# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Health and social care directorate Quality standards and indicators Briefing paper

Quality standard topic: Breast cancer

Output: Prioritised quality improvement areas for development.

Date of Quality Standards Advisory Committee meeting: 12 November 2015

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#### 1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for breast cancer. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

#### 1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

# 1.2 Development source

The key development sources referenced in this briefing paper are:

<u>Familial breast cancer</u> (2013) NICE guideline CG164

<u>Advanced breast cancer</u> (2009) NICE guideline CG81

<u>Early and locally advanced breast cancer</u> (2009) NICE guideline CG80

A review decision is expected December 2015 as to whether any of these guidelines require updating.

#### 2 Overview

# 2.1 Focus of quality standard

This quality standard will cover the management of early (ductal carcinoma in situ and invasive), locally advanced and advanced breast cancer, recurrent breast cancer and familial 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. It will not cover adults with non- cancerous breast tumours.

It will update and replace the existing quality standard for breast cancer which will be withdrawn.

#### 2.2 Definition

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.

Familial breast cancer typically occurs in people with an unusually high number of family members affected by breast, ovarian or a related cancer. If more cases of breast, ovarian or a related cancer are seen in a family than would be expected by chance alone, this can be a sign that genes have caused or contributed to its development. Breast cancer in people who have a family history of breast, ovarian or a related cancer may need different management from that in people without a family history of these cancers. This is because of differences in the future risk of developing contralateral breast cancer. The risk of developing breast cancer depends on the nature of the family history, number of relatives who have developed breast, ovarian or a related cancer, age at which relatives developed breast cancer and age of the person.

#### 2.3 Incidence and prevalence

Breast cancer is the most common cancer for women in England and Wales, with about 40,500 new cases diagnosed and 10,900 deaths 1,2 recorded in England and Wales each year. In men breast cancer is rare, with about 260 cases diagnosed and 68 deaths in England and Wales each year 12. Of these new cases in women and men, 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.

## 2.4 Management

People with suspected breast cancer should be assessed by primary care; urgent care or have a routine referral to an assessment clinic. An assessment of the breast is undertaken during a consultation and clinical examination with mammography and/or ultrasound or core biopsy/fine needle aspiration cytology performed and the diagnostic test results discussed at an MDT meeting. The patient then has their results discussed and treatment options explained at an outpatient clinic or undergoes further investigations if results are inconclusive.

All patients with breast cancer should also be assigned to a named breast care nurse specialist who will support them throughout diagnosis, treatment and follow-up and be offered prompt access to specialist psychological support and, where appropriate, psychiatric services.

<sup>&</sup>lt;sup>1</sup> Office for National Statistics, Cancer statistics registrations: registrations of cancer diagnosed in 2005

<sup>&</sup>lt;sup>2</sup> Welsh Cancer Intelligence and Surveillance Unit (2008) Cancer incidence in Wales. Cardiff: Welsh Cancer Intelligence and Surveillance Unit

Surgery may not be appropriate for all patients, and for some patients primary systemic therapy precedes surgery. Some patients may have breast conserving surgery whilst others may be advised to have mastectomy. For those advised to have mastectomy immediate breast reconstruction should be discussed, except where comorbidities or adjuvant therapy may preclude this option. Breast reconstruction options should be offered and discuss with all patients irrespective of whether they are all available locally.

Whole lymph node analysis is recommended as an option for detecting sentinel lymph node metastases during breast surgery in people with early invasive breast cancer who have a sentinel lymph node biopsy and in whom axillary lymph node dissection will be considered. Complications of local treatments e.g. Lymphoedema and reduced arm mobility and menopausal symptoms should be discussed with information and counselling offered where appropriate.

After surgery, the MDT will consider adjuvant therapy and record their decision. Decisions about adjuvant therapy will be based on assessment of prognostic and predictive factors and potential benefits and side effects of the treatment. Decisions will be made following discussion of these factors with the patient.

After adjuvant treatment (including chemotherapy and/or radiotherapy, where indicated) is completed, patients should have a discussion where they agree where they would like follow-up care to be undertaken. They may choose primary, secondary or shared 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. There is some evidence of practice variation across the country and of inconsistent availability of certain treatments and procedures.

#### 2.5 National Outcome Frameworks

Tables 1–2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

# Table 1 NHS Outcomes Framework 2015–16

| Domain                   | Overarching indicators and improvement areas                               |
|--------------------------|--|
| 1 Preventing people from | Improvement areas  |
| dying prematurely        | Reducing premature mortality from the major causes of death                |
|                          | 1.4 Under 75 mortality rate from cancer*                                   |
|                          | i One- and ii Five-year survival from all cancers                          |
|                          | iii One- and iv Five-year survival from breast, lung and colorectal cancer |
|                          | v One- and vi Five-year survival from cancers diagnosed at stage 1 & 2**   |
|                          |  |

# Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework

- \* Indicator is shared
- \*\* Indicator is complementary

Indicators in italics in development

#### Table 2 Public health outcomes framework for England, 2013–2016

| Domain  | Objectives and indicators  |
|---|--|
| 4 Healthcare public health and preventing premature mortality | Objective Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities Indicators 4.5 Under 75 mortality rate from cancer* |
| Alignment with Adult Social C<br>Framework                    | Care Outcomes Framework and/or NHS Outcomes  |

# 3 Summary of suggestions

# 3.1 Responses

In total 14 stakeholders responded to the 2-week engagement exercise 18 September 2015 – 02 October 2015.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

Full details of all the suggestions provided are given in appendix 4 for information.

Table 3 Summary of suggested quality improvement areas

| Suggested area for improvement   | Stakeholders   |
|--|--|
| Diagnosis and pathology  Timely diagnosis  MRI in breast cancer assessment  Genetic testing  | BSBR, RCP, BCN<br>GSTFT &KHPCGS,<br>SCM, SDFT                        |
| Pathology and staging  • ER and HER2 status  • Staging   | BCN, NBT, SCM  |
| <ul><li>Management</li><li>MDT care</li><li>Key worker</li></ul>   | SCMx2, BCC<br>BCN, BCC, SCM<br>SCM. BCN, BCC, NHSE<br>, SCM, BASO    |
| Communication and support  • Provision of information and follow up care   | SCMX2, BCC   |
| <ul> <li>Treatment</li> <li>Surgery</li> <li>Complications of surgery – lymphedema</li> <li>Chemoprevention</li> <li>Adjuvant therapy</li> </ul>               | SCM, SCR, SCM,<br>BCN,BCN, SCM<br>SCR<br>BSBR, BCC, SCM<br>BCN,SCMx2 |
| Metastasis     Timely provision of care     Treatment for metastatic breast cancer   | BASO   |
| Other areas  Data reporting Effect of treatment on fertility New therapies Indications for deep inspirational breath hold Management of internal mammary chain | RCP,SCMx2,BCC,ABS<br>ABS,SCR<br>BCN, SCM                             |

ABS, Association of Breast Surgery

BCC, Breast Cancer Care

BCN, Breast Cancer NOW

BASO, British Association of Surgical Oncology

BSBR, British Society of Breast Radiologists

Genomic Health UK

GSTFT &KHPCGS, Guys & St Thomas NHS Foundation Trust & King's Health Partners Cancer Genetics Service

NHSE,NHS England

NBT, North Bristol NHS Trust

RCN, Royal College of Nursing

RCP, Royal College of Pathologists

SDFT, South Devon NHS Foundation Trust

SCR, The Society and College of Radiographers

# 3.2 Identification of current practice evidence

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 18 studies were identified for breast cancer. In addition, current practice examples were suggested by stakeholders at topic engagement (10 studies).

Of these studies, 8 were assessed as having potential relevance to this topic and the suggested areas for quality improvement identified by stakeholders. A summary of relevant studies is included in the current practice sections for each suggested area of improvement.

# 4 Suggested improvement areas

#### 4.1 Diagnosis

#### 4.1.1 Summary of suggestions

#### **Timely diagnosis**

Stakeholders highlighted the need to ensure trusts meet the new cancer target of diagnosis within 28 days. It was suggested that if women receive a biopsy and imaging on the same day this will help improve patient experience. It was suggested that this is currently not happening across all cancer units.

#### Use of MRI in breast cancer assessment

Stakeholders suggested the overuse of MRI scanning in pre-operative settings has led to increased delays to treatment as well as unnecessary biopsies being carried out. Stakeholders also suggested this has led to increased mastectomy rates.

#### **Genetic testing**

Stakeholders highlighted rapid genetic testing for high risk cancer predisposition in women with cancer (for those who meet the testing criteria) is important to inform breast cancer treatment and offer concurrent risk reduction within the diagnostic pathway. It was commented by stakeholders that an ability to provide and discuss this option is a fundamental aspect of enabling informed decision making and patient choice.

#### 4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

| Suggested quality improvement area     | Suggested source guidance recommendations       |
|--|---|
| Timely diagnosis                       | Referral, diagnosis and preoperative assessment |
|  | NICE CG80 Recommendation 1.1.3 (KPI)            |
| Use of MRI in breast cancer assessment | Referral, diagnosis and preoperative assessment |
|  | NICE CG80 Recommendation 1.1.2 (KPI)            |
|  | Diagnosis and assessment                        |
|  | NICE CG81 Recommendation 1.1.1, 1.1.2 and 1.1.4 |

| Genetic testing | Referral to a specialist genetic clinic |
|-----------------|---|
|                 | NICE CG164 Recommendation 1.4.4 (KPI)   |

#### **Timely diagnosis**

#### NICE CG80 – Recommendation 1.1.3 (key priority for implementation)

Pretreatment ultrasound evaluation of the axilla should be performed for all patients being investigated for early invasive breast cancer and, if morphologically abnormal lymph nodes are identified, ultrasound-guided needle sampling should be offered.

#### Use of MRI in breast cancer assessment

#### NICE CG80 – Recommendation 1.1.2 (key priority for implementation)

Offer MRI of the breast to patients with invasive breast cancer:

- if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment
- if breast density precludes accurate mammographic assessment
- to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer.

#### NICE CG81 – Recommendation 1.1.1

Assess the presence and extent of visceral metastases using a combination of plain radiography, ultrasound, computed tomography (CT) scans and magnetic resonance imaging (MRI).

#### NICE CG81 – Recommendation 1.1.2

Assess the presence and extent of metastases in the bones of the axial skeleton using bone windows on a CT scan or MRI or bone scintigraphy.

#### NICE CG81 – Recommendation 1.1.4

Use MRI to assess bony metastases if other imaging is equivocal for metastatic disease or if more information is needed (for example, if there are lytic metastases encroaching on the spinal canal)

#### **Genetic testing**

#### NICE CG164 – Recommendation 1.4.4

People who meet the following referral criteria should be offered a referral to a specialist genetic clinic.

- At least the following female breast cancers only in the family:
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 50 years (at least one must be a first-degree relative) or
  - three first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years (at least one must be a first-degree relative) or
  - four relatives diagnosed with breast cancer at any age (at least one must be a first-degree relative). or
- Families containing one relative with ovarian cancer at any age and, on the same side of the family:
  - one first-degree relative (including the relative with ovarian cancer) or seconddegree relative diagnosed with breast cancer at younger than age 50 years or
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years or
  - o another ovarian cancer at any age. or
- Families affected by bilateral cancer (each breast cancer has the same count value as one relative):
  - one first-degree relative with cancer diagnosed in both breasts at younger than an average age 50 years or
  - one first-degree or second-degree relative diagnosed with bilateral cancer and one first or second degree relative diagnosed with breast cancer at younger than an average age of 60 years. or
- Families containing male breast cancer at any age and, on the same side of the family, at least:
  - one first-degree or second-degree relative diagnosed with breast cancer at younger than age 50 years [2004] or
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years. [2004] or
- A formal risk assessment has given risk estimates of:
  - o a 10% or greater chance of a gene mutation being harboured in the family (see recommendations 1.5.8–1.5.13) or

- o a greater than 8% risk of developing breast cancer in the next 10 years or
- o a 30% or greater lifetime risk of developing breast cancer.

#### 4.1.3 Current UK practice

#### **Timely diagnosis**

The national statistics on waiting times for suspected and diagnosed cancer patients<sup>3</sup> published by NHS England show achievement against the 2 week wait target (between breast symptoms being identified and a referral being made) was 90.3% in quarter 1 of 2014/15 and 93.5% in quarter 2 of the same year.

A National Audit Office report<sup>4</sup> found that between April and June 2014, the NHS did not achieve the 2-week waiting time standard that 93% of patients should be seen by a specialist when referred urgently with breast symptoms, where cancer was not initially suspected. This was the first time the standard was not achieved since early 2010.

#### MRI in breast cancer assessment

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### **Genetic testing**

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

<sup>&</sup>lt;sup>3</sup> NHS England, Provider-based-cancer-waiting-times-for-q4-2014-15,

<sup>&</sup>lt;sup>4</sup> National Audit Office, Progress in moving cancer services and outcomes in England,

#### 4.2 Pathology and staging

#### 4.2.1 Summary of suggestions

#### **ER and HER2 status**

Stakeholders highlighted the importance of assessing the hormone receptor status (ER and HER2) in people with newly diagnosed invasive breast cancer and those with recurrent disease (if clinically appropriate) within 2 weeks of diagnosis for the planning of systemic treatment. Stakeholders also referred to evidence showing that when breast cancer reoccurs, the subtype can change from what it was in the primary site, and a second biopsy is needed to determine the most appropriate course of treatment. Stakeholders added that this has not become standard of care and practice varies around the UK.

#### **Staging**

Stakeholders highlighted the importance of staging the axilla commenting that pretreatment ultrasound evaluation of the axilla and sentinel lymph node biopsy should be performed to stage the axilla. This is covered in the current breast cancer quality standard. Stakeholders stated this is important as it enables patients with significant axillary nodal malignancy to have appropriate axillary staging at initial surgery.

#### 4.2.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

| Suggested quality improvement area | Suggested source guidance recommendations              |
|------------------------------------|--|
| ER and HER2 status                 | Postoperative assessment and adjuvant therapy planning |
|                                    | NICE CG80 Recommendation 1.6.3 to 1.6.4                |
|                                    | Diagnosis and assessment                               |
|                                    | NICE CG81 Recommendation 1.1.6 to 1.1.8 (KPI)          |
| Staging                            | Surgery to axilla NICE CG80 Recommendation 1.4.7       |

#### **ER and HER2 status**

#### NICE CG80 - Recommendation 1.6.3

Test human epidermal growth receptor 2 (HER2) status of all invasive breast cancers, using a standardised and qualitatively assured methodology.

#### NICE CG80 – Recommendation 1.6.4

Ensure that the results of ER and HER2 assessments are available and recorded at the multidisciplinary team meeting when guidance about systemic treatment is made.

#### NICE CG81 – Recommendation 1.1.6

Patients with tumours of known oestrogen receptor (ER) status whose disease recurs should not have a further biopsy just to reassess ER status

#### NICE CG81 – Recommendation 1.1.7

Patients with tumours of known human epidermal growth factor receptor 2 (HER2) status whose disease recurs should not have a further biopsy just to reassess HER2 status

#### NICE CG81 – Recommendation 1.1.8 (key priority for implementation)

Assess ER and HER2 status at the time of disease recurrence if receptor status was not assessed at the time of initial diagnosis. In the absence of tumour tissue from the primary tumour, and if feasible, obtain a biopsy of a metastasis to assess ER and HER2 status

#### Staging

#### NICE CG80 Recommendation 1.4.7

Offer further axillary treatment to patients with early invasive breast cancer who:

- have macrometastases or micrometastases shown in a sentinel lymph node
- have a preoperative ultrasound-guided needle biopsy with histologically proven metastatic cancer.

The preferred technique is axillary lymph node dissection (ALND) because it gives additional staging information.

# 4.2.3 Current UK practice

#### **ER and HER2 status**

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### **Staging**

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### 4.3 Management

#### 4.3.1 Summary of suggestions

#### **MDT** care

Stakeholders highlighted multidisciplinary team (MDT) working is widely recognised as best practice in the care of cancer patients, helping to ensure that each patient receives consistent information and co-ordinated treatment from all those involved in their care. Stakeholders also commented all breast cancer patients irrespective of route to diagnosis should be managed by an MDT.

#### **Key worker**

Stakeholders highlighted every patient with acute and advanced breast cancer should have a key worker namely a Clinical Nurse Specialist to support and communicate throughout the journey. This support should be extended to the wider family.

#### 4.3.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 5 Specific areas for quality improvement

| Suggested quality improvement area | Selected source guidance recommendations                        |
|------------------------------------|---|
| MDT care                           | Managing complications  |
|                                    | NICE CG81 Recommendation 1.5.11 (KPI)                           |
|                                    | Care of people in secondary care and specialist genetic clinics |
|                                    | NICE CG164 Recommendation 1.4.1                                 |
|                                    | Genetic testing   |
|                                    | NICE CG164 Recommendation 1.5.16                                |
| Key worker                         | Providing information and psychological support                 |
|                                    | NICE CG80 Recommendation 1.2.2                                  |
|                                    | Supportive care   |
|                                    | NICE CG81 Recommendation 1.4.1 (KPI)                            |

#### MDT care

NICE CG81 – Recommendation 1.5.11 (key priority for implementation)

A breast cancer multidisciplinary team should assess all patients presenting with uncontrolled local disease and discuss the therapeutic options for controlling the disease and relieving symptoms.

#### NICE CG164 – Recommendation 1.4.1

Care of people in secondary care (such as a breast care team, family history clinic or breast clinic) should be undertaken by a multidisciplinary team. It should include the following:

- written protocols for management
- central, standardised resources
- mammographic surveillance available to standard of the national breast screening programmes
- access to surveillance
- access to a team offering risk-reducing surgery
- standardised written information
- designated/lead clinicians
- a designated contact for primary care
- a designated contact in a specialist genetic clinic
- audit
- clinical trials access
- access to psychological assessment and counselling
- information about support groups and voluntary organisations
- administrative support.

#### NICE CG164 - Recommendation 1.5.16

Discuss the individual needs of the person with the specialist genetics team as part of the multidisciplinary approach to care.

#### **Key Worker**

#### NICE CG80 - Recommendation 1.2.2

All patients with breast cancer should be assigned to a named breast care nurse specialist who will support them throughout diagnosis, treatment and follow-up.

#### NICE CG81 – Recommendation 1.4.1 (key priority for implementation)

Healthcare professionals involved in the care of patients with advanced breast cancer should ensure that the organisation and provision of supportive care services comply with the recommendations made in Improving outcomes in breast cancer: manual update (NICE cancer service guidance [2002]) and Improving supportive and palliative care for adults with cancer (NICE cancer service guidance [2004]), in particular the following two recommendations:

- 'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'
- 'Mechanisms should be developed to promote continuity of care, which might include the nomination of a person to take on the role of "key worker" for individual patients

#### 4.3.3 Current UK practice

#### **MDT** care

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### **Key worker**

The recurrent and metastatic breast cancer data collection project<sup>5</sup> conducted a pilot study that looked at the quality of care received by people with breast cancer. The report published in March 2012 by the National Cancer Intelligence Network (NCIN) found just over half (53%) of women were offered any form of supportive care from a clinical nurse specialist, palliative care professional or other key worker.

<sup>&</sup>lt;sup>5</sup> <u>National Cancer Intelligence Network (NCIN) Recurrent and Metastatic Breast Cancer Data Collection Project Pilot report,</u>

#### 4.4 Communication and support

#### 4.4.1 Summary of suggestions

#### Provision of information and follow up care

Stakeholders highlighted the need for breast cancer patients to receive information and support throughout their care regardless of the diagnosis route. It was highlighted that this should be a continuous process as patient needs changes through the different stages of treatment. Stakeholders also commented patients with early breast cancer should receive structured information at the completion of primary treatments which should include advice on diet and lifestyle and routine follow-up is not necessary unless dictated by clinical trial participation. Stakeholders also highlighted a number of areas where follow up care would be required by people with breast cancer. Some stakeholders highlighted the importance of psychological support for people with breast cancer. Depression was specifically highlighted as being prevalent with people diagnosed with breast cancer. Some stakeholders also suggested mammographic follow up following breast cancer surgery should be extended to 10 years.

#### 4.4.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 5 Specific areas for quality improvement

| Suggested quality improvement area          | Selected source guidance recommendations                        |
|---|---|
| Provision of information and follow up care | Care of people in secondary care and specialist genetic clinics |
|   | NICE CG164 Recommendation 1.4.1                                 |
|   | Follow-up   |
|   | NICE CG81 Recommendation 1.14.1 (KPI), 1.14.5 and 1.14.6 (KPI)  |
|   | Supportive care   |
|   | NICE CG81 Recommendation 1.4.1 (KPI)                            |
|   | Information and support   |
|   | NICE CG164 Recommendation 1.2.1 (KPI)                           |
|   | Care of people in secondary care and specialist genetic clinics |
|   | NICE CG164 Recommendation 1.4.1                                 |

#### Provision of information and follow up care

#### NICE CG80 Recommendation 1.14.1 (key performance indicator)

Offer annual mammography to all patients with early breast cancer, including DCIS, until they enter the NHSBSP/BTWSP. Patients diagnosed with early breast cancer who are already eligible for screening should have annual mammography for 5 years.

#### NICE CG80 Recommendation 1.14.5

After completion of adjuvant treatment (including chemotherapy, and/or radiotherapy where indicated) for early breast cancer, discuss with patients where they would like follow-up to be undertaken. They may choose to receive follow-up care in primary, secondary, or shared care.

#### NICE CG80 Recommendation 1.14.6 (key performance indicator)

Patients treated for breast cancer should have an agreed, written care plan, which should be recorded by a named healthcare professional (or professionals), a copy sent to the GP and a personal copy given to the patient. This plan should include:

- designated named healthcare professionals
- dates for review of any adjuvant therapy
- details of surveillance mammography
- signs and symptoms to look for and seek advice on
- contact details for immediate referral to specialist care, and
- contact details for support services, for example support for patients with lymphoedema.

#### NICE CG81 Recommendation 1.4.1

Healthcare professionals involved in the care of patients with advanced breast cancer should ensure that the organisation and provision of supportive care services comply with the recommendations made in Improving outcomes in breast cancer: manual update and Improving supportive and palliative care for adults with cancer, in particular the following two recommendations:

 'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'

 'Mechanisms should be developed to promote continuity of care, which might include the nomination of a person to take on the role of "key worker" for individual patients.

#### NICE CG164 – Recommendation 1.2.2 (Key performance indicator)

To ensure a patient–professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organisations). [2004]

#### NICE CG164 – Recommendation 1.4.1

Care of people in secondary care (such as a breast care team, family history clinic or breast clinic) should be undertaken by a multidisciplinary team. It should include the following:

- written protocols for management
- central, standardised resources
- mammographic surveillance available to standard of the national breast screening programmes
- access to surveillance
- access to a team offering risk-reducing surgery
- standardised written information
- designated/lead clinicians
- a designated contact for primary care
- a designated contact in a specialist genetic clinic
- audit
- clinical trials access
- access to psychological assessment and counselling
- information about support groups and voluntary organisations
- administrative support.

#### 4.4.3 Current UK practice

#### **Provision of information**

The recurrent and metastatic breast cancer data collection project report<sup>6</sup> published in March 2012 by the National Cancer Intelligence Network (NCIN) reports levels of patient satisfaction among people with breast cancer were highest around levels of information received on the surgical procedure: how it was performed, recovery time, and possible complications. Around one-half of women were very satisfied with the information they received on what their scars would look like and what postoperative pain to expect.

#### Follow up care

The recurrent and metastatic breast cancer data collection project report<sup>7</sup> published in March 2012 by the National Cancer Intelligence Network (NCIN) reports that 53% of patients in the pilot were recorded as being offered any form of supportive care from a CNS, palliative care professional or other key worker. Although it is possible that some patients already had ongoing supportive care or were referred without it being recorded, this finding is consistent with research showing that patients with a diagnosis of metastatic breast cancer receive less supportive care compared to when they had their primary breast cancer diagnosis. Such support may not be available from their previous breast nurse; a survey of 276 breast cancer nurses reported that 57% felt unable to adequately care for patients with metastatic breast cancer due to not having the time or the necessary skills.

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<sup>&</sup>lt;sup>6</sup> <u>National Cancer Intelligence Network (NCIN) Recurrent and Metastatic Breast Cancer Data</u> <u>Collection Project Pilot report,</u>

<sup>&</sup>lt;sup>7</sup> National Cancer Intelligence Network (NCIN) Recurrent and Metastatic Breast Cancer Data Collection Project Pilot report,

#### 4.5 Treatment

#### 4.5.1 Summary of suggestions

#### Surgery

Stakeholders highlighted specific aspects of breast cancer surgery as key improvements areas. The specific areas identified were:

- Techniques for excision margins and sentinel node biopsies,
- Completion of axillary clearance,
- Alternative approaches to surgery for multifocal disease

#### **Complications of surgery**

Stakeholders highlighted people who have undergone surgery for breast cancer can experience complications that can impact on quality of life and be debilitating. Lymphoedema was a complication specifically mentioned that can occur following breast and/or axilliary surgery. Stakeholders commented on the variation in availability of specialty services required to treat these complications.

#### Chemoprevention

Stakeholders highlighted the benefits of chemoprevention e.g. Tamoxifen for people with an increased risk of breast cancer including familial breast cancer. Stakeholders suggested chemoprevention should therefore be offered to all women with an increased risk of breast cancer but highlight this does not always happen.

#### Adjuvant therapy

Stakeholders highlighted the benefits of adjuvant therapy to some people with breast cancer. Stakeholders specifically suggested a statement around offering adjuvant bisphosphonate therapy to reduce the risk of bone metastases and breast cancer mortality to post-menopausal women with early breast cancer. Recommending adjuvant anti HER-2 therapies was also suggested for people with HER-2 positive cancers larger than 1 cm.

#### 4.5.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

Table 6 Specific areas for quality improvement

| Suggested quality improvement area | Selected source guidance recommendations                            |
|------------------------------------|---|
| Surgery                            | Surgery to breast   |
|                                    | NICE CG80 Recommendation 1.3.1 and 1.3.4                            |
|                                    | Surgery to axilla   |
|                                    | NICE CG80 Recommendation 1.4.1 (KPI)                                |
|                                    | Breast reconstruction   |
|                                    | NICE CG80 Recommendation 1.5.1(KPI)                                 |
| Complications of surgery           | Complications of local treatment and menopausal symptoms            |
|                                    | NICE CG80 Recommendation 1.13.1 to 1.13.3                           |
|                                    | Lymphoedema   |
|                                    | NICE CG81 Recommendation 1.5.7                                      |
| Chemoprevention                    | Endocrine therapy   |
|                                    | NICE CG80 Recommendation 1.7.2                                      |
|                                    | Chemoprevention for women with no personal history of breast cancer |
|                                    | NICE CG164 Recommendation 1.7.21 to 1.7.23                          |
| Adjuvant therapy                   | Postoperative assessment and adjuvant therapy planning              |
|                                    | NICE CG80 Recommendation 1.6.5 to 1.6.8 (KPI)                       |
|                                    | Endocrine therapy   |
|                                    | NICE CG80 Recommendation 1.7.2 and 1.7.6                            |

#### Surgery

#### NICE CG80 Recommendation 1.3.1

For all patients treated with breast conserving surgery for DCIS a minimum of 2 mm radial margin of excision is recommended with pathological examination to NHSBSP reporting standards. Re-excision should be considered if the margin is less than 2 mm, after discussion of the risks and benefits with the patient.

#### NICE CG80 Recommendation 1.3.4

Offer breast conserving surgery with removal of the nipple-areolar complex as an alternative to mastectomy for patients with Paget's disease of the nipple that has been assessed as localised. Offer oncoplastic repair techniques to maximise cosmesis.

#### NICE CG80 Recommendation 1.4.1 (Key performance indicator)

Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique.

#### NICE CG80 Recommendation 1.5.1(Key performance indicator)

Discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.

#### **Complications of surgery**

#### NICE CG80 Recommendation 1.13.1

Inform all patients with early breast cancer about the risk of developing lymphoedema and give them relevant written information before treatment with surgery and radiotherapy.

#### NICE CG80 Recommendation 1.13.2

Give advice on how to prevent infection or trauma that may cause or exacerbate lymphoedema to patients treated for early breast cancer.

#### NICE CG80 Recommendation 1.13.3

Ensure that all patients with early breast cancer who develop lymphoedema have rapid access to a specialist lymphoedema service.

#### NICE CG81 Recommendation 1.5.7

Provide patients with lymphoedema with clear, written information and the contact details of local and national lymphoedema support groups

#### Chemoprevention

#### NICE CG80 Recommendation 1.7.2

Offer adjuvant ovarian ablation/suppression in addition to tamoxifen to premenopausal women with ER-positive early invasive breast cancer who have been offered chemotherapy but have chosen not to have it.

#### NICE CG164 Recommendation 1.7.21

Offer tamoxifen for 5 years to premenopausal women at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.

#### NICE CG164 Recommendation 1.7.22

Offer tamoxifen for 5 years to postmenopausal women without a uterus and at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or they have a past history of endometrial cancer.

#### NICE CG164 Recommendation 1.7.23

Offer either tamoxifen or raloxifene for 5 years to postmenopausal women with a uterus and at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.

#### Adjuvant therapy

#### NICE CG80 Recommendation 1.6.5

Consider adjuvant therapy for all patients with early invasive breast cancer after surgery at the multidisciplinary team meeting and ensure that decisions are recorded.

#### NICE CG80 Recommendation 1.6.6

Decisions about adjuvant therapy should be made based on assessment of the prognostic and predictive factors, the potential benefits and side effects of the treatment. Decisions should be made following discussion of these factors with the patient.

#### NICE CG80 Recommendation 1.6.7

Consider using Adjuvant! Online to support estimations of individual prognosis and the absolute benefit of adjuvant treatment for patients with early invasive breast cancer.

#### NICE CG80 Recommendation 1.6.8 (Key performance indicator)

Start adjuvant chemotherapy or radiotherapy as soon as clinically possible within 31 days of completion of surgery in patients with early breast cancer having these treatments.

#### NICE CG80 Recommendation 1.7.2

Offer adjuvant ovarian ablation/suppression in addition to tamoxifen to premenopausal women with ER-positive early invasive breast cancer who have been offered chemotherapy but have chosen not to have it.

#### NICE CG80 Recommendation 1.7.6

The aromatase inhibitors anastrozole, exemestane and letrozole, within their licensed indications, are recommended as options for the adjuvant treatment of early ER-positive invasive breast cancer in postmenopausal women.

#### 4.3.3 Current UK practice

#### Surgery

The national breast screening audit<sup>8</sup> highlights the following findings around breast cancer surgery:

- In 2013/14, 75% (3041) of non-invasive cancers were treated with breast conserving surgery and 69 apparently received no surgery: 105 potentially large, high cytonuclear grade non-invasive cancers were treated with breast conserving surgery.
- In 2013/14, 78% of invasive breast cancers had breast conserving surgery. Two hundred and ninety eight invasive cancers (2%) had no surgery recorded within the audit period: of these 58% had neo-adjuvant therapy recorded. Since 2005/06, the mastectomy rate for small (<15mm) invasive cancers has decreased to an all time low of 13% in 2013/14. Only 7% of cancers with whole tumour size <15mm were treated with mastectomy compared to 83% of small invasive (<15mm diameter) cancers with whole tumour diameter >50mm. These data indicate that the presence of non-invasive disease which extends beyond the invasive lesion accounts for a proportion of the mastectomies performed on small invasive cancers.
- Of the cancers treated with mastectomy in 2013/14, 30% were recorded as having immediate reconstruction.

#### Complications of surgery - lymphoedema

A Cancer Research UK<sup>9</sup> reports currently about 1 in 5 people (20%) will have lymphoedema of the arm after breast cancer treatment that includes surgery to remove lymph nodes or radiotherapy to the lymph nodes in the armpit.

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<sup>&</sup>lt;sup>8</sup> Public Health England, NHS breast screening programme and association of breast surgery,

<sup>&</sup>lt;sup>9</sup> Cancer Research UK, Lymphoedema after breast cancer treatment

The cancer experience survey 2014 national report <sup>10</sup>also highlights that 79% of breast cancer patients asked felt possible side effects of treatment were explained to them properly.

#### Chemoprevention

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

#### Adjuvant therapy

The Breast screening audit for 2012/13 reports that radiotherapy was the main adjuvant treatment for women with invasive cancer at all ages, followed by endocrine therapy: 77% of the 855 women with invasive cancer with radiotherapy recorded and no endocrine therapy had ER negative tumours11. The audit also reports that in 2012/13, 96% of invasive cancers, 86% of micro-invasive cancers and 58% of noninvasive cancers treated with breast conserving surgery had adjuvant radiotherapy: 35% of invasive cancers and 3% of non-invasive cancers treated with mastectomy had adjuvant radiotherapy. Chemotherapy was the least used adjuvant therapy; being recorded for only 20% of women with invasive cancer. Overall, a higher proportion of women treated with mastectomy than breast conserving surgery received chemotherapy (45% compared with 23%) and this difference was evident in every age group.

Quality Health, 2014 National Cancer Patient Experience Survey
 Public Health England, NHS breast screening programme and association of breast surgery,

#### 4.6 Metastasis

#### 4.6.1 Summary of suggestions

#### Timely provision of care

Stakeholders suggested that currently there is variability in resource allocation and standards in the provision of care for people with metastatic breast cancer. It was also highlighted that people with a history of breast cancer who have symptoms that are suggestive of an increased risk of recurrence should have prompt access back to their surgical team or their oncologist for metastatic disease.

#### Treatment for metastatic breast cancer

Stakeholders highlighted surgery for brain and bone metastasis as a key area for quality improvement stating it is now more complex and more widely used that in previous years and so requires further focus in guidance.

#### 4.6.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

| Table 7 | Specific areas | for quality i | mprovement |
|---------|----------------|---------------|------------|
|---------|----------------|---------------|------------|

| Suggested quality improvement area     | Selected source guidance recommendations   |
|--|--|
| Timely provision of care               | Diagnosis and assessment   |
|  | NICE CG81 Recommendation 1.1.1 to  |
|  | 1.1.5 (KPI)  |
| Treatment for metastatic breast cancer | Surgery to axilla  |
|  | NICE CG80 Recommendation 1.4.7   |
|  | Managing complications   |
|  | NICE CG81 Recommendation 1.5.14 (KPI), 1.5.15, 1.5.16 (KPI), 1.5.18 (KPI) and 1.5.21 |

#### Timely provision of care

#### NICE CG81 Recommendation 1.1.1

Assess the presence and extent of visceral metastases using a combination of plain radiography, ultrasound, computed tomography (CT) scans and magnetic resonance imaging (MRI).

#### NICE CG81 Recommendation 1.1.2

Assess the presence and extent of metastases in the bones of the axial skeleton using bone windows on a CT scan or MRI or bone scintigraphy.

#### NICE CG81 Recommendation 1.1.3

Assess proximal limb bones for the risk of pathological fracture in patients with evidence of bone metastases elsewhere, using bone scintigraphy and/or plain radiography.

#### NICE CG81 Recommendation 1.1.4

Use MRI to assess bony metastases if other imaging is equivocal for metastatic disease or if more information is needed (for example, if there are lytic metastases encroaching on the spinal canal).

#### NICE CG81 Recommendation 1.1.5 (Key performance indicator)

Positron emission tomography fused with computed tomography (PET-CT) should only be used to make a new diagnosis of metastases for patients with breast cancer whose imaging is suspicious but not diagnostic of metastatic disease.

#### Treatment for metastatic breast cancer

#### NICE CG80 Recommendation 1.4.7

Offer further axillary treatment to patients with early invasive breast cancer who:

- have macrometastases or micrometastases shown in a sentinel lymph node
- have a preoperative ultrasound-guided needle biopsy with histologically proven metastatic cancer.

The preferred technique is axillary lymph node dissection (ALND) because it gives additional staging information

#### NICE CG81 Recommendation 1.5.14 (Key performance indicator)

Consider offering bisphosphonates to patients newly diagnosed with bone metastases to prevent skeletal-related events and reduce pain.

#### NICE CG81 Recommendation 1.5.15

The choice of bisphosphonate for patients with bone metastases should be a local decision, taking into account patient preference and limited to preparations licensed for this indication.

#### NICE CG81 Recommendation 1.5.16 (Key performance indicator)

Use external beam radiotherapy in a single fraction of 8Gy to treat patients with bone metastases and pain.

#### NICE CG81 Recommendation 1.5.18 (Key performance indicator)

Offer surgery followed by whole brain radiotherapy to patients who have a single or small number of potentially resectable brain metastases, a good performance status and who have no or well controlled other metastatic disease.

#### NICE CG81 Recommendation 1.5.21

Offer referral to specialist palliative care to patients for whom active treatment for brain metastases would be inappropriate.

#### 4.6.3 Current UK practice

#### Timely provision of care

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### Treatment for metastatic breast cancer

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience

#### 4.7 Additional areas

#### **Summary of suggestions**

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 12 November 2015.

#### **Data reporting**

A stakeholder highlighted the importance of data reporting specifically around patient experience and assessing if the pathology minimum dataset is provided for all Breast cancer reports. This area is not contained within the development sources.

#### Effect of treatment on fertility

Stakeholders highlighted it is important people diagnosed with breast cancer are able to discuss the possible effect of treatment on their fertility and future pregnancies, and how likely this is, before treatment starts. This area is not contained within the development sources. This is however covered in the <a href="NICE">NICE</a> quality standard for fertility (QS73).

#### **New therapies**

New therapies were suggested as key areas for quality improvement by a number of stakeholders. This area is not contained within the development source.

#### Indicators for deep inspirational breath hold

A stakeholder highlighted in order to reduce the radiotherapy dose to the heart many centres are employing techniques to avoid treating the heart including voluntary deep inspiration breath hold which has been shown to reduce average heart dose by approximately 50%. This area is not contained within the development sources.

#### Management of internal mammary chain

A stakeholder felt that a lack of guidance around the use of internal mammary chain radiation could lead to varying approaches breast cancer management between radiotherapy centres. This area is not contained within the development source.

#### **Appendix 1: Key priorities for implementation (CG80)**

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

#### **Preoperative assessment of the breast**

- Offer magnetic resonance imaging (MRI) of the breast to patients with invasive breast cancer:
  - if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment
  - o if breast density precludes accurate mammographic assessment
  - to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer.

#### Staging of the axilla

Pretreatment ultrasound evaluation of the axilla should be performed for all
patients being investigated for early invasive breast cancer and, if
morphologically abnormal lymph nodes are identified, ultrasound-guided
needle sampling should be offered.

#### Surgery to the axilla

 Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique.

#### **Breast reconstruction**

Discuss immediate breast reconstruction with all patients who are being
advised to have a mastectomy, and offer it except where significant
comorbidity or (the need for) adjuvant therapy may preclude this option. All
appropriate breast reconstruction options should be offered and discussed
with patients, irrespective of whether they are all available locally.

#### Adjuvant therapy planning

• Start adjuvant chemotherapy or radiotherapy as soon as clinically possible within 31 days of completion of surgery in patients with early breast cancer having these treatments.

#### **Aromatase inhibitors**

• Postmenopausal women with oestrogen receptor (ER)-positive early invasive breast cancer who are not considered to be at low risk<sup>[4]</sup> should be offered an aromatase inhibitor, either anastrozole or letrozole, as their initial adjuvant therapy. Offer tamoxifen if an aromatase inhibitor is not tolerated or contraindicated.

#### Assessment of bone loss

- Patients with early invasive breast cancer should have a baseline dual energy X-ray absorptiometry (DEXA) scan to assess bone mineral density if they:
  - o are starting adjuvant aromatase inhibitor treatment
  - have treatment-induced menopause
  - o are starting ovarian ablation/suppression therapy.

#### **Primary systemic therapy**

 Treat patients with early invasive breast cancer, irrespective of age, with surgery and appropriate systemic therapy, rather than endocrine therapy alone, unless significant comorbidity precludes surgery.

#### Follow-up imaging

 Offer annual mammography to all patients with early breast cancer, including DCIS, until they enter the NHS Breast Screening Programme/Breast Test Wales Screening Programme. Patients diagnosed with early breast cancer who are already eligible for screening should have annual mammography for 5 years.

#### Clinical follow-up

- Patients treated for breast cancer should have an agreed, written care plan, which should be recorded by a named healthcare professional (or professionals), a copy sent to the GP and a personal copy given to the patient. This plan should include:
  - designated named healthcare professionals
  - dates for review of any adjuvant therapy
  - o details of surveillance mammography
  - signs and symptoms to look for and seek advice on

- o contact details for immediate referral to specialist care, and
- $_{\circ}$   $\,$  contact details for support services, for example support for patients with lymphoedema.

#### **Appendix 2: Key priorities for implementation (CG81)**

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

#### Diagnosis and assessment

- Positron emission tomography fused with computed tomography (PET-CT) should only be used to make a new diagnosis of metastases for patients with breast cancer whose imaging is suspicious but not diagnostic of metastatic disease. [2009]
- Assess oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status at the time of disease recurrence if receptor status was not assessed at the time of initial diagnosis. In the absence of tumour tissue from the primary tumour, and if feasible, obtain a biopsy of a metastasis to assess ER and HER2 status. [2009]

#### Systemic disease-modifying therapy

- Offer endocrine therapy as first-line treatment for the majority of patients with ER-positive advanced breast cancer. [2009]
- For patients with advanced breast cancer who are not suitable for anthracyclines (because they are contraindicated or because of prior anthracycline treatment either in the adjuvant or metastatic setting), systemic chemotherapy should be offered in the following sequence:
  - first line: single-agent docetaxel
  - o second line: single-agent vinorelbine or capecitabine
  - third line: single-agent capecitabine or vinorelbine (whichever was not used as second-line treatment). [2009]
- For patients who are receiving treatment with trastuzumab [3] for advanced breast cancer, discontinue treatment with trastuzumab at the time of disease progression outside the central nervous system. Do not discontinue trastuzumab if disease progression is within the central nervous system alone. [2009]

#### **Supportive care**

 Healthcare professionals involved in the care of patients with advanced breast cancer should ensure that the organisation and provision of supportive care services comply with the recommendations made in Improving outcomes in breast cancer: manual update (NICE cancer service guidance [2002]) and Improving supportive and palliative care for adults with cancer (NICE cancer service guidance [2004]), in particular the following two recommendations:

- 'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'
- 'Mechanisms should be developed to promote continuity of care, which might include the nomination of a person to take on the role of "key worker" for individual patients.' [2009]

#### **Managing complications**

- A breast cancer multidisciplinary team should assess all patients presenting with uncontrolled local disease and discuss the therapeutic options for controlling the disease and relieving symptoms. [2009]
- Consider offering bisphosphonates to patients newly diagnosed with bone metastases, to prevent skeletal-related events and reduce pain. [2009]
- Use external beam radiotherapy in a single fraction of 8Gy to treat patients with bone metastases and pain. [2009]
- Offer surgery followed by whole brain radiotherapy to patients who have a single or small number of potentially resectable brain metastases, a good performance status and who have no or well-controlled other metastatic disease. The following recommendations have been identified as priorities for implementation. [2009]

#### **Appendix 3: Key priorities for implementation (CG164)**

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

#### Family history and carrier probability

When available in secondary care, use a carrier probability calculation method
with demonstrated acceptable performance (calibration and discrimination) as
well as family history to determine who should be offered referral to a
specialist genetic clinic. Examples of acceptable methods include <u>BOADICEA</u>
and the Manchester scoring system. [new 2013]

#### **Information and support**

 To ensure a patient—professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organisations). [2004]

#### Carrier probability at which genetic testing should be offered

- Offer genetic testing in specialist genetic clinics to a relative with a personal history of breast and/or ovarian cancer if that relative has a combined BRCA1 and BRCA2 mutation carrier probability of 10% or more. [new 2013]
- Offer genetic testing in specialist genetic clinics to a person with no personal history of breast or ovarian cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more and an affected relative is unavailable for testing. [new 2013]

#### Surveillance for women with no personal history of breast cancer

- Offer annual mammographic surveillance to women:
  - o aged 40-49 years at moderate risk of breast cancer
  - aged 40–59 years at <u>high risk</u> of breast cancer but with a 30% or lower probability of being a *BRCA* or *TP53* carrier
  - aged 40–59 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
  - aged 40–69 years with a known BRCA1 or BRCA2 mutation. [new 2013]
- Offer annual MRI surveillance to women:

- aged 30–49 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
- o aged 30–49 years with a known *BRCA1* or *BRCA2* mutation
- aged 20–49 years who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier
- o aged 20–49 years with a known *TP53* mutation. [new 2013]

#### Surveillance for women with a personal and family history of breast cancer

- Offer annual mammographic surveillance to all women aged 50–69 years with a personal history of breast cancer who:
  - remain at <u>high risk</u> of breast cancer (including those who have a BRCA1 or BRCA2 mutation), and
  - o do not have a *TP53* mutation. [new 2013]
- Offer annual MRI surveillance to all women aged 30–49 years with a personal history of breast cancer who remain at <u>high risk</u> of breast cancer, including those who have a *BRCA1* or *BRCA2* mutation. [new 2013]

#### Chemoprevention for women with no personal history of breast cancer

Offer either tamoxifen<sup>[1]</sup> or raloxifene<sup>[2]</sup> for 5 years to postmenopausal women with a uterus and at <a href="high-risk">high-risk</a> of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer. [new 2013]

# Risk-reducing mastectomy for women with no personal history of breast cancer

 All women considering bilateral risk-reducing mastectomy should be able to discuss their breast reconstruction options (immediate and delayed) with a member of a surgical team with specialist oncoplastic or breast reconstructive skills. [2004]

# Appendix 4: Suggestions from stakeholder engagement exercise – registered stakeholders

| Stakeholder   | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
|---|---|--|---|---|
| British Society of<br>Breast<br>Radiologists<br>endorsed by The<br>Royal College of<br>Radiologists | Ensure that<br>women get<br>their imaging<br>and biopsy<br>same day as<br>the clinic visit            | To ensure we meet the new cancer target of diagnosis within 28days. Also improves the patient journey by minimising number of visits | Women presenting with breast symptoms are anxious and the gold standard is triple assessment. If we are able to perform imaging and biopsy same day it is better for the women and will help to achieving the new cancer targets. This currently not happening across all units and is something we should be aiming to achieve | Please see Best practice diagnostic guidelines for patients presenting with breast symptoms 2010. |
| Royal College of<br>Pathologists  | shorten the<br>turnaround<br>from the<br>current 2<br>weeks to<br>perhaps 1<br>week/7<br>working days |  |   |   |
| SCM – William   | MRI Breast in breast cancer   | Since previous NICE guidance, there has been increased use of  | The existing NICE guidance encourages routine use of pre-   | Houssami meta-analysis on pre-  |

| Stakeholder          | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information   |
|----------------------|---|---|--|--|
| Teh                  | assessment  | MRI in pre-operative setting leading to increased delays to treatment as well as over biopsies.   | operative breast MRI leading to delays and increased mastectomy rates  | operative breast MRI.  CA Cancer J Clin 2009;59:290–302.   |
| Genomic Health<br>UK | [NICE-approved] Gene expression profiling for guiding adjuvant chemotherapy decisions in early breast cancer management | Gene expression profiling for guiding adjuvant chemotherapy decisions in early breast cancer management is recommended within NICE guidance. The positive recommendation applies to the Onco <i>type</i> DX <sup>®</sup> breast cancer test and is specific to a sub-set of early breast cancer patients, for whom there is uncertainty about the adjuvant chemotherapy treatment decision. | Use of gene expression profiling to guide chemotherapy decisions in early breast cancer management is still limited due mainly to a lack of a permanent funding solution, despite being recommended in NICE DG 10 in September 2013. <u>Use of the Oncotype DX® breast cancer test should be included in Quality Statement 8</u> . | NICE DG 10 guidance  (https://www.nice.org.uk/guidance/dg10)  Please see the report of the Independent Cancer Taskforce "Achieving World-class cancer outcomes, A Strategy for England 2015-2020" (see Page 41, Recommendation 37) |
|                      | (NICE DG 10)  | The Onco <i>type</i> DX <sup>®</sup> breast cancer test guides the use of adjuvant chemotherapy, cost-effectively improves health outcomes and  | Use of this test in the group of patients for which it is recommended as an option, may lead to more   | (https://www.cancerresearchuk.<br>org/sites/default/files/achieving<br>world-class_cancer_outcomes<br>a_strategy_for_england_2015-   |

| Stakeholder | Key area for quality improvement | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
|-------------|----------------------------------|--|---|---|
|             |                                  | quality of life of people with early stage breast cancer, compared with current decision-making protocols alone. | equitable and standardised treatment decision-making across the country. Testing with the Oncotype DX® breast cancer test has also been shown to reduce overall chemotherapy use, resulting in important cost-savings in countries where it has been reimbursed, such as Ireland.   | 2020.pdf)  Please see recently published observational data from Ireland which highlights the important impact of testing on chemotherapy treatment decisions since it's reimbursement in 2011. |
|             |                                  |  | Development of a quality standard for such gene expression profiling is also directly in line with Recommendation 37 of The Cancer Strategy for England: "NHS England should transform access to molecular diagnostics to guide treatment for cancer". "NHS England should nationally commission access to molecular diagnostic tests to guide treatment, starting with the following cancer types in 2016: melanoma, lung, colorectal, breast and all paediatric | (http://www.ncbi.nlm.nih.gov/pub<br>med/26364296)   |

| Stakeholder  | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information  |
|--|--|---|--|---|
|  |  |   | cancers."  |   |
| Guy's & St Thomas' NHS Foundation Trust / King's Health Partners Cancer Genetics Service | Access to family history cancer risk assessment services                           | Accurate risk stratification for individuals questioning familial cancer risk can only occur through access to specialists with the appropriate skills and training to undertake cancer risk assessments. Patient access to local family history clinics enhances the quality, timeframe and uptake of this assessment. | The number and quality of referrals to tertiary services is better in areas with well established family history services. These also help decrease unnecessary waiting times for individuals at average or moderately increased cancer risk within cancer genetics services.  Improving access to education, training and clinical support for clinicians in secondary care will improve referral pathways for risk assessment and screening. | Royal College of Nursing<br>Cancer and Breast Care<br>conference, Kati Harris, Friday<br>25 November 2011                     |
| Guy's & St<br>Thomas' NHS<br>Foundation Trust<br>/ King's Health<br>Partners Cancer      | Rapid genetic<br>testing for<br>high risk<br>cancer<br>predispositio<br>n in women | Genetic testing is now undertaken routinely through massively parallel sequencing platforms which have decreased turnaround times and reduced cost. Results can now be used to inform breast  | Research has shown improved overall chemotherapy response to platinum based therapy as opposed to conventional taxanes in metastatic ER/PR/HER-2 negative breast cancer in BRCA1/2 mutation  | Tutt A, et al: The TNT trial. 2014<br>San Antonio Breast Cancer<br>Symposium. Abstract S3-01.<br>Presented December 11, 2014. |

| Stakeholder             | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information  |
|-------------------------|--|---|---|---|
| Genetics Service        | with cancer<br>meeting<br>testing<br>criteria  | cancer treatment and offer concurrent risk reduction within the diagnostic pathway. An ability to provide and discuss this option is a fundamental aspect of enabling informed decision making and patient choice.  | carriers.   |   |
| SCM – Anne<br>Armstrong | Gene expression profiling to determine adjuvant chemotherapy choices                   | Molecular profiling can better select the use of chemotherapy for ER+ breast cancer at intermediate risk of recurrence.   | New since last quality standard. Reduces the use of adjuvant chemotherapy and are able to spare some women the toxicities of such treatments.   | http://www.nice.org.uk/guidance/dg10  |
| Breast Cancer<br>Now    | Quality statement 5: People with newly diagnosed invasive breast cancer and those with | Cumulative evidence has shown that when breast cancer recurs, the subtype can change from what it was in the primary site, and a second biopsy is needed to determine the most appropriate course of treatment. However, this has not become standard of care | Currently, NICE's Advanced Breast Cancer Guideline (CG81) states that patients should not have a second biopsy when their disease recurs or metastasises to re-assess their ER or HER2 status. However, since the last full update in 2009, evidence has shown that the subtype can | In October 2013, a landmark review of breast cancer research was published, facilitated by Breast Cancer Campaign (one of Breast Cancer Now's legacy charities), which comprehensively analysed the current gaps in |

| Stakeholder Key area for quality improvement   | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
|--|--|---|---|
| recurrent disease (if clinically appropriate) have the ER and HER2 status of the tumour assessed and the results made available within two weeks to allow planning of systemic treatment by the multidisciplinar y team. | and practice varies around the UK.  At present, evidence shows that around 1 in 6 breast cancer patients with a recurrence are found to have a different subtype to their primary diagnosis, and therefore need to have their treatment changed. Having the wrong treatment plan is extremely detrimental to the patient and incredibly inefficient for the NHS. | change when breast cancer recurs, making a second biopsy appropriate. We accept that it is currently unrealistic to make a rebiopsy mandatory, but we believe that the recommendation <i>not</i> to take a second biopsy should be reviewed in light of this evidence, so that where clinically appropriate, patients are able to have their metastatic receptor status assessed. | breast cancer research and the strategic solutions to these. The paper was a unique collaboration of over 100 internationally recognised scientists, clinicians and healthcare professionals:  • Critical research gaps and translational priorities for the successful prevention and treatment of breast cancer. Breast Cancer Research 2013, 15:R92 <a href="http://breast-cancer-research.com/content/15/5/R92">http://breast-cancer-research.com/content/15/5/R92</a> In this review, the issue of receptor status in recurrent or metastatic disease is addressed on page 15 / footnotes 279-281: |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information  |
|-------------|----------------------------------|------------------------|---|---|
|             |                                  |                        |   | <ul> <li>Thompson AM, Jordan LB, Quinlan P, Anderson E, Skene A, Dewar JA, Purdie CA: Prospective comparison of switches in biomarker status between primary and recurrent breast cancer: the Breast Recurrence In Tissues Study (BRITS). Breast Cancer Res 2010, 12:R92</li> <li>Amir E, Clemons M, Purdie CA, Miller N, Quinlan P, Geddie W, Coleman RE, Freedman OC, Jordan LB, Thompson AM: Tissue confirmation of disease recurrence in breast cancer patients: pooled analysis of multi-centre, multi-disciplinary prospective studies. Cancer Treat Rev 2012,</li> </ul> |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information  |
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|             |                                  |                        |   | <ul> <li>Moussa O, Purdie C,         Vinnicombe S,         Thompson AM:         Biomarker discordance:         prospective and         retrospective evidence         that biopsy of recurrent         disease is of clinical         utility. Cancer Biomark         2012, 12:231-239</li> </ul> |
|             |                                  |                        |   | Since the review was published in October 2013, we are aware of the following paper which you might find useful in terms of demonstrating the feasibility of metastatic biopsy:  • Comparative genomic hybridisation array and DNA sequencing to direct treatment of                              |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information   |
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|             |                                  |                        |   | metastatic breast cancer: a multicentre, prospective trail (SAFIR01/UNICANCER) . The Lancet Oncology, Volume 15 Issue 3, Pages 267-274, March 2014 <a href="http://thelancet.com/journals/lanonc/article/PIIS1">http://thelancet.com/journals/lanonc/article/PIIS1</a> 470-2045(13)70611- 9/abstract |
|             |                                  |                        |   | However, we have not completed a comprehensive review of evidence specifically for this purpose, and there may be further studies, particularly post-2013 that we are not presently aware of.  See also: NICE Advanced   |

| Stakeholder           | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|                       |  |   |   | Breast Cancer Guideline (CG81).  |
| SCM- Kieran<br>Horgan | Patients with<br>HER-2 positive<br>cancers larger<br>than 1 cm are<br>recommended<br>adjuvant anti<br>HER-2<br>therapies.                    |   |   |  |
| Breast Cancer<br>Care | Retaining statement 11 from the current quality standard: People who develop local recurrence, regional recurrence and/or distant metastatic | Multidisciplinary team (MDT) working is widely recognised as best practice in the care of cancer patients, helping to ensure that each patient receives consistent information and co-ordinated treatment from all those involved in their care.  This approach is especially important for those living with | A report by Breast Cancer Care's Secondary Breast Cancer Taskforce in 2008 recommended that the care of metastatic (secondary) breast cancer patients should be undertaken by an MDT that includes members of the oncology and palliative care teams. The Taskforce, which included oncologists, palliative care professionals, clinical psychologists, secondary breast care nurses, support group | Breast Cancer Care (2008), Secondary Breast Cancer Taskforce Report: Improving the Lives of People with Metastatic Breast Cancer. Please contact the Commenter for a copy of this report.  The Independent Cancer Taskforce (2015), Achieving world-class cancer outcomes: A |

| Stakeholder  | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|              | disease have their treatment and care discussed by the multidisciplinar y team | secondary (metastatic) breast cancer, where support needs are often more complex and cancer pathways less well defined.  The new Cancer Strategy for England echoes the need for MDT time for more complex cases, recommending that:                        | facilitators, counsellors and primary care clinicians, was concerned that if metastatic breast cancer patients were not discussed at MDT meetings this could mean they were not receiving the best possible streamlined care.  We know from talking to people                             | strategy for England 2015-2020.  Available at: <a href="http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomesastrategy_for_england_2015-2020.pdf">http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomesastrategy_for_england_2015-2020.pdf</a> There may be the potential to |
|              |  | 'Recommendation 38: NHS England should encourage providers to streamline MDT processes such that specialist time is focused on those cancer cases that don't follow well- established clinical pathways, with other patients being discussed more briefly.' | living with secondary breast cancer, as well as with healthcare professionals, that it is still the case that not all patients with a secondary diagnosis are having their treatment and care discussed by an MDT. We therefore believe this is still a key area for quality improvement. | measure progress on this through the emerging Quality Surveillance Team, which is superseding the National Peer Review Programme.  |
| SCM – Ursula | People being treated for   | To ensure that all breast cancer  | Patients with advanced breast cancer may present at A&E or other  | NICE guideline cg80 and cg81   |

| Stakeholder           | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information                       |
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| Van Mann              | breast cancer (early or advanced) should be managed within an MDT for breast cancer.  | patients irrespective of route to diagnosis are managed by a mutli disciplinary team. | hospital wards. It is essential that these patients are identified as breast cancer patients and referred to a breast MDT` |  |
| SCM- Kieran<br>Horgan | Patients with early breast cancer should receive structured information at the completion of primary treatments which should include advice on diet and lifestyle and routine followup is not necessary |   |  | See "Calderdale Model of discharge-follow up |

| Stakeholder           | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information  |
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|                       | unless dictated<br>by clinical trial<br>participation   |   |   |   |
| SCM- Kieran<br>Horgan | Patients who have a new diagnosis of breast sarcoma or angiosarcoma should be reviewed at a Soft Tissue Sarcoma MDT |   |   | See national guidelines all patients with sarcomas should be reviewed at a Sarcoma MDT)   |
| Breast Cancer<br>Care | Retaining statement 12 from the current quality standard: People with recurrent or advanced breast cancer           | The National Cancer Patient Experience Survey has shown that having access to a Clinical Nurse Specialist who can support them is the single most important factor associated with a high patient score (i.e. a good experience of care). | We would like to see this statement retained in the update of this quality standard, as the standard has not yet been achieved.  There is still a great variation in levels of access to a secondary Clinical Nurse Specialist across the | Please see the 2014 report of The National Cancer Patient Experience Survey (p.6), which shows that access to a Clinical Nurse Specialist is the single most important factor associated with a good experience of care. Report available at: <a href="https://www.quality-">https://www.quality-</a> |

| Stakeholder Key area for quality improveme   |   | Why is this a key area for quality improvement?  | Supporting information   |
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| have access a 'key worke who is a clinical nurs specialist whose role i to provide continuity of care and support, offe referral to psychologic services if required and liaise with other healthcare professional including the GP and specialist palliative ca services. | We know that levels of access to a CNS are generally good for people diagnosed with primary breast cancer, but that this is not the case for those with secondary (metastatic) breast cancer, where support needs are often more complex. | A 2010 study (Reed E. et al) found that there were just 19 dedicated secondary breast cancer nurse postholders across the UK. Breast Cancer Care estimates that this will now be at approximately 15-25 posts. This is compared to around 600 conventional breast care nurse posts.  Improvement is needed to ensure that the NHS is more adequately able to support the estimated 36,000 (Maher J. et al) people living with a secondary breast cancer diagnosis. | health.co.uk/resources/surveys/ national-cancer-experience- survey/2014-national-cancer- patient-experience-survey/2014- national-cancer-patient- experience-survey-national- reports/688-2013-national- cancer-patient-experience- survey-national-report-pdf/file  36,000 estimate taken from Maher,J. and McConnell, H. (2011), New pathways of care for cancer survivors: adding the numbers, British Journal of Cancer. Available at:  http://www.ncbi.nlm.nih.gov/pmc /articles/PMC3251951/  Reed E., Scanlon K. & Fenlon D. (2010) A survey of provision of breast care nursing for |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information  |
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|             |                                  |                        |   | with metastatic breast cancer – implications for the role, European Journal of Cancer Care, 19, pp. 575–580  Available online at: <a href="http://www.researchgate.net/publication/227868739">http://www.researchgate.net/publication/227868739</a> A survey of provision of breast care nursing for patients with metastatic breast cancer implications for the role  Possible data sources to |
|             |                                  |                        |   | measure progress on this statement:  1) The Cancer Patient Experience Survey (CPES) collects responses on a number  |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information      |
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|             |                                  |                        |   | of questions on access      |
|             |                                  |                        |   | to a Clinical Nurse         |
|             |                                  |                        |   | Specialist. Please see      |
|             |                                  |                        |   | questions no. 21-24 of      |
|             |                                  |                        |   | the survey:                 |
|             |                                  |                        |   | https://www.quality-        |
|             |                                  |                        |   | health.co.uk/resources/s    |
|             |                                  |                        |   | urveys/national-cancer-     |
|             |                                  |                        |   | experience-survey/2014-     |
|             |                                  |                        |   | national-cancer-patient-    |
|             |                                  |                        |   | experience-survey/2014-     |
|             |                                  |                        |   | national-cancer-patient-    |
|             |                                  |                        |   | experience-survey-          |
|             |                                  |                        |   | materials/689-2013-         |
|             |                                  |                        |   | national-cancer-patient-    |
|             |                                  |                        |   | experience-survey-          |
|             |                                  |                        |   | questionnaire-pdf/file      |
|             |                                  |                        |   |                             |
|             |                                  |                        |   |                             |
|             |                                  |                        |   | 2) It should be possible to |
|             |                                  |                        |   | measure progress on         |
|             |                                  |                        |   | this via service providers' |
|             |                                  |                        |   | Cancer Outcomes and         |
|             |                                  |                        |   | Services Dataset            |
|             |                                  |                        |   | (COSD) data                 |

| Stakeholder   | Key area for quality improvement | Why is this important?                                       | Why is this a key area for quality improvement?                         | Supporting information  |
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|               |                                  |  |   | submissions. This would<br>be via the Clinical Nurse<br>Specialist Indication<br>Code. However, we are<br>aware that COSD<br>submissions are<br>variable.   |
|               |                                  |  |   | Please see p.39 of the COSD user guide for a description of this data item:  http://www.ncin.org.uk/view?rid=2897  'Metastatic site' is a core data item (required) in COSD, and could be used to identify metastatic patients. |
| Breast Cancer | Quality statement 12:            | The role of the clinical nurse specialist (CNS) in secondary | The number of specialist CNSs in the UK is low, particularly outside of | Access to a key worker is highlighted in NICE's Advanced  |

| Stakeholder | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information  |
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| Now         | 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 support if required and liaise with other healthcare professionals, including the GP and specialist palliative care | breast cancer was established in recognition of the fact that patients attending hospital for treatment of secondary breast cancer did not have access to a nurse specialist in the same way that patients undergoing treatment for early breast cancer had, and that this group of patients had different support needs.  The principal aim of this role is to offer increased levels of support, advice and guidance to patients who have been diagnosed with secondary breast cancer and their families and carers. Contact with patients consists of telephone support when they are out of hospital and providing symptom control, emotional and practical support when they attend outpatient clinics or are inpatients. Secondary CNSs can | London. A UK-wide, cross-sectional survey representing 276 breast care nurses carried out by Breast Cancer Care in 2009 revealed that 19 of the Trusts questioned had a dedicated secondary breast cancer nurse and 25 had a named nurse within the team for patients with secondary breast cancer. However, just over half (57%) of the 276 participants believed specialist nursing care provided to patients with secondary breast cancer was inadequate in their workplace. Many of the participants expressed a need for a designated secondary breast cancer nurse, and some were working towards this within their NHS Trust or private hospital. | Breast Cancer Guidelines (CG81). In addition, Achieving World-Class Cancer Outcomes: A Strategy for England 2015-2020 highlights the importance of CNSs as well as the difference in support needs between patients with primary and secondary cancers. |

| Stakeholder | Key area for quality improvement | Why is this important?  | Why is this a key area for quality improvement? | Supporting information |
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|             | services.                        | give specialist support such as providing information on secondary breast cancer; information on treatments, including side effects; breaking bad news; symptom control; liaising with hospital teams; and providing an increased level of emotional support to patients and their families, including young children. CNSs also support patients during the terminal phase of their disease, and can support discussions about patients' wishes for when they reach the end of their life. |   |                        |
|             |                                  | CNSs working in metastatic breast cancer can help prevent emergency admissions to hospital. They provide an alternative to unscheduled care by helping keep patients in the community, by working with  |   |                        |

| Stakeholder     | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information   |
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|                 |                                    | community teams and GPs to provide clinical solutions to complex problems. They can reduce new to follow-up ratios in cancer units, releasing clinic and outpatient time for new patients. Therefore, CNSs working with metastatic breast cancer patients can speed up pathways and help Trusts meet targets It is vital that this good practice is replicated more widely across the country, so that all patients diagnosed with secondary breast cancer are able to benefit from the specialist support a secondary CNS can provide. |  |  |
| SCM Nicola West | Key area for quality improvement 1 | Every Patient with Acute and Advanced breast cancer should have a key worker namely a Clinical Nurse Specialist to support and communicate throughout the journey. This support should be for the wider   | There is wide variation throughout the country and patients with advanced breast cancer have the least amount of input from a specialist nurse | National Cancer Patient Experience Survey Programme 2010. (NICE cancer service guidance, 2004): National cancer patient survey 2015 showed that patients very satisfied with care and better |

| Stakeholder           | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information   |
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|                       |  | family.   |  | communication throughout MDTwhen a specialist nurse involved.  |
| Breast Cancer<br>Care | Ensuring patients are given information about ways to reduce their risk of breast cancer recurrence, such as taking regular moderate exercise and eating a healthy diet. | There is evidence (Schmid, D. et al) to show that those who take regular exercise and maintain a healthy weight can reduce their risk of a breast cancer recurrence, sometimes to the same degree as with adjuvant medical treatment.  The new Cancer Strategy for England recommends that:  'Recommendation 8: NHS providers should ensure that all patients treated for cancer are given advice, tailored to their individual circumstances and risk level, on how to improve their lifestyle. This advice should | We know from talking to people affected by breast cancer that the levels of information provided to breast cancer patients about reducing their risk of recurrence through regular exercise and healthy eating is not consistent.  People tell us that they would welcome the consistent and regular provision of information on this topic as a tangible solution to dealing with (some of) the anxiety that exists over the possibility of recurrence. | Schmid, D & Leitzmann, M. F. (2014), Association between physical activity and mortality among breast cancer and colorectal cancer survivors: a systematic review and meta-analysis, Annals of Oncology, 25(7), pp. 1293-1311. Available at: <a href="http://annonc.oxfordjournals.org/content/25/7/1293.full.pdf+html">http://annonc.oxfordjournals.org/content/25/7/1293.full.pdf+html</a> The Independent Cancer Taskforce (2015), Achieving world-class cancer outcomes: A strategy for England 2015-2020. Available at: <a href="http://www.cancerresearchuk.or">http://www.cancerresearchuk.or</a> |

| Stakeholder | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information   |
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|             |  | include healthy eating, weight control, physical activity levels, smoking cessation and alcohol consumption, to help prevent secondary cancers. This advice should be recorded in their medical notes.'   |  | g/sites/default/files/achieving_w<br>orld-class_cancer_outcomes<br>a_strategy_for_england_2015-<br>2020.pdf  |
| NHS England | Management<br>of depression<br>in patients with<br>breast cancer<br>throughout the<br>pathway from<br>diagnosis to<br>survivorship | Major depression occurs in 10 percent of breast cancer patients.  There is strong evidence that a systematic approach to identification and treatment in patients with breast cancer can greatly improve patient outcomes, including quality of life. | Integration of mental and physical care is a key aim of the NHS five-year forward view.  Delivering parity of esteem for patients' mental and physical needs is an NHS England policy. | Please see the latest research evidence indicating effectiveness and cost – effectiveness of systematic integrated management of depression in cancer patents at: http://www.thelancet.com/depression-and-cancer |
|             |  | Cancer services should use systematic screening for   | Screening for distress is required as part of the accreditation of Comprehensive Cancer Centres in the USA from 2015. It is delivered by   | The 2015 cancer taskforce report p58 at: <a href="http://www.cancerresearchuk.org/sites/default/files/achieving_w">http://www.cancerresearchuk.org/sites/default/files/achieving_w</a>                           |

| Stakeholder              | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|                          |   | depression and be able to provide appropriate treatment that is integrated with cancer care.  | few if any cancer services in the UK.  Screening is only useful if linked to a system of treatment.  A system to provide better depression care for cancer patients was described and advocated on page 58 of the 2015 Cancer Taskforce report. | orld-class_cancer_outcomes<br>a_strategy_for_england_2015-<br>2020.pdf |
| SCM – Ursula<br>Van Mann | Communication n and support.  All breast cancer patients (early or advanced) and those at increased risk of familial breast cancer should receive the appropriate | Breast cancer patients face many challenges through their treatment stages. Difficult choices sometimes have to be made amidst a bewildering amount of information. Sometimes patients have to travel to different sites for part of their treatment. It is vital to maintain a continuity of contact to assist with decision making and assessment of needs which may change through the various | I believe that there is a shortage of BCNs and anecdotal evidence suggests there is variation in the field, especially amongst women with advanced breast cancer.   | NICE guideline cg80, cg81 and cg164.                                   |

| Stakeholder                   | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|                               | information and support including referral to psychological or genetic counselling services. Breast Care Nurses and key workers form a vital part of this need. | stages of treatment.  |   |  |
| Association of Breast Surgery | ADM reconstruction  |   |   |  |
| Breast Cancer<br>Now          | Quality statement 6: People with early invasive breast cancer,  | Breast cancer risk increases with age and a third of breast cancer cases in the UK now occur in women over the age of 70. Breast cancer in older women is | Despite the current Quality Statement and guidance from the International Society of Geriatric Oncology (SIOG) stating that treatment decisions should not be | In 2013, the All Party Parliamentary Group on Breast Cancer conducted an inquiry into older people and breast cancer. The report from this |

| Stakeholder | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|             | irrespective of age, are offered surgery, radiotherapy and appropriate systemic therapy, unless significant comorbidity precludes it. | predicted to roughly quadruple over the next three decades. Women in this age group with breast cancer are more likely to die from the disease than their younger counterparts. Although breast cancer survival rates are increasing, five-year survival for women aged 70-79 is 81%, compared to 90% for women aged 60-69. | age-based, evidence suggested that these recommendations are not being followed and inequalities in treatment continue to occur.  Although some treatments, such as chemotherapy, may not be of overall benefit for a particular patient due to underlying health problems, such decisions should be based on the patient's fitness rather than their chronological age. Studies asking clinicians to make treatment decisions on hypothetical cases have shown that some clinicians base recommendations for chemotherapy on age alone. Another study found that chemotherapy was less likely to be offered to older breast cancer patients and, as age increased, clinicians were more likely to state that comorbidities and frailty were the reasons it was not offered, even | inquiry, Age Is Just A Number, and the follow up report from 2015, Two Years On: Age Is Still Just A Number, can be found at www.breastcancernow.org/appg.  The studies referred to are:  Protière C, Viens P, Rousseau F, Moatti JP Prescribers' attitudes towards elderly breast cancer patients: Discrimination or empathy? Crit Rev Oncol Hematol. 2010;75(2):138-50  Ring A The influences of age and comorbidities on treatment decisions for patients with HER2-positive early breast |

| Stakeholder                                     | Key area for quality improvement | Why is this important?                      | Why is this a key area for quality improvement?  | Supporting information   |
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|   |                                  |   | though these factors were not recorded in a third of cases.  | cancer. Crit Rev Oncol Hematol. 2010;76(2):127-32  Ring A, Harder H, Langridge C, Ballinger RS, Fallowfield LJ Adjuvant chemotherapy in elderly women with breast cancer (AChEW): an observational study identifying MDT perceptions and barriers to decision making. Ann Oncol.2013;24(5):1211-9. |
| British Association of Surgical Oncology (BASO) | 1                                | Excision margins for breast cancer and DCIS | 2mm for DCIS in NICE guidance<br>2009; no minimum margin for<br>completeness of excision stated for<br>breast cancer   | ASCO guidance is now no cancer on ink. Association of Breast Surgery (UK) – 1mm. Need to discuss and approve 1mm   |
| British Association of Surgical Oncology        | 2                                | Completion axillary clearance               | NICE guidance 2009 recommends clearance if micro or macro metastases seen in sentinel nodes – current standard is to clear only if macrometastasis and even then |  |

| Stakeholder                                     | Key area for quality improvement | Why is this important?   | Why is this a key area for quality improvement?  | Supporting information                              |
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| (BASO)  |                                  |  | some selectivity may be appropriate  |   |
| British Association of Surgical Oncology (BASO) | 3                                | Sentinel node biopsy techniques  | Variation exists with some surgeons using radioisotope alone and others blue dye alone. Gold standard is the combined technique (radioisotope and blue dye) – 2009 guidance needs updating |   |
| British Association of Surgical Oncology (BASO) | 4                                | Surgery for multifocal disease   | Currently multifocal and multicentric disease is usually offered mastectomy but there is increasing recognition that conservative approaches may be used with certain caveats              | Literature  |
| North Bristol<br>NHS Trust                      |                                  | The use of One Step Nucleic Acid amplification in the assessment of sentinel lymph nodes in breast cancer. | Recently there has been a change in the management of patients with positive sentinel lymph nodes in breast cancer with much less axillary surgery. Patients with a positive               | CHOUDHRY ET AL. EJSO 2014.  Donker et al The Lancet |
|   |                                  | Patients at higher risk of significant sentinel node involvement may not be suitable                       | axilla after surgery are being treated with radiotherapy or relying on systemic therapy to eradicate   | Oncology 2014: Vol 15: 1303-                        |

| Stakeholder          | Key area for quality improvement          | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
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|                      |   | for no further treatment to the axilla as has been the case recently and minimising local recurrence is still important. | possible residual disease in the axilla. Whilst it is true that axillary recurrent disease occurs in only 1.2% of patients after 5 years, the trials are underpowered for using this approach in the following circumstances  1 Patients undergoing mastectomy  2 Patients with high risk disease (larger tumours, triple negative tumours, grade 3 tumours).  3 Patients who have undergone neoadjuvant chemotherapy  The key area is to identify patients with 4 or more positive lymph nodes for which this approach may not be appropriate. | 1310  |
| SCM – William<br>Teh | Immediate Breast Reconstruction (IBR) and | Women should be offered IBR but there is variability in practice if  | Variation in clinical practice has led to inconsistent practice and access to IBR.  | Brian p. Kelley et al, May 2014,<br>'A systematic review of<br>morbidity associated with<br>autologous breast |

| Stakeholder           | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information   |
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|                       | chest wall radiotherapy  | chest wall radiotherapy is being considered. This has led to inconsistent and variability in access to IBR in this group of patients. |  | reconstruction before and after exposure to radiation therapyare current practices ideal?', ann surg oncol.; 21(5): 1732–1738. |
| SCM – William<br>Teh  | Additional developmental areas of emergent practice  Vacuum excision of screen detected B3 lesions | High risk (B3) screen detected lesions are usually managed with diagnostic surgery leading to increased morbidity.                    | There is evidence to suggest that large vacuum excisions may be equivalent to surgical excisions therefore allowijng for a less invasive and non-surgical approach to the management of these lesions. | Published literature on vacuum excisions. Pending NHSBSP Pathology publication update.   |
| SCM- Kieran<br>Horgan | It is not<br>necessary for<br>postmenopaus<br>al patients who<br>receive breast                    |   |  |  |

| Stakeholder           | Key area for quality improvement  | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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|                       | conservation surgery and whole breast radiotherapy and who have good prognosis tumours to proceed with further axillary treatments if an axillary sentinel node biopsy reveals one or two macrometasta ses. |                        |   |                        |
| SCM- Kieran<br>Horgan | It is not recommended that patients with an axillary nodal biopsy which shows only  |                        |   |                        |

| Stakeholder           | Key area for quality improvement   | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
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|                       | micrometastas<br>es and/or<br>isolated<br>tumour cells to<br>receive further<br>axillary nodal<br>treatment. |  |   |   |
| SCM- Kieran<br>Horgan | A histopathologic ally clear margin of 1-2 mm is sufficient clearance in breast conservation surgery.        |  |   |   |
| SCM Nicola West       | Key area for quality improvement 2   | Every Patients should have access to all the different breast reconstruction and oncoplastic technique's. Plastic surgeons should be part of the MDT | Again there is wide variation in breast reconstruction rates throughout the UK.Women have to travel to units that offer all the techniques. | Benefits of Breast reconstruction<br>evident in the literature.Ananian<br>et al 2004, Wilkins et al<br>2000,AL-Ghazal et al 2000.A<br>national audit of provision and |

| Stakeholder                            | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
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|  |   |  |   | outcomes of mastectomy and<br>breast reconstruction surgery for<br>women in England Fourth<br>Annual Report 2011  |
| South Devon<br>NHS Foundation<br>Trust | Intra-operative tests (RD -100i OSNA system and Metasin test for detecting sentinel lymph node metastases in breast cancer 2013 NICE diagnostics guidance DG8 | The 2013 guidance is supported because it has enabled our centre to introduce intra-operative sentinel node biopsy in January 2014. It is important because it enables patients with significant axillary nodal malignancy to have appropriate axillary staging at initial surgery. Our oncologists value the information gained from surgical staging of the axilla in determining adjuvant therapy | Patients having the OSNA test have been uniformly pleased to avoid both the physical and psychological morbidity of having a delayed second operation should their sentinel nodes prove malignant on later H&E analysis.  It is unfortunate that the National OSNA audit advised in the guidance was not funded or implemented. We maintain our own audit which we share at annual user group meetings. | Since introducing the test we have modified our practice to avoid axillary clearance for patients with solitary micrometastasis defined by copy number 5000 (in line with ABS consensus statement January 2015) The axilla is still regarded as positive for micrometastasis within NICE guidance and NPI calculation and adjuvant therapy adjusted accordingly. Our current axillary clearance rate for clinically negative but OSNA positive macrometastais is <20% |
|  |   |  | The OSNA test is avoided in all   |   |

| Stakeholder                              | Key area for quality improvement | Why is this important?                           | Why is this a key area for quality improvement?   | Supporting information   |
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|  |                                  |  | DCIS patients   |  |
| The Society and College of Radiographers | 3                                | Surgical and RT management of the axilla and SCF | The AMAROS trial has shown that axillary lymph node dissection versus axillary RT provide comparable regional control (5). However, if breast units are opting for axillary RT as opposed to surgical management, what are the guidelines for treating this complex target volume? Implementation of the ESTRO consensus guidelines (6) may be seen as the goldstandard, but may have limitations to its implementation outside of clinical trials due to the additional planning and treatment delivery times. This could lead to variation in techniques between centres.  The Z0011 trial (7) investigates no treatment to the axilla at all, either surgical or RT following positive | 5. Donker et al (2014). Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS): a randomised, multicentre, open-label, phase 3 non-inferiority trial. Lancet Oncol 15(2); pp.1303-10.  6. Offersen et al (2015). ESTRO consensus guideline for elective radiation therapy for early stage breast cancer. Radiother Oncol. Available online.  7. Guiliano et al (2011). Axillary dissection vs No axillary dissection in women with invasive breast cancer and sentinel node metastasis. JAMA 305(6); |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?                            | Supporting information |
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|             |                                  |                        | SLNB, and reports that no treatment  | pp569-575.             |
|             |                                  |                        | is not inferior. However, this study                                       |                        |
|             |                                  |                        | has provoked much controversy with   |                        |
|             |                                  |                        | regard to protocol deviations  |                        |
|             |                                  |                        | (deployment of 'high tangentials' for the no ALN treatment arm), with only |                        |
|             |                                  |                        | 430 patients with macromets in the   |                        |
|             |                                  |                        | SLN, <50% of target accrual and  |                        |
|             |                                  |                        | 20% patients lost to follow up. The  |                        |
|             |                                  |                        | practice of no treatment to the axilla                                     |                        |
|             |                                  |                        | following positive SLN has been  |                        |
|             |                                  |                        | rapidly implemented into ASCO  |                        |
|             |                                  |                        | guidelines. Some UK breast units   |                        |
|             |                                  |                        | may be following this practice, which                                      |                        |
|             |                                  |                        | leads to potential uncertainty of RT                                       |                        |
|             |                                  |                        | target volumes – should the SCF be   |                        |
|             |                                  |                        | irradiated when it is not known how  |                        |
|             |                                  |                        | many positive ALN are involved, or   |                        |
|             |                                  |                        | should the whole ALN chain be  |                        |
|             |                                  |                        | irradiated if a positive axilla is not                                     |                        |
|             |                                  |                        | surgically cleared? In summary,  |                        |
|             |                                  |                        | interpretation of Z0011 into clinical                                      |                        |
|             |                                  |                        | practice must be appraised and   |                        |
|             |                                  |                        | management of a positive axilla  |                        |
|             |                                  |                        | included in the NICE guidelines to ensure a uniform, evidence based        |                        |
|             |                                  |                        | ensure a uniform, evidence based   |                        |

| Stakeholder              | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information |
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|                          |   |   | and safe approach.   |                        |
| SCM – Ursula<br>Van Mann | Complications of surgery. People who have had breast and/or axilliary surgery sometimes develop lymphoedema. This requires referral to a specialist lymphoedema clinic. | Lymphoedema is a painful life long condition which cannot be cured. It is extremely debilitating and some patients experience severe difficulties in their day to day activities. Specialist clinics are able to offer treatments and support which cannot be supplied elsewhere. | Services for this treatment vary widely across the country.  | NICE guideline cg80    |
| SCM – Ursula<br>Van Mann | Staging of the axilla.  Pretreatment ultrasound   | Surgery to the axilla can leave patients with difficulties in arm movement and numbness. It can also lead to lymphoedema. Reducing unnecessary surgery  | To ensure that all breast units adhere to the guidelines and use the dual blue dye and isotope method of SNLB. | NICE guidelinecg80     |

| Stakeholder          | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
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|                      | evaluation of<br>the axlla and<br>sentinel lymph<br>node biopsy<br>should be<br>performed to<br>stage the<br>axilla.                              | benefits both the patient and the NHS  |   |   |
| Breast Cancer<br>Now | New quality statement: People with increased risk of breast cancer because of a family history are offered chemopreventi on to reduce their risk. | NICE's Familial Breast Cancer Guideline (CG164) recommends that chemoprevention (with tamoxifen or raloxifene) should be discussed with all women at high or moderate risk of developing breast cancer because of their family history in order to reduce their risk. Since the publication of these guidelines, evidence has emerged that the aromatase inhibitor anastrozole is also effective in reducing breast cancer risk for women at increased risk. | Although familial breast cancer is rare, for women who have a family history of the disease, their risk of developing breast cancer is substantially higher than that of women who do not have a family history. Women who have a family history of breast cancer may have several potential courses of action, depending on their individual level of risk. These include:  • Preventative surgery such as a double mastectomy to dramatically reduce their chances of developing breast | Results of the IBIS-II breast cancer prevention trial involving 3,000 postmenopausal women showed that at an average follow-up of 5 years, there was a 53% reduction in the number of breast cancers in post-menopausal women who were randomised to receive anastrozole rather than placebo:  Anastrozole for prevention of breast cancer in high-risk |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?  | Supporting information   |
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|             |                                  |                        | <ul> <li>Additional screening to ensure that any breast cancer that does develop is identified and treated at the earliest possible stage.</li> <li>Risk reducing drugs such as tamoxifen, raloxifene and anastrozole which can significantly reduce risk.</li> <li>Currently tamoxifen and raloxifene are recommended in NICE's Familial Breast Cancer Guideline but the evidence for anastrozole has emerged since the publication of that guideline.</li> </ul> | postmenopausal women (IBIS-II): an international, double-blind, randomised placebocontrolled trial Cuzick, Jack et al. The Lancet, Volume 383, Issue 9922, 1041 – 1048.  • NICE clinical guideline 164 Familial breast cancer: Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer (June 2013). |
|             |                                  |                        | In addition, all of these chemoprevention drugs are offpatent and as a consequence are   |  |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?  | Supporting information |
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|             |                                  |                        | available at minimal cost. However, because they are off-patent, they are not 'owned' by a single pharmaceutical company and so noone is likely to act as an advocate for the drugs in their new indications. A pharmaceutical advocate would normally sponsor a drug indication through the national licensing process and ensure its adoption in the NHS, including by applying for a NICE technology appraisal. |                        |
|             |                                  |                        | Without a licence to act as a 'kitemark' of safety for a treatment, and a NICE technology appraisal to give the NHS a mandate to provide it, there are multiple disincentives to the treatment being prescribed to patients routinely. Without a licence for this new indication, it is also illegal for this treatment to be advertised to health professionals.  |                        |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?  | Supporting information |
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|             |                                  |                        | There have been significant challenges getting this treatment into routine commissioning, despite very strong evidence to support a change in clinical practice, with some GPs refusing to prescribe it because it is not licensed for this indication.  Therefore, we believe every opportunity should be taken to highlight the supporting evidence and to encourage health professionals and commissioners to implement it routinely. |                        |
|             |                                  |                        | Consequently, we think it is imperative that it is included in the revised Breast Cancer Quality Standard.   |                        |

| Stakeholder              | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?  | Supporting information  |               |
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| SCM – Ursula<br>Van Mann | The provision of chemopreventi on for high risk women.  | Tamoxifen for certain women at high risk of breast cancer can reduce their risk of the disease by up to 40% if taken for 5 years. It also gives an alternative choice to these women who may not want to undergo risk reducing surgery. | Tamoxifen is currently unlicensed for this indication. This may make it difficult for some women to obtain.  | NICE guideline cg164  |               |
| SCM – William<br>Teh     | Chemoprevent<br>ion in women<br>with increased<br>risk  | In spite of CG141, there is still no formal commissioning and process to offer chemoprevention.   | There should be evidence to support offering chemoprevention to all women who are at risk of breast cancer and not only those with familial history. Best practice guidance in how to do this should also be in place. | NICE CG141 for chemoprevention still not widely implemented and only applies to those with familial history only. |               |
| Breast Cancer<br>Care    | Post-<br>menopausal<br>women with<br>early breast<br>cancer to be<br>offered<br>adjuvant<br>bisphosphonat | SCM Nicola West   | Key area for quality improvement 3   | Every patient should have access to psychological assessment and counselling if they need it                      | Nice Guidelir |

| Stakeholder          | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information  |
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|                      | e therapy to reduce the risk of bone metastases and breast cancer mortality.  |   |   |   |
| Breast Cancer<br>Now | Quality statement 8: 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 | We believe that these two quality statements can be merged as they both cover information and support for people with early breast cancer. We suggest a new quality statement:  People with early invasive breast cancer are offered personalised information about all stages of the treatment pathway including information to allow them to make an informed choice about treatments including risks and | It is essential that patients are given information about the treatments they are being offered and are aware of the potential side effects of such treatment, as well as the benefits the treatments may provide. This allows patients to make an informed choice about their treatment options.  In the latest National Cancer Patient Experience Survey report, fewer than 80% of patients reported that:  • They were given written | Details of the National Cancer Patient Experience Survey results can be found at: https://www.quality- health.co.uk/resources/surveys/ national-cancer-experience- survey/2014-national-cancer- patient-experience-survey/2014- national-cancer-patient- experience-survey-national- reports.  The studies referred to are: |

|   | /hy is this a key area for quality nprovement?   | Supporting information |
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| personalised information effective and support, including a written follow- | information about the type of cancer they had  • Their views were taken into account when discussing their treatment options  • The potential side effects of treatment were explained  • They were involved as much as they wanted to be in decisions about their treatment  enly 60% of breast cancer patients aid that they were told about side effects of their treatment that may effect them in the future. Only 22% of breast cancer patients were effered a written assessment or care lan. | Makubate et al (2013): |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?   | Supporting information |
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|             | a named healthcare professional. |                        | In addition, it has become clear that patients with early invasive breast cancer need support and information to help them to continue to adhere to their adjuvant treatment plan, and therefore have better survival outcomes. |                        |
|             |                                  |                        | Support with managing side effects and information about the impact of continued/discontinued treatment could play an important role in encouraging adherence.  |                        |
|             |                                  |                        | Makubate et al (2013) showed that many women do not take the medication as directed and they stop treatment before completing the standard 5-year duration.   |                        |
|             |                                  |                        | McCowan et al (2013) showed that  |                        |

| Stakeholder          | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?  | Supporting information  |
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|                      |   |  | patients with low adherence have shorter time to recurrence, increased medical costs and worse quality of life. They concluded that interventions that encourage patients to continue taking their treatment on a daily basis for the recommended 5-year period may be highly costeffective. Indeed, they estimated the expected value of changing a patient from low to high adherence as £33, 897 (95% CI: £28,322–£39,652). |   |
| Breast Cancer<br>Now | New quality statement: Postmenopaus al women with early invasive breast cancer are offered treatment with bisphosphonat | Secondary breast cancer (also known as advanced or metastatic breast cancer) currently claims the lives of nearly 12,000 women and 80 men each year in the UK alone.  Significant new evidence was | Bisphosphonates are off-patent and as a consequence are available at minimal cost. However, because they are off-patent, they are not 'owned' by a single pharmaceutical company and so no-one is likely to act as an advocate for the drug(s) in its new indication. A pharmaceutical advocate would normally sponsor a   | The study referred to is:  • Early Breast Cancer Trialists' Collaborative Group (2015): "Adjuvant bisphosphonate treatment in early breast cancer: meta-analyses of individual patient data |

| Stakeholder | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?  | Supporting information   |
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|             | es to reduce<br>the risk of<br>breast cancer<br>spreading to<br>the bone. | published in July 2015 which supports a change in clinical practice – that adjuvant bisphosphonate therapy with zoledronate should be offered to women with early breast cancer who are post-menopausal or otherwise ovarian-suppressed (e.g. with an LHRH analogue) to reduce the risk of bone recurrence and improve breast cancer survival.  This evidence shows that in post-menopausal women with early breast cancer, bisphosphonate therapy reduced the 10-year risk of breast cancer spreading to the bone by 28% and the 10-year risk of dying from breast cancer by 18%. | drug indication through the national licensing process and ensure its adoption in the NHS, including by applying for a NICE technology appraisal.  Without a licence to act as a 'kitemark' of safety for a treatment, and a NICE technology appraisal to give the NHS a mandate to provide it, there are multiple disincentives to the treatment being prescribed to patients routinely. Without a licence for this new indication, it is also illegal for this treatment to be advertised to health professionals.  Therefore, because there are likely to be particular challenges around | from randomised trials",  The Lancet Volume 386, Issue 10001, 1353 - 1361  It is difficult to give an exact price for zoledronic acid as a lot of drugs in hospitals are bought 'on contract' which may be local, regional or national and can give significant savings.  However, estimates from hospital pharmacy colleagues indicate that the cost of a 6- monthly dose is likely to be "less than £10". In context, we know that the likely recommendation for adjuvant bisphosphonates is going to be two 4mg doses per year, for 3-5 years. Therefore, |
|             |   | 10 /0.   | getting this treatment into routine commissioning, despite very strong evidence to support a change in   | the estimated average total cost is (less than) £80 per patient being treated for an average   |

| Stakeholder           | Key area for quality improvement                            | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information |
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|                       |   | The researchers estimate that if every post-menopausal woman diagnosed with primary breast cancer in the UK each year (around 34,000) took a bisphosphonate for 3-5 years, after 10 years around 1,000 more of these women would still be alive – this amounts to saving around 1,000 lives every year <i>if</i> the treatment is implemented for routine use. | clinical practice, we believe every opportunity should be taken to highlight this new evidence and to encourage health professionals and commissioners to implement it routinely.  Consequently, we think it is imperative that it is included in the revised Breast Cancer Quality Standard. | period of four years.  |
|                       |   | The prevention of 1,000 cases of secondary breast cancer every year would also amount to significant cost-savings for the NHS.   |   |                        |
| SCM- Kieran<br>Horgan | Postmenopaus al patients with invasive breast cancer should |  |   |                        |

| Stakeholder             | Key area for quality improvement  | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information   |
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|                         | have a discussion of the benefits of bisphosphonat e drugs as adjuvant therapy. |   |   |  |
| SCM – Anne<br>Armstrong | Access back to specialist services after a diagnosis of breast cancer           | Patients with a history of breast cancer who have symptoms that raise the possibility of recurrence should have prompt access back to their surgical team (for? Local recurrence) or their oncologist for ? metastatic disease. | The breast cancer follow up pathway is changing with less face to face follow-up. Late recurrences are more common that other tumour types. Patients with a history suspicious of recurrence need rapid access to diagnostic services. Current referral pathways make this challenging. | Department of Health (2013) Living with and beyond cancer: taking action to improve outcomes |
| SCM – William<br>Teh    | Provision of care to patients with metastatic breast cancer                     | To address variability in resource allocated and standards in the provision of care to patients with metastatic breast cancer.  | Inspite of taskforce recommendations in 2008, a recent audit in London June 2015 still shows considerable variation in practice and resource available to   | Breast Cancer Care Secondary<br>Breast Cancer Taskforce 2008.                                |

| Stakeholder                                     | Key area for quality improvement | Why is this important?                       | Why is this a key area for quality improvement?  | Supporting information   |
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|   |                                  |  | this group of patients.  |  |
| British Association of Surgical Oncology (BASO) | 5                                | Surgical treatment in the metastatic setting | Surgery for bone and brain<br>metastases is now more complex<br>and widely used and should be<br>updated in the guidelines   | New national guidelines from professional asociations  |
| The Society and<br>College of<br>Radiographers  | 1                                | INTRABEAM appraisal                          | Will the NICE technology Appraisal Advisory committee decision about INTRABEAM from your August meeting be added to the list of 'Key policy documents, reports and national audits'? | http://www.england.nhs.uk/com<br>missioning/wp-<br>content/uploads/sites/12/2015/0<br>1/b01-policy-stat-iort.pdf |
|   |                                  |  | And/or the clinical commissioning policy statement: Intra-operative radiotherapy for the treatment of early breast cancer  |  |

| Stakeholder                      | Key area for quality improvement                                | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| Association of<br>Breast Surgery | PROMS on breast reconstruction – outcomes including information |                        |   |                        |
| Association of<br>Breast Surgery | New ablative<br>therapies for<br>early breast<br>cancer         |                        |   |                        |
| Association of<br>Breast Surgery | Management<br>of B3 screen-<br>detected<br>lesions              |                        |   |                        |

| Stakeholder           | Key area for quality improvement   | Why is this important?   | Why is this a key area for quality improvement?  | Supporting information   |
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| Breast Cancer<br>Care | People diagnosed with breast cancer are able to discuss the possible effect of treatment on their fertility and future pregnancies, and how likely this is, before treatment starts. They are offered a prompt referral to a fertility specialist, | The impact of treatment on a person's fertility can have a significant impact on a person's quality of life.  Increases in survival rates mean that more and more women are living with the long-term effects of their treatment for breast cancer. Many women are not aware that treatment can impact on their fertility.  The NICE guideline CG156 Fertility: Assessment and | Although this is not an issue specific to breast cancer, this is a key area for quality improvement as referrals are not happening consistently and there is wide-ranging variation in the information that people receive about the possible impact of their treatment on their fertility.  Research conducted by Breast Cancer Care in 2014 found the majority (88%) of younger women with a breast cancer diagnosis are not being referred to a fertility clinic to discuss the possibility of freezing eggs or embryos ahead of treatment. | For details of research conducted by Breast Cancer Care in 2014, please see:  Brauten-Smith, G. (2014) Fertility Preservation After Breast Cancer, European Oncology & Haematology, 10(2), pp. 80–1. Available at: <a href="http://www.touchoncology.com/system/files/private/articles/21608/pdf/bsmith-0.pdf">http://www.touchoncology.com/system/files/private/articles/21608/pdf/bsmith-0.pdf</a> NICE Guideline CG156 Fertility: |
|                       | whether they have a partner or not, to discuss options for   | treatment for people with fertility problems (2013) makes recommendations on this, including:  | This is leaving an estimated 5000 younger breast cancer patients across the UK missing out on fertility care.  | Assessment and treatment for people with fertility problems (2013), section 1.16. Available at: <a href="https://www.nice.org.uk/guidanc">https://www.nice.org.uk/guidanc</a>  |

| Stakeholder | Key area for quality improvement  | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information  |
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|             | trying to preserve fertility before starting chemotherapy or hormone treatment. | 1.16.1.2 At diagnosis, the impact of the cancer and its treatment on future fertility should be discussed between the person diagnosed with cancer and their cancer team. [new 2013]  The NICE guideline also recommends that clinicians follow the recommendations in The Royal College of Physicians' 'The effects of cancer treatments on reproductive functions' (2007).  This guidance recommends that, 'for women who wish to retain the possibility of future fertility, urgent referral to a specialist infertility service is recommended to discuss the available options including embryo and egg | People affected by breast cancer tell us:  • 'I was single and wasn't offered the opportunity to speak to a specialist about preserving my fertility. Despite having a nursing background I didn't fully realise the damaging impact treatment would have on my fertility.  • It was only much later I realised the option of having my own children was gone and that has made | e/cg156/resources/guidance-fertility-pdf  Royal College of Physicians (2007) Guidance on management of the effects of cancer treatment on reproductive functions. Available at:  https://www.rcplondon.ac.uk/sites/default/files/documents/effects-of-cancer-treatment-reproductive-functions.pdf |

| Stakeholder          | Key area for quality improvement | Why is this important?  | Why is this a key area for quality improvement?   | Supporting information |
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|                      |                                  | storage'  | moving forward from my diagnosis so much harder. Just having the opportunity to discuss options with the right people would have been invaluable in helping me' |                        |
| Breast Cancer<br>Now | Additional comments              | The NHS England Breast Cancer Clinical Reference Group (CRG), chaired by Professor Ian Smith, has developed a breast cancer service specification, which should be published soon. This covers essential services for people with early, recurrent and metastatic breast cancer, and focusses specifically on areas where significant progress is needed to improve breast cancer |   |                        |

| Stakeholder | Key area for quality improvement | Why is this important?   | Why is this a key area for quality improvement? | Supporting information |
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|             |                                  | outcomes and ensure that patients have the best possible experience of care. Breast Cancer Now provides the Secretariat to the CRG and would be happy to share a confidential draft of the service specification with NICE.  |   |                        |
|             |                                  | The Independent Cancer Taskforce's recently published report recommends that "all commissioners should commission to NICE guidelines and CRG-approved service specifications as a minimum". Given this, it would make sense to ensure that the two are in alignment and we would urge you to add the service specification to the list of guidance you are considering in updating the quality standard. |   |                        |

| Stakeholder                    | Key area for quality improvement   | Why is this important?  | Why is this a key area for quality improvement? | Supporting information      |  |
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| British<br>Association of      | Additional developmental   | Oncoplastic surgery guidelines  There are lots of other changes                     | These need to be formally adopted by NICE       | ABS guidelines              |  |
| Surgical<br>Oncology<br>(BASO) | areas of emergent practice   | required in this fast moving field and a detailed review is needed across all areas |   |                             |  |
| Royal College of<br>Nursing    | This is to inform you that the RCN has no comments to submit to inform on the above topic engagement at this time. |   |   |                             |  |
| Royal College of Pathologists  | To assess if a pathology minimum dataset is provided for all Breast cancer reports                                 |   |   |                             |  |
| SCM – William                  | Surveillance of  | Surveillance strategy should be by  | There is existing NICE guidance for             | NICE CG141 does not include |  |

| Stakeholder           | Key area for quality improvement   | Why is this important?   | Why is this a key area for quality improvement?   | Supporting information   |
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| Teh                   | women with<br>increased risk<br>of breast<br>cancer  | risk and not just according to family history. There needs to be a consistent way of classifying risk and surveillance strategy. | risk according to family history but<br>not for other risk factors such as<br>personal history of breast cancer,<br>biopsy risk factors such as atypia,<br>and breast density. This means<br>different surveillance strategies in<br>different clinical situations exist. | Different risk stratification to NICE CG141 http://www.cancerscreening.nhs. uk/breastscreen/publications/rep ort-working-party-higher-risk- breast-screening.pdf |
| SCM- Kieran<br>Horgan | Patients with a diagnosis of inflammatory breast cancer should initially receive systemic therapy. |  |   |  |
| SCM Nicola West       | Key area for quality   | All patients should have a discussion about fertility and have access to a fertility team re                                     | Younger patients having chemotherapy have fertility issues that are not addressed or  | Breast Cancer Cancer Survey<br>2015  |

| Stakeholder                              | Key area for quality improvement | Why is this important?                                 | Why is this a key area for quality improvement?  | Supporting information  |
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|  | improvement 4                    | options  | acknowledged. There is variation across the country regarding access to services and treatment   |   |
| The Society and College of Radiographers | 2                                | Indications for Deep Inspiration<br>Breath Hold (DIBH) | In order to reduce the radiotherapy dose to the heart many centres are employing techniques to avoid treating the heart including voluntary deep inspiration breath hold (vDIBH)(1) which has been shown to reduce average heart dose by approximately 50%(1). While there is substantial evidence now about the benefits of techniques such as voluntary DIBH (vDIBH) but little standardization in the application of the technique across centres. For example, in a recent audit of techniques from members of a special interest group on breast radiotherapy that has members from the UK and beyond (Breast radiotherapy Interest Group- BRIG) only 30% of respondents indicated that vDIBH was applied routinely for | <ol> <li>Hayden A RM, Tiver K. Deep inspiration breath hold technique reduces heart dose from radiotherapy for left sided breast cancer. Journal of Medical Imaging Radiation Oncology. 2012;56(4):464-72.</li> <li>Shah C, Badiyan S, Berry S, Khan AJ, Goyal S, Schulte K, et al. Cardiac dose sparing and avoidance techniques in breast cancer radiotherapy. Radiotherapy and Oncology. 2014;112(1):9-16.</li> <li>Rochet N, Drake JI, Harrington K, Wolfgang JA, Napolitano B, Sadek BT, et al. Deep inspiration breath-hold technique in left-sided breast</li> </ol> |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?  | Supporting information  |
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|             |                                  |                        | women with a left sided breast cancer, with other centres either not using the technique or only using within a clinical trial setting. There remains uncertainty about whether this technique should be for all left-sided cases or those whose heart dose exceeds a certain amount? Anecdotal evidence suggests some centres base patient selection on age and use of cardio toxic chemotherapy if limited by resources to provide to all.  Additional imaging and additional set-up time required for vDIBH can limit the overall workload capacity of busy radiotherapy machines restricting the widespread implementation of this technique in many centres. The benefit of vDIBH can been seen in the reductions in the mean heart dose, dose to the left anterior descending coronary artery (LAD) and left ventricle of the heart (LV) and this is unequivocal(2). | cancer radiation therapy: Evaluating cardiac contact distance as a predictor of cardiac exposure for patient selection. 2015 Practical Radiation Oncology May- Jun;5(3):e127-34.  4. Darby SC, Ewertz M, McGale P, Bennet AM, Blom- Goldman U, Bronnum D, et al. Risk of ischemic heart disease in women after radiotherapy for breast cancer. N Engl J Med. 2013;368(11):987-98. |

| Stakeholder | Key area for quality improvement | Why is this important? | Why is this a key area for quality improvement?   | Supporting information |
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|             |                                  |                        | However, some women benefit less from vDIBH than others(3). A retrospective dosimetric analysis (n=35) identified a reduction in the mean heart dose from 2.4Gy(free breathing) to 0.9Gy (vDIBH). However, dose reductions ranged from 0.1Gy to 2.9Gy. Using recent data to estimate risk reduction for ischemic heart disease post radiotherapy(4) this range of dose reduction achieved with vDIBH equates to 1% to 21% reduction in relative risk. For those that only gain 1% reduction in risk of developing ischaemic heart disease or the 25% of cases in this study where the reduction in mean heart dose using vDIBH was <0.9Gy (or the 10% where the reduction in dose to the LAD was <0.9Gy) does the additional on-treatment imaging exposure to the whole breast required to achieve accurate |                        |

| Stakeholder                              | Key area for quality improvement | Why is this important?                   | Why is this a key area for quality improvement?  | Supporting information   |
|--|----------------------------------|--|--|--|
|  |                                  |  | radiotherapy set up with vDIBH or<br>the additional time required to plan<br>and treat using this technique justify<br>the limited overall benefit to heart<br>dose achieved?  |  |
| The Society and College of Radiographers | 4                                | Management of the internal mammary chain | 2 recent publications (8&9) have shown a slight survival advantage to some patient groups receiving IMC irradiation. However, interpreting this data into current early breast cancer management (improvements in systemic therapy) to increase local control and improve survival may be ambiguous in terms of patient selection for IMC RT. In the absence of NICE guidance, this could lead to varying approaches to management between RT centres, with some already considering its use for certain patient groups. | 8. Poortmans et al (2015). Internal mammary and medial supraclavicular irradiation in breast cancer. New Eng J Med 373; pp317-327.  9. Whelan et al (2015). Regional nodal irradiation in early stage breast cancer. New Eng J Med 373; pp307-316. |