team are equal.
phylloide(s) (tumour)	A variant of mammary fibroadenoma, usually of large size, with an unusually cellular, sarcoma-like stroma.
primary care	The conventional first point of contact between a patient and the NHS. This is the care given to patients outside hospitals and is typically, though not always, delivered through general practices. Other providers include dentists, pharmacists, optometrists and ophthalmic medical practitioners. Primary care services are the most frequently used of all services provided by the NHS.
primary tumour	Original site of the cancer. The mass of tumour cells at the original site of abnormal tissue growth.
procedure	Set operational instructions to regulate activity.
progesterone receptor (PR)	A specific site on the surface of a cell that binds to the hormone progesterone. If cancer cells have progesterone receptors this can be a sign of a hormone sensitive cancer, as they may depend on progesterone for growth.
prognosis	An assessment of the expected future course and outcome of a person's disease.
protocol	Operational instructions which regulate and direct activity. Protocols may be national, or agreed locally to take into account local requirements.
quadrantectomy	A surgical procedure in which a 'quadrant' (approximately one-fourth) of the breast, including tissue surrounding a cancerous tumour, is removed. It is also called a partial or segmental mastectomy.
R3, R4, R5	The interpretation of the findings from X-ray examination of the breast in relation to possible breast cancer (eg R3 – benign finding/probably benign).
radiographer	A person who is trained in the technique of taking X-ray pictures of parts of the body.
radiography	The technique of examining the body by directing X-rays through it to produce images on photographic films or fluorescent screens.

radiologist	A qualified doctor who has specialised in the use of medical imaging techniques such as X-rays, ultrasound, CT, MRI and fine needle biopsy.
radiology	The use of X-rays in the diagnosis, treatment and monitoring of disease.
radiotherapy	The use of radiation, usually X-rays or gamma rays, to kill tumour cells.
recurrence	When new cancer cells are detected at the site of the original tumour, following treatment.
Regional Cancer Advisory Groups (RCAGS)	There are three Regional Cancer Advisory Groups – North, West and South East Scotland, each providing a strategic, advisory and planning focus for their respective locality cancer services and NHS boards.
sarcoma	A form of cancer that arises in the supportive tissues such as bone, cartilage, fat or muscle.
Scottish Breast Screening Programme (SBSP)	The programme of free population-based screening for breast cancer in Scotland. The SBSP is commissioned by the National Services Division, and is provided through six regional screening centres and 13 mobile screening units across Scotland.
Scottish Cancer Group (SCG)	Leads and directs the cancer services reconfiguration programme in Scotland. The SCG is a multidisciplinary group which advises Ministers, the Chief Medical Officer and the Scottish Government on the strategic priorities and objectives for the development of cancer services, including service quality, research and audit, clinical trial, and clinical effectiveness. The Group also provides advice on trends in incidence and mortality, scientific advances and on the implementation of nationally agreed initiatives for the delivery of cancer services, programmes of prevention and screening. Website address: www.show.scot.nhs.uk/sehd/cancerinscotland/pages/SCgroupmeetings.htm
Scottish Government Health Directorates (SGHD)	The SGHD is responsible for both NHSScotland and for the development and implementation of health and community care policy. It is also responsible for social work policy and for community care and voluntary issues. Website address: www.show.scot.nhs.uk/sghd
secondary care	Hospital-based (acute) health services which are provided on an inpatient or outpatient basis. See acute care.
segmentectomy	Excision of a segment of any organ or gland.
sentinel lymph node	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. If there is a cancer in the organ, this lymph node may be the one most likely to contain cancer cells if the cancer has begun to spread.
sentinel lymph node biopsy (SLNB)	A technique whereby both blue and radioactive markers are injected into the breast. As these travel to the sentinel node it can be identified and removed to see if the cancer has spread.
sonographer	A medical professional who operates ultrasonic imaging devices to produce diagnostic images and scans. The sonographer usually reviews the images after the examination and reports back to patient's doctor.
staging	The process of determining whether cancer has spread. Staging involves clinical, surgical, radiological and pathological assessment.
systemic	Involving the whole body, for example via the blood system.
systemic therapy	Treatment that goes through the system, usually via the blood, and reaches and affects cells all over the body.

tertiary care	Specialised consultative care, usually on referral from primary or secondary care personnel, by specialists working in a centre that has personnel and facilities for special investigation and treatment.
TNM staging	TNM classification provides a system for staging the extent of cancer. T refers to the size of the primary tumour. N refers to the involvement of the lymph nodes. M refers to the presence of metastases or distant spread of the disease.
trastuzumab	A manufactured antibody (a small part of our immune defences) which is attracted to the HER2 receptor on some breast cancers. It signals to the immune system to destroy these cells.
triple assessment	A diagnostic procedure used for symptomatic women, and women recalled for assessment following screening. The procedure consists of clinical examination, imaging (mammography and/or ultrasound), and fine needle aspiration or core biopsy.
tumour	A lump or mass of cells which can be either benign (not cancerous) or malignant. Also known as a neoplasm.
U3, U4, U5	The findings from ultrasound examination of the breast and axilla in a patient suspected of having breast cancer (eg U3 – suspicious – probably benign).
ultrasound	An imaging test that bounces sound waves off tissues and converts the echoes into pictures.
wide local excision	The removal of the breast lump together with some surrounding tissue.