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Briefing paper

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Introduction

This briefing paper presents a structured review of draft indicator statements. These indicator statements have been derived either from the NICE quality standard on breast cancer or from other sources, for example, relevant indicators in the NHS operating framework. For the purposes of this paper, an indicator statement is defined as a high level statement which, with development and testing, can be used to specify a potential quality indicator for use in the COF.

This briefing paper is intended to help inform and guide the selection of indicator statements by the COF Advisory Committee for indicator development.

Structure of the briefing paper

This briefing paper includes 7 sections. These sections address the requirements of the selection criteria for potential COF indicators as outlined in the COF process guide.

Section 1 presents an overview of the NICE quality standard on breast cancer and its link to the NHS outcomes framework.

Section 2 presents a brief definition and epidemiological summary of breast cancer and its clinical management.

Section 3 presents the quality statements as presented in the published quality standard alongside the developed indicator statements. This section also includes:

- an evidence summary for the proposed indicator statement
- a brief overview of current clinical practice including, where data is available, current baseline and any variation in practice
- indicator development issues, including a feasibility assessment carried out in collaboration with the Health and Social Care Information Centre.
Section 4 presents outcome indicator statements, and in some cases additional process indicator statements, that the COF indicator Breast Cancer Review Group considered would reflect the provision of high quality care as defined in the Quality Standard as a whole.

Section 5 presents a supporting statement by the Chair of the COF indicator Breast Cancer Review Group for consideration by the COF Advisory Committee.

Section 6 presents indicators identified from other sources, with an assessment against pre-defined criteria.

Section 7 presents an initial technical feasibility assessment of COF the draft indicator statements.
Section 1 Overview

Background

The proposed indicator statements presented in this briefing paper have been identified in three ways:

- by the COF indicator Breast Cancer Review Group
- from other sources

The scope of the quality standard covers the management of early (ductal carcinoma in situ and invasive), locally advanced and advanced breast cancer in adults. This includes the management of both screen-detected and symptomatic breast cancers from the point of referral to a specialist team. The scope does not include adults with rare breast tumours, benign breast disease, lobular carcinoma in situ, or the care of women with an increased risk of breast cancer because of family history.

The proposed indicator statements included in this briefing paper relate to healthcare processes or outcomes that can be influenced, at least in part, by the actions of Clinical Commissioning Groups (for example through decisions on which services to commission, the setting of contracts and the monitoring of the quality of services commissioned and the performance of providers).

NHS priorities

The quality standard for breast cancer, from which some of the proposed indicator statements presented in this report are derived, describes markers of high-quality care that, when delivered collectively, should contribute to improving the effectiveness, safety and experience of care for people with breast cancer in the following ways [Department of Health, 2010b]:

- preventing people from dying prematurely
- enhancing quality of life for people with long-term conditions
• helping people to recover from episodes of ill health, or following injury
• ensuring that people have a positive experience of care
• treating and caring for people in a safe environment and protecting them from avoidable harm.

Relevant overarching indicators

• potential years of life lost (PYLL) from causes considered amenable to healthcare

• life expectancy at 75:
  o males
  o females

Relevant improvement areas

• reducing premature mortality from the major causes of death:
  o one- and five-year survival from breast cancer
  o under 75 mortality rate from cancer

The extent to which indicators identified from other sources reflect improvements in the outcomes framework are identified in section 6.
Section 2 Definition, epidemiological summary and clinical management

**Definition of breast cancer**

Early breast cancer is subdivided into two major categories, in situ disease, mainly in the form of ductal carcinoma in situ (DCIS), and invasive cancer. Both are heterogeneous processes with very variable appearances, biology and clinical behaviour.

DCIS grows within a single duct system of the breast but it can vary in size and is sometimes extensive. However, DCIS, by definition, has not spread outside the boundaries of the normal structures of the breast and therefore cannot have metastasised. Unlike DCIS, invasive breast cancer infiltrates into the breast stroma and thus has the potential to spread to lymph-vascular spaces and to metastasis. Not all invasive breast cancers are the same; some are more aggressive and some may spread earlier to distant sites.

Of newly diagnosed cases of breast cancer a small proportion are diagnosed in the advanced stages, when the tumour has spread significantly within the breast or to other organs of the body. In addition, a considerable number of women who have been previously treated with curative intent subsequently develop either a local recurrence or metastases.

**Incidence and prevalence**

Breast cancer is the most common cancer in women, and the second biggest cause of death after lung cancer. In 2008, 40,585 people were diagnosed with breast cancer in England (40,260 women and 325 men)\(^1\). The lifetime prevalence is 1 in 8 women. There is a trend of increasing incidence because of lifestyle factors and improved detection, and decreasing mortality because of earlier detection and improvements in the quality and availability of effective treatments.

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\(^1\) Cancer Research UK Website  
There are more than 500,000 people in the UK today who have, or have had, a diagnosis of breast cancer. It is estimated that around 40 to 50% of these may develop metastases in the future, and therefore require treatment for advanced breast cancer.² Unusually, lifestyle and environmental issues mean that the prevalence of breast cancer is greater in higher socioeconomic groups. However, mortality is higher among lower socioeconomic groups, highlighting issues of later identification because of a lower uptake of screening, barriers to accessing treatment among these groups and the impact of comorbidities.

**Management**

Breast cancer is identified through mammography as part of the national screening programme or through the presentation of symptomatic patients in primary care. Patients presenting in primary care are referred urgently for assessment by a specialist team (within 2 weeks). Imaging and biopsy are arranged to confirm the diagnosis, and treatment planned and initiated by a multidisciplinary team. Surgery is the most common primary treatment, either through a local excision to remove the cancer alone (conserving the breast), or mastectomy. Other treatment options include radiotherapy, hormonal therapy and chemotherapy. Post-treatment follow up and supportive care may be managed in primary care.

Over recent years there have been important developments in the investigation and management of breast cancer, including new types of chemotherapy, and biological and hormonal agents. Nationally there is evidence of some variation in practice in the identification and treatment of breast cancer, and of inconsistent availability of certain treatments and procedures.

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Section 3 Proposed indicator statements: quality standard on breast cancer

A total of 29 indicator statements developed from the NICE quality standard for breast cancer (NICE, 2011) have been identified as appropriate by the COF indicator Breast Cancer Review Group for consideration by the COF advisory committee.

These indicator statements have been rated valid by the COF indicator Breast Cancer Review Group. As part of the selection of indicator statements, the Review Group may have rated indicators low where they considered indicators to be low priority or not feasible. These are therefore not presented in this document.

It is expected that some of the concepts and timeframes within the indicator may require further clarification as part of the indicator development process.

Square brackets have been used to denote concepts within the indicator statement wording where further clarification may be required. For example,

Of people with newly diagnosed breast cancer, the proportion who had been previously seen with [symptoms suggestive of breast cancer] and discharged undiagnosed within one year of initial presentation.

The COF indicator Breast Cancer Review Group has advised that these concepts can be clarified.

The clinical and cost effectiveness evidence summaries presented in this section are based on the following sources:

- The full clinical guideline on ‘Early and locally advanced breast cancer’. The National Collaborating Centre for Cancer.
- The full clinical guideline on ‘Advanced breast cancer’. The National Collaborating Centre for Cancer.
**QS01  Referral**

**NICE quality standard statement**

People presenting with symptoms that suggest breast cancer are referred to a unit that performs diagnostic procedures in accordance with NHS Breast Screening Programme guidance.

**Proposed indicator(s) relevant to the quality statement**

BC01 Of people with [newly diagnosed breast cancer], the proportion who had [been previously seen] with [symptoms suggestive of breast cancer] and discharged undiagnosed [within one year of initial presentation].

**Assessment against prioritisation criteria**

**Discussion of clinical and cost-effectiveness evidence**

The topic expert group that developed the quality standard had identified a need to strengthen access to the highest quality diagnostic services. The quality statement aims to raise the quality of symptomatic services to that of screening centres and is based on the consensus of the group.

The COF Review Group noted that the quality statement is structural, but that a process indicator could be developed that would be a proxy for measuring the quality of diagnostic services as well as link to an outcome that is important to patients (early diagnosis).

**Current clinical practice including evidence of variation**

Anecdotal evidence from the COF Review Group is that there is significant variation in the quality of diagnostic services.

**Indicator development issues**

**Feasibility assessment**

[3] This indicator will require a new collection (or system).
QS02  Clinical assessment

NICE quality standard statement

People with early invasive breast cancer are offered a pre-treatment ultrasound evaluation of the axilla and, if abnormal lymph nodes are identified, ultrasound-guided needle biopsy (fine needle aspiration or core). Those with no evidence of lymph node involvement on needle biopsy are offered sentinel lymph node biopsy when axillary surgery is performed.

Proposed indicator(s) relevant to the quality statement

BC02  Of people with [early invasive breast cancer], the proportion who receive a pre-treatment ultrasound evaluation of the axilla.

BC03  Of node positive patients, the proportion identified by pre-operative ultrasound-guided needle biopsy.

BC04  Of people with [early invasive breast cancer] and no pre-treatment ultrasound evidence of lymph node involvement, the proportion who receive sentinel lymph node biopsy.

BC05  Of people with [early invasive breast cancer] who receive axillary surgery, the proportion who undergo further definitive treatment of the axilla within 6 months of the [last operation on the axilla].

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

The clinical guideline noted good evidence, including from a meta-analysis, of clinical effectiveness in reducing the number of patients who undergo SLNB and then need further axillary surgery, and reasonable evidence of cost effectiveness. Identifying those patients who can be shown to have involved lymph nodes by preoperative testing has the benefit of reduced complications following SLNB for those patients whose removed lymph nodes are tumour free, since further axillary treatment is avoided. Eight studies reported a median proportion of 81% of cases in whom it was possible to visualise...
axillary lymph nodes on ultrasound. Using ultrasound-guided needle biopsy to stage the axilla compared to SLNB for all patients undergoing staging, was considered cost effective in terms of a reduction in the number of patients undergoing SLNB, and the fact that ultrasound guided needle biopsy is a less invasive staging procedure than SLNB and can translate into gains in quality of life.

SLNB is a targeted technique to identify and remove the SLN, causing minimal disruption to the axilla. There is a large volume of evidence from both RCTs and case series confirming the accuracy of SLNB in staging the axilla. It is a less invasive axillary staging technique than axillary clearance and has been shown to reduce the complication rate. There is RCT evidence of less morbidity with SLNB and study findings that patients treated by SLNB do not appear to have poorer rates of disease free survival or overall survival, or higher rates of axillary recurrence.

Current clinical practice including evidence of variation

Ultrasound and ultrasound-guided needle sampling are routinely available in diagnostic breast clinics and can be used for preoperative staging of the axilla.

The NHS Cancer Screening Programme All Breast Cancer Report (2006) found that 27% of invasive breast cancers known to have had axillary node assessment had an SLNB. Patients were more likely to undergo an SLNB if they were in the most affluent group.

An audit of screen detected breast cancers for the screening year 2009/10 found that 59% of patients with invasive cancer had axillary ultrasound recorded, although there was variation between regions from 39% to 97%. 15% of the invasive cancers having an axillary ultrasound examination had an abnormal ultrasound result, and 86% of these had an axillary node sample (ultrasound-guided needle biopsy). An SLNB procedure was recorded for 67% of invasive cancers with axillary surgery. Although the use of SLNB has

increased by 9% since 2008/09, there is still widespread variation. 8 screening units used SLNB for fewer than 20% of their patients with invasive cancer, while in 15 screening units over 90% of the patients with invasive cancers had an SLNB. 41% of invasive cancers with a positive nodal status had a repeat operation to the axilla. This varied across regions from 30% to 53%, and from 0% in 3 screening units to over 60% in 17 units.4

The Second All Breast Cancer report (2011) notes that the use of SLNB was higher for women with screen-detected breast cancer than for symptomatic women (38% compared to 29%). Over 80% of UK breast surgeons have now been trained in SLNB so it is anticipated that the increased use of this technique, particularly in the treatment of early breast cancer, will continue. Older women were significantly less likely to have a SLNB; 20% of women aged at least 80 years had the procedure compared with 32% of all patients.5

**Indicator development issues**

**Feasibility assessment**

[3] These indicators will require a new collection (or system).

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4 NHS Breast Screening Programme and Association of Breast Surgery: An audit of screen detected breast cancers for the year of screening 2009 to March 2010
5 NHS Cancer Screening Programme (2011) Second All Breast Cancer Report
**QS03 Breast conserving surgery**

**NICE quality standard statement**

People with early breast cancer undergoing breast conserving surgery, which may include the use of oncoplastic techniques, have an operation that both minimises local recurrence and achieves a good aesthetic outcome.

**Proposed indicator(s) relevant to the quality statement**

BC06 Ratio of mastectomy to breast conserving surgery.

BC07 Of people with [early breast cancer] who receive breast conserving surgery, the proportion who undergo [re-surgery] [within 6 months of the last operation].

BC08 Of people who have had breast conserving surgery, the proportion who have had ipsilateral breast cancer occurrences.

BC09 Patient satisfaction with outcome of breast surgery.

**Assessment against prioritisation criteria**

**Discussion of clinical and cost-effectiveness evidence**

Following diagnosis of early invasive breast cancer surgery is normally the first definitive treatment. If disease has been assessed as unifocal, wide excision (breast conserving surgery) is an option for some patients as an alternative to mastectomy. Evidence from observational studies shows that there is no single size of clear margin that is the optimum for reduced local recurrence rate and most existing studies agree that margins containing tumour cells are associated with local recurrence or bear the risk of residual cancer. The risk of local recurrence is reduced with very wide margins but the wider the margin, the more breast tissue is removed and the greater the detrimental effect on cosmesis.

However, residual disease is present in up to 60% of cases when further surgery (re-excision or mastectomy) is performed after wide local excision. Even when the surgical margin of a wide local excision is 1-2mm, 31-64% of...
patients have histological proven residual disease. Local recurrence rates are generally considered to be the best indicator of adequate excision with or without radiotherapy.

Crude local recurrence rates of 20-38% are reported for excision margins of 1mm or less and rates of 13-34% are seen with margins 2mm or less. Whilst crude local recurrence rates at the lower end of this range (13-19%) are obtained with the addition of radiotherapy to 1-2mm margins, when margins of 2mm or more are achieved, local recurrence rates of 2% (with radiotherapy) to 11% (without radiotherapy) are reported.

**Current clinical practice including evidence of variation**

The mastectomy to breast conserving surgery ratio varies across the regions in the UK from 1:1.1 to 1:1.7. The ratio is lower for screen-detected breast cancers than for symptomatic breast cancer. Ratios are also influenced by age and deprivation status.

With earlier detection and diagnosis of the disease, breast conservation surgery with local excision of the tumour has been more frequently performed rather than mastectomy. In the UK in 2007, 57% of women with surgically treated breast cancer had breast conserving surgery and the remaining 43% had a mastectomy.¹

**Indicator development issues**

**Feasibility assessment**

The Mastectomy and Breast Reconstruction Audit looked at the determinants and outcomes of care for women with breast cancer having a mastectomy with or without breast reconstruction. No data has been collected on patients diagnosed after 31 March 2009.

⁶ These indicators will require a new collection (or system).

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¹ NHS Cancer Screening Programme (2011) *Second All Breast Cancer Report*
Other issues

- The Review Group emphasised that indicators BC08 and BC09 must be adopted as a package in order to capture the balanced assessment intended of local recurrence against aesthetic outcome.
QS04 Mastectomy

NICE quality standard statement

People with early breast cancer who are to undergo mastectomy have the options of immediate and planned delayed breast reconstruction discussed with them.

Proposed indicator(s) relevant to the quality statement

BC10 Of people with [early breast cancer] having mastectomy, the proportion who have an [immediate] or [planned delayed] [breast reconstruction].

BC11 Of people with [early breast cancer] who are to undergo mastectomy, the proportion who have the options of [immediate] or [planned delayed] [breast reconstruction] [discussed with them].

BC12 Patient satisfaction with discussion about breast surgery options.

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

A large quantity of information about reconstruction has to be discussed with patients for them to make informed decisions. All methods of reconstruction have potential complications which might delay subsequent adjuvant therapy. There are pros and cons of each method which need to be combined with other patient characteristics when deciding which approach is best for each individual. There is limited clinical evidence from observational studies for breast reconstruction following mastectomy for breast cancer, and expert consensus that immediate reconstruction is an acceptable procedure that does not disadvantage patients compared to delayed reconstruction.

Current clinical practice including evidence of variation

Where mastectomy is still necessary, routine management increasingly includes breast reconstruction, performed at the time of primary surgery when possible.
The 2011 report of the National Mastectomy and Breast Reconstruction Audit identified a comparatively low rating of satisfaction among women undergoing mastectomy on whether the consultant surgeon had involved them in the decision-making process, and the percentage of those who were very satisfied with involvement was lower than for other audit criteria by women undergoing immediate reconstruction. Half of mastectomy-only patients were very satisfied with the reconstructive options they were provided with before (and after, in some cases), their surgery. Conversely, two-thirds of immediate reconstruction and three-quarters of delayed reconstruction patients were very satisfied with their options. Variation between hospitals in terms of patient reported outcomes was within the range expected, suggesting that levels of performance across organisations are broadly similar.\(^7\)

The National Cancer Peer Review Programme Report 2010/11 noted that over 40% of respondents to an online survey regarding the clinical lines of enquiry indicated that they had introduced changes to ensure reconstruction of the breast became part of the discussion with the patient when offering mastectomy.\(^8\)

**Indicator development issues**

**Feasibility assessment**

[3] These indicators will require a new collection (or system).

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\(^7\) NHS Information Centre (2011) *National Mastectomy and Breast Reconstruction Audit*

\(^8\) National Cancer Peer Review Programme *Report 2010/11*
**ITEM 11 – Breast Cancer**

**QS05 Pathology – ER and HER2 status**

**NICE quality standard statement**

People with newly diagnosed invasive breast cancer and those with recurrent disease (if clinically appropriate) have the ER and HER2 status of the tumour assessed and the results made available within 2 weeks to allow planning of systemic treatment by the multidisciplinary team.

**Proposed indicator(s) relevant to the quality statement**

BC13 Of people with [newly diagnosed invasive breast cancer], the proportion who have the ER status of the tumour [assessed].

BC14 Of people with [newly diagnosed invasive breast cancer], the proportion who have the HER2 status of the tumour [assessed].

BC15 Of people with [histologically confirmed recurrent breast cancer] and [deemed eligible for further testing], the proportion who have the ER status of the tumour [assessed].

BC16 Of people with [histologically confirmed recurrent breast cancer] and [deemed eligible for further testing], the proportion who have the HER2 status of the tumour [assessed].

BC17 Of people with [newly diagnosed invasive breast cancer] or [recurrent disease], the proportion who have ER status results [available] [within 2 weeks].

BC18 Of people with [newly diagnosed invasive breast cancer] or [recurrent disease], the proportion who have HER2 status results [available] [within 2 weeks].

**Assessment against prioritisation criteria**

**Discussion of clinical and cost-effectiveness evidence**

There is evidence from observational studies that ER status is a useful predictor of survival and response to tamoxifen. Expert consensus is that
knowledge of receptor status will significantly affect management. Seventeen observational studies of patients with advanced breast cancer showed that approximately 15% of patients showed a changed in endocrine receptor status, from positive to negative, comparing primary with locoregional or metastatic tumour samples. 93% of patients tested for HER2 status showed no change between paired samples.

**Current clinical practice including evidence of variation**

ER status is routinely determined on all invasive breast cancers and reported using a standardised technique. Current practice in some centres is to establish ER and progesterone receptor and HER2 status on all newly diagnosed breast cancers. It is not routine practice to reassess receptor status on recurrence.

According to the Second All Breast Cancer Report (2011) ER status was known for 56% of all invasive cancers, with variation across regions from 32% to 96%. HER2 status was known for 43% of all invasive cancers, varying from 26% to 87% across regions.\(^9\)

The National Cancer Peer Review Programme Report of 2010/11 highlighted variation both within and between networks as to the availability of HER2 receptor status results at MDT discussion prior to treatment decisions, which led to some inequity of service within networks. HER2 receptor status not being available at the point of treatment decision was identified as one of the immediate risks for some breast services.\(^10\)

**Indicator development issues**

**Feasibility assessment**

[2] Indicators BC13 and BC14 are available from existing data sources given amendments to the collection (e.g. a new data field).

[3] Indicators BC15 – BC18 will require a new collection (or system).

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\(^9\) NHS Cancer Screening Programme (2011) *Second All Breast Cancer Report*

\(^10\) National Cancer Peer Review Programme *Report 2010/11*
Other issues

- Indicators BC15 and BC16 must be defined clearly in terms of people “deemed eligible for further testing” given that it is not always appropriate to assess ER and HER2 status in people with recurrent disease.
**QS06 Management**

**NICE quality standard statement**

People with early invasive breast cancer, irrespective of age, are offered surgery, radiotherapy and appropriate systemic therapy, unless significant comorbidity precludes it.

**Proposed indicator(s) relevant to the quality statement**

BC19 Of people [older than 70] with [early invasive breast cancer], the proportion who receive [appropriate therapy].

BC20 Of people [aged 70 and under] with [early invasive breast cancer], the proportion who receive [appropriate therapy].

**Assessment against prioritisation criteria**

**Discussion of clinical and cost-effectiveness evidence**

A systematic review of RCTs reported no significant difference in overall survival between surgery and primary endocrine treatment for patients older than 70 years. There was evidence of a non-significant trend in favour of surgery plus endocrine therapy over primary endocrine therapy. There is a statistically significant effect in favour of surgery plus endocrine therapy over endocrine therapy for breast cancer specific survival.

**Current clinical practice including evidence of variation**

The BCCOM audit data (2007) showed variation in treatment modalities by age for cases of symptomatic breast cancer diagnosed from 2002 to 2004. A lower percentage of those over 80 years received radiotherapy or chemotherapy compared to those less than 50 years. The opposite was seen in the use of hormonal therapy. Those in the older age groups are less likely to receive surgical treatment than younger women. For symptomatic breast cancers, surgical treatment decreased with age at diagnosis with only 74% of

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women aged 70-79 and 39% of women aged 80 and above having surgical treatment compared with 90% of women aged under 50.\textsuperscript{12}

**Indicator development issues**

**Feasibility assessment**

[3] These indicators will require a new collection (or system).

**Other issues**

- These indicators will require a clear definition and criteria for “appropriate” therapy.

- The Review Group made a decision to bundle the aspects of the quality statement into two composite indicators that could identify differences in the treatments offered to people over 70 compared to people under 70, between clinical commissioning groups. It was noted however that this should be an indicator for improvement rather than judgement.

\textsuperscript{12} NHS Cancer Screening Programme (2011) Second All Breast Cancer Report
QS07  Staging

NICE quality standard statement

People with early invasive breast cancer do not undergo staging investigations for distant metastatic disease in the absence of symptoms.

Proposed indicator(s) relevant to the quality statement

BC21 Of people with [early invasive breast cancer], the proportion who undergo [staging investigation] for [distant metastatic disease] in the absence of symptoms suggestive of distant metastatic disease.

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

In early operable breast cancer there is no current evidence to support routine screening for metastatic disease in asymptomatic women and consensus among the expert review group that it is often done unnecessarily, and can cause harm to patients and waste resources.

Current clinical practice including evidence of variation

There is anecdotal evidence from the expert review group that staging investigations for distant metastatic disease are often done unnecessarily and cause harm to patients and waste resources.

Indicator development issues

Feasibility assessment

[3] This indicator will require a new collection (or system).

Other issues

- A list of accepted symptoms suggestive of distant metastasis would be required in order to source the data directly from the operational record.
QS08  Adjuvant therapy planning

NICE quality standard statement

People with early invasive breast cancer are involved in decisions about adjuvant therapy after surgery, which are based on an assessment of the prognostic and predictive factors, and the potential benefits and side effects.

Proposed indicator(s) relevant to the quality statement

BC22 Of people with [early invasive breast cancer], the proportion who are [involved in decisions] about [adjuvant therapy after surgery], which are based on an assessment of the prognostic and predictive factors, and the potential benefits and side effects.

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

The quality statement and proposed indicator is derived from the consensus opinion of the topic experts on the review group.

Current clinical practice including evidence of variation

The National Cancer Patient Experience Survey Report (2010) showed that of those patients who thought that more than one type of treatment was suitable for them, 71% said that they were definitely involved as much as they wanted to be in decisions about their treatment; 22% said they were involved to some extent and 6% said they would have liked to have been more involved. The difference between cancer groups was not significant. Results from individual trusts show that there are significant variations in the proportion of patients saying they were definitely involved in decisions about treatment. Scores in Trusts ranged from 51% as the lowest score to 87% as the highest trust score.13

Indicator development issues

Feasibility assessment

[3] This indicator will require a new collection (or system).
QS09 Clinical follow up

NICE quality standard statement

People having treatment for breast cancer are offered personalised information and support, including a written follow-up care plan and details of how to contact a named healthcare professional.

Proposed indicator(s) relevant to the quality statement

BC23 Of people having treatment for [early breast cancer], the proportion who receive [personalised information and support], including treatment options, a [written follow-up care plan] and [details of how to contact a named healthcare professional] following the [completion of initial surgical treatment].

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

The clinical guideline notes the absence of any good quality data in this area and the underpinning recommendations are based on expert consensus.

Current clinical practice including evidence of variation

NICE guidance (2002) advised that breast cancer patients should be followed up in hospital setting for a minimum of 3 years. Some units however, according to local policy, continue to review patients in the hospital-based setting after this time for clinical and mammographic surveillance.

The National Cancer Peer Review 2009/10 found that although provision of a permanent record of consultation and the presence of agreed and recorded individual treatment plans was much improved from the previous review (2004/2007), there were still areas where patients were not offered a permanent record, and notification of diagnosis to the GP in 24 hours was not always achieved or audited.¹⁴

¹⁴ National Cancer Peer Review Programme Report 2009/10
The National Cancer Patient Experience Survey Report (2010) showed that 92% of patients overall said that hospital staff told them who to contact if they felt worried about their condition or treatment after leaving hospital; 8% said they were not told. Results from individual trusts show a significant variation; scores ranged from 81% to 100% of patients.\textsuperscript{15}

**Indicator development issues**

**Feasibility assessment**

[3] This indicator will require a new collection (or system).

**Other issues**

- This is a multipart indicator which may be difficult to extract from an operational record.

\textsuperscript{15} Department of Health (2010) National Cancer Patient Experience Survey Report
**QS010  Follow up imaging**

**NICE quality standard statement**

Women treated for early breast cancer have annual mammography for 5 years after treatment. After 5 years, women who are 50 or older receive breast screening according to the NHS Breast Screening Programme timescales, whereas women younger than 50 continue to have annual mammography until they enter the routine NHS Breast Screening Programme.

**Proposed indicator(s) relevant to the quality statement**

- **BC24** Of women treated for [early breast cancer] and [45 or older] [at the time the post-treatment surveillance started], the proportion who [have had 5 years of annual mammography] before [entering the NHS Breast Screening Programme].

- **BC25** Of women treated for [early breast cancer] and [younger than 45] [when post-treatment surveillance started], the proportion who have had annual mammography until they [entered the NHS Breast Screening Programme] [at the age of 50].

- **BC26** Of women treated for [early breast cancer] who are [within 5 years of finishing their treatment], the proportion who [have had a mammography] [within the previous year].

**Assessment against prioritisation criteria**

**Discussion of clinical and cost-effectiveness evidence**

The consensus of those providing breast cancer treatment is that routine follow-up is beneficial for patient welfare and for monitoring effectiveness of treatment. Evidence from three systematic reviews of observational studies does not confirm that routine follow-up mammography directly improves survival in patients treated for breast cancer, although one study is suggestive of improved 5 year survival for patients in whom ipsilateral recurrence is detected by mammography. Systematic reviews of observational studies
estimate the median proportion of cases of recurrent breast cancer that are first detected by follow-up mammography to be 26% for ipsilateral local recurrence, and 36% for contralateral breast cancer. Two poor quality retrospective studies suggest that follow up mammography is able to detect locally recurrent breast cancer in some patients treated initially for DCIS.

**Current clinical practice including evidence of variation**

It is routine practice in virtually all breast units in the UK to provide post-treatment follow-up with regular clinical examination and mammography for at least 5 years. This routine follow-up is usually provided in the secondary care setting and requires significant resources.

There is anecdotal evidence from topic experts on the review group that there is varied practice across the country in terms of how often and at what age surveillance takes place.

**Indicator development issues**

**Feasibility assessment**

[2] These indicators are available from existing data sources given amendments to the collection (e.g. a new data field).

The HSCIC collect and publish aggregate returns on numbers of women screened as part of a screening programme (not related to whether they have been treated for breast cancer). These indicators may be feasible through the linkage of data from screening programmes and primary care data. Further investigation is required.
QS011  Multidisciplinary team

NICE quality standard statement

People who develop local recurrence, regional recurrence and/or distant metastatic disease have their treatment and care discussed by the multidisciplinary team.

Proposed indicator(s) relevant to the quality statement

BC27  Of people who develop [local recurrence], [regional recurrence] and/or [distant metastatic disease], the proportion who are [discussed by the multidisciplinary team].

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

There is expert consensus that the management of uncontrolled local disease needs to be individualised and will usually involve a combination of treatments. A team approach is therefore considered very important and will include nurses, surgeons, oncologists and psychological support.

Current clinical practice including evidence of variation

The National Cancer Peer Review Programme Report 2010/11 identified inadequate support and discussion for metastatic breast patients as a serious concern for some breast services.\(^{16}\)

Indicator development issues

Feasibility assessment

[3]  This indicator will require a new collection (or system).

\(^{16}\) National Peer Review Programme [Report 2010/11](#)
QS012  Key worker

NICE quality standard statement

People with recurrent or advanced breast cancer have access to a ‘key worker’, who is a clinical nurse specialist whose role is to provide continuity of care and support, offer referral to psychological services if required and liaise with other healthcare professionals, including the GP and specialist palliative care services.

Proposed indicator(s) relevant to the quality statement

BC28 Of people with [newly diagnosed], [recurrent] or [advanced breast cancer], the proportion who have a [key worker] who is a [clinical nurse specialist].

Assessment against prioritisation criteria

Discussion of clinical and cost-effectiveness evidence

Support from breast care nurse specialists has shown to be linked with a reduction in psychological morbidity. Moderate quality evidence suggested that adding the services of an advanced practice care nurse to standard care significantly reduced uncertainty, complexity, inconsistency and unpredictability without influencing quality of life or mood. Other studies found that support from a breast care nurse specialist following cancer surgery alleviated depression over time but made no significant difference to anxiety. However, receiving support from the breast care nurse specialist before and after receiving a pre-surgical diagnosis significantly lowered clinically relevant anxiety when measured two weeks after surgery, regardless of eventual diagnosis. The anecdotal evidence and experience of experts on the review group produced a consensus that access to a key worker who is a clinical nurse specialist would improve patients’ experience.
Current clinical practice including evidence of variation

The National Cancer Peer Review Programme Report 2010/11 identified inadequate clinical nurse specialist provision as one of the immediate risks for some breast services.

The National Cancer Patient Experience Survey report 2010 showed that 84% of patients overall said that they had been given the name of a Clinical Nurse Specialist; 16% were not. Of patients with breast cancer, 93% said they were given the name of a clinical nurse specialist. Results from individual trusts show significant variation, ranging from 59% to 97% (of all cancer patients).17

**Indicator development issues**

Feasibility assessment

[3] This indicator will require a new collection (or system).

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17 National Cancer Patient Experience Survey Report 2010
QS013  Brain metastases

NICE quality standard statement
People who have a single or small number of potentially resectable brain metastases, a good performance status and who have no (or minimal) other sites of metastatic disease are referred to a neuroscience brain and other rare CNS tumours multidisciplinary team.

Proposed indicator(s) relevant to the quality statement
BC29  Of people who have a [single or small number] of [potentially resectable] [brain metastases], a [good performance status] and who have [no or minimal] [other sites of metastatic disease], the proportion who are referred to a [neuroscience brain and other rare CNS tumours multidisciplinary team].

Assessment against prioritisation criteria
Discussion of clinical and cost-effectiveness evidence
Some patients with advanced breast cancer will develop symptomatic brain metastases, the diagnosis of which can have profound physical and psychological effects on the patient (and their family and carers). There are a number of treatment options which can provide symptom relief and improve function. The evidence addressing the management of brain metastases were mainly retrospective case series, none of which were considered by the guideline development group to be of particularly good quality, however, expert opinion was that specialist management was warranted to ensure consideration of appropriate treatment.

Current clinical practice including evidence of variation
There was consensus among the experts on the review group that there was a tendency for patients with advanced disease not to see a surgeon, and that this was more common for patients with breast cancer. It was agreed that an active programme of treatment for brain metastases required encouragement.
**Indicator development issues**

**Feasibility assessment**

[3] This indicator will require a new collection (or system).

**Other issues**

- This is a complex indicator statement which may be difficult to extract from operational records.

- The Review Group noted that locally defined eligibility criteria may be used for referral to the neuroscience brain and other rare CNS tumours multidisciplinary team.
Section 4 Other outcome indicators identified by the Review Group for Breast Cancer

As part of the indicator development process, the COF indicator Breast Cancer Review Group considered whether there were any outcome indicators that would reflect the provision of high quality care for people with breast cancer as defined in the Quality Standard as a whole or other system wide levers.

Indicators that the COF indicator Breast Cancer Review Group considered appropriate are provided below.

**Other outcome indicators**

BC30  Breast cancer mortality rates.

BC31  Survival rates by cancer stage at diagnosis at one, two and five years.

BC32  Recurrence rates of breast cancer by site and type of primary surgery.

BC33  Rates of specific complications detected, within one year of discharge from hospital, among patients having undergone in-patient treatment for breast cancer.

BC34  Psychosocial/quality of life outcomes

BC35  Breast cancer patient experience

**Assessment against prioritisation criteria**

**Current clinical practice including evidence of variation**

BC30  Across the UK the European age-standardised mortality rate is 27.7 per 100,000. The recent trend in age-standardised breast cancer mortality in the UK has been downward. Reduction in mortality has been greatest in women aged 40-49, with progressively smaller reductions realised in older age groups. There is 10% variation between the regions in the UK with the highest and lowest breast cancer mortality. Mortality from breast cancer follows the same
ITEM 11 – Breast Cancer

socioeconomic gradient as incidence; women in higher socioeconomic groups are more likely to have breast cancer recorded as their cause of death than those in lower socioeconomic groups. Studies using country of birth as a factor have found consistent results that, in UK residents, those born outside the UK have a lower mortality from breast cancer than those born within the UK.

BC31 Estimated 5 year relative survival for women aged 50-69 years diagnosed with breast cancer between 2001 and 2003 was over 80%. Amongst younger women survival is slightly lower. In women aged 70 or over at diagnosis, 5 year survival is 70%. Survival varies by staging at time of diagnosis (from almost 80% for stage I tumours to less than 5% for stage IV tumours for example). There are inequalities in survival for breast cancer, with poorer survival in the lower socioeconomic groups at every stage of the disease. The survival of South Asian women with breast cancer has been found to be better than others in the UK with similar levels of deprivation. Black women have also been found to be younger at diagnosis and to have more aggressive tumour types and poorer survival. Women from higher socioeconomic groups are more likely to attend for breast screening and women with tumours detected by screening have a better prognosis.

BC32 Local recurrence rates are generally considered to be the best indicator of adequate excision with or without radiotherapy. Several observational studies report a linear correlation between margin widths in breast conserving surgery and recurrence, although there is no consensus on the optimum margin size for a reduced local recurrence rate. National data on recurrence rates is not currently collected.

BC33 National data is not currently collected on rates of complications detected within one year of discharge from hospital among patients having undergone in-patient treatment for breast cancer.
There is little national data available on psychosocial or quality of life outcomes for people with breast cancer. The National Mastectomy and Breast Reconstruction Audit reported on the experience of patients undergoing mastectomy, and assessed their satisfaction with not only the treatment and care received, but with their emotional, physical and sexual well being following surgery. The audit concluded that breast reconstruction was effective in improving quality of life for women following mastectomy, and that performance levels are broadly similar across English hospitals.

The National Cancer Experience Survey 2010 measured the satisfaction of cancer patients with the level of care they received. Results indicated that while cancer inpatients were significantly more satisfied with their care in hospital than inpatients generally, worse experiences were recorded overall for cancer patients from ethnic minority groups, older patients, those with long-term conditions and those from the most deprived communities. The report analysed the findings for the ‘big 4’ cancer groups (which includes breast cancer), and found generally more positive views than patients in other cancer groups. Particular attention was drawn to the gap between the ‘big 4’ and other cancer groups in terms of the proportion of patients given the name of a cancer nurse specialist.

**Indicator development issues**

**Feasibility assessment**

[1] Indicators BC30 and BC31 are available from existing data.

[2] Indicators BC32 and BC33 are available from existing data sources given amendments to the collection (e.g. a new data field).

[3] Indicators BC34 and BC35 will require a new collection (or system).
Section 5 Statement from the Chair of the Breast Cancer Review Group

The indicator statements presented in this briefing paper are clinically valid and important from a commissioning perspective. There are definitions that require further clarification and supporting items that can be collected to a greater or lesser extent.

Indicator BC01 is of particular importance for patients who wish to receive a thorough and rapid investigation. Consideration should be given to the fact that this indicator is a strong measure of diagnostic efficiency.

Within the clinical assessment indicators, BC02 and BC05 are particularly vital as they measure use of the latest techniques to ensure that patients do not undergo unnecessary surgery where possible, and also the thoroughness of axillary treatment. Indicator BC08 is a measure of the overall quality of the treatment a patient has received, by assessing recurrence rates. It is an important marker of quality in a service.

BC011 is particularly valuable for patient choice, as it is important that patients are enable to make an informed choice by having all reconstructive options made available to them, and discussed with them. It is recognised that measuring whether a discussion has taken place may pose a challenge, but it could potentially be achieved and supported by patient reported outcome measures.

It should be noted that indicators BC13 and BC14 are to be considered together as linked indicators; they are of equal significance in terms of treatment outcomes, as the information will facilitate better targeted treatment. Equality of treatment options for older patients is an important consideration in the treatment of breast cancer, with evidence of continued variation in treatment modalities by age. Indicators BC19 and BC20 are important in terms of outcomes for older people. Indicator BC27 can make a difference to outcomes for people with recurrent disease.
Indicators BC24, BC25 and BC26 have the potential to improve outcomes for patients by ensuring follow-up imaging is undertaken with sufficient regularity to enable identification of any recurrence quickly, which can be critical in terms of survival.

J Winstanley
Section 6 Indicators identified from other sources

The following indicator statements have been identified from other sources.

- Cancers diagnosed by emergency routes [Indicator number 1.9]
- Cancers stage at diagnosis [Indicator number 1.10]
- Cancers detected at stage 1 or 2 [Indicator number 1.11]
- Patient Reported Outcome Measures (PROMs) Cancer [Indicator 2.18]
- Patient experience of cancer services [Indicator 4.11]
Section 7 Candidate indicators

The below tables present those indicator statements that are considered to fall into the following three categories:

1) No significant feasibility issues have been identified *at this stage* in the process to preclude recommendation for indicator development

2) Indicators can be developed that could be measured through available information systems provided that new data fields are added to existing systems

3) Indicators can be developed, but these will require new data collections for the indicator to be produced in a meaningful manner

**Table 1 No significant feasibility issues have been identified at this stage in the process to preclude recommendation for indicator development**

<table>
<thead>
<tr>
<th>Area of care</th>
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<tbody>
<tr>
<td></td>
<td>BC30</td>
<td>Breast cancer mortality rates.</td>
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**Table 2 Indicators can be developed that could be measured through available information systems provided that new data fields are added to existing systems**

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<tbody>
<tr>
<td>Follow up imaging</td>
<td>BC24</td>
<td>Of women treated for early breast cancer and 45 or older at the time the post-treatment surveillance started, the proportion who have had 5 years of annual mammography before entering the NHS Breast Screening Programme.</td>
</tr>
<tr>
<td>Follow up imaging</td>
<td>BC25</td>
<td>Of women treated for early breast cancer and younger than 45 when post-treatment surveillance started, the proportion who have had annual mammography until they entered the NHS Breast Screening Programme at the age of 50.</td>
</tr>
<tr>
<td>Follow up imaging</td>
<td>BC26</td>
<td>Of women treated for early breast cancer who are within 5 years of finishing their treatment, the proportion who have had a mammography within the previous year.</td>
</tr>
<tr>
<td></td>
<td>BC32</td>
<td>Recurrence rates of breast cancer by site and type of primary surgery.</td>
</tr>
<tr>
<td></td>
<td>BC33</td>
<td>Rates of specific complications detected, within one year of discharge from hospital, among patients having undergone in-patient treatment for breast cancer.</td>
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## Table 3

Indicators can be developed, but these will require new data collections for the indicator to be produced in a meaningful manner.

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<tr>
<td>Referral</td>
<td>BC01</td>
<td>Of people with newly diagnosed breast cancer, the proportion who had been previously seen with symptoms suggestive of breast cancer and discharged undiagnosed within one year of initial presentation.</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>BC02</td>
<td>Of people with early invasive breast cancer, the proportion who receive a pre-treatment ultrasound evaluation of the axilla.</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>BC03</td>
<td>Of node positive patients, the proportion identified by pre-operative ultrasound-guided needle biopsy.</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>BC04</td>
<td>Of people with early invasive breast cancer and no pre-treatment ultrasound evidence of lymph node involvement, the proportion who receive sentinel lymph node biopsy.</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>BC05</td>
<td>Of people with early invasive breast cancer who receive axillary surgery, the proportion who undergo further definitive treatment of the axilla within 6 months of the last operation on the axilla.</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>BC06</td>
<td>Ratio of mastectomy to breast conserving surgery.</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>BC07</td>
<td>Of people with early breast cancer who receive breast conserving surgery, the proportion who undergo re-surgery within 6 months of the last operation.</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>BC08</td>
<td>Of people who have had breast conserving surgery, the proportion who have had ipsilateral breast cancer occurrences.</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>BC09</td>
<td>Patient satisfaction with outcome of breast surgery.</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>BC10</td>
<td>Of people with early breast cancer having mastectomy, the proportion who have an immediate or planned delayed breast reconstruction.</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>BC11</td>
<td>Of people with early breast cancer who are to undergo mastectomy, the proportion who have the options of immediate or planned delayed breast reconstruction discussed with them.</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>BC12</td>
<td>Patient satisfaction with discussion about breast surgery options.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC13</td>
<td>Of people with newly diagnosed invasive breast cancer, the proportion who have the ER status of the tumour assessed.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC14</td>
<td>Of people with newly diagnosed invasive breast cancer, the proportion who have the HER2 status of the tumour assessed.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC15</td>
<td>Of people with histologically confirmed recurrent breast cancer and deemed eligible for further testing, the proportion who have the ER status of the tumour assessed.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC16</td>
<td>Of people with histologically confirmed recurrent breast cancer and deemed eligible for further testing, the proportion who have the HER2 status of the tumour assessed.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC17</td>
<td>Of people with newly diagnosed invasive breast cancer or recurrent disease, the proportion who have HER2 status results available within 2 weeks.</td>
</tr>
<tr>
<td>Pathology – ER and HER2</td>
<td>BC18</td>
<td>Of people with newly diagnosed invasive breast cancer or recurrent disease, the proportion who have HER2 status results available within 2 weeks.</td>
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<td>Management</td>
<td>BC19</td>
<td>Of people older than 70 with early invasive breast cancer, the proportion who receive appropriate therapy.</td>
</tr>
<tr>
<td>Management</td>
<td>BC20</td>
<td>Of people aged 70 and under with early invasive breast cancer, the proportion who receive appropriate therapy.</td>
</tr>
<tr>
<td>Staging</td>
<td>BC21</td>
<td>Of people with early invasive breast cancer, the proportion who undergo staging investigation for distant metastatic disease in the absence of symptoms suggestive of distant metastatic disease.</td>
</tr>
<tr>
<td>Adjuvant therapy planning</td>
<td>BC22</td>
<td>Of people with early invasive breast cancer, the proportion who are involved in decisions about adjuvant therapy after surgery, which are based on an assessment of the prognostic and predictive factors, and the potential benefits and side effects.</td>
</tr>
<tr>
<td>Clinical follow up</td>
<td>BC23</td>
<td>Of people having treatment for early breast cancer, the proportion who receive personalised information and support, including treatment options, a written follow-up care plan and details of how to contact a named healthcare professional following the completion of initial surgical treatment.</td>
</tr>
<tr>
<td>Multidisciplinary team</td>
<td>BC27</td>
<td>Of people who develop local recurrence, regional recurrence and/or distant metastatic disease, the proportion who are discussed by the multidisciplinary team.</td>
</tr>
<tr>
<td>Key worker</td>
<td>BC28</td>
<td>Of people with newly diagnosed, recurrent or advanced breast cancer, the proportion who have a key worker who is a clinical nurse specialist.</td>
</tr>
<tr>
<td>Brain metastases</td>
<td>BC29</td>
<td>Of people who have a single or small number of potentially resectable brain metastases, a good performance status and who have no or minimal other sites of metastatic disease, the proportion who are referred to a neuroscience brain and other rare CNS tumours multidisciplinary team.</td>
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