NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Breast cancer

Date of Quality Standards Advisory Committee post-consultation meeting:
10 March 2016.

2 Introduction

The draft quality standard for breast cancer was made available on the NICE website for a 4-week public consultation period between 21 January 2016 and 17 February 2016. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 16 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in the appendix.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- A number of stakeholders outlined their support for their support for the quality standard.
- Some concerns were raised that two of the three primary sources for the quality standard (CG80 and 81) are in the process of being updated.
- Suggested the ordering of statements 3 and 4 should be reversed
- A number of suggested amendments were requested and are covered under the individual statements
- Stakeholders also outlined a number of potential additional quality statements

Consultation comments on data collection

- Stakeholders commented that with further refinement the majority of measures outlined in the quality standard are potentially measurable.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with suspected breast cancer referred to specialist services receive the triple diagnostic assessment in a single hospital visit.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Support for statement around prompt diagnosis for people with suspected cancer.
- Appears to align with NHS England Breast Cancer Clinical Reference Group (CRG) guidance.
- Concern over the feasibility of this were raised as currently non-cancer referrals are treated in the same way as suspected cancer referrals. Ensuring all of these people receive the triple diagnostic assessment in a single hospital visit would therefore represent a considerable work load.
- Commented that the accompanying measures are measurable if the date that each of the individual tests was performed is recorded.

5.2 Draft statement 2

People with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS) are not offered a preoperative MRI scan without specific clinical indication.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Increased MRI usage but low levels of positive results for some types of breast cancer was highlighted. Unnecessary delays in the service cause by unnecessary MRIs being performed was also reported.
- MRI to assess response to neoadjuvant chemotherapy (NAC) and plan surgery is an appropriate indication but this could be included in the definition section.
- Indications for pre-operative MRI use should be reviewed as new evidence was highlighted that MRI use is not recommended in the management of lobular breast cancers treated with breast conserving surgery.
- The specific clinical indications referred to in the statement wording need to be clearly defined for the measures to be measurable.

5.3 Draft statement 3

People with oestrogen receptor-positive (ER-positive), human epidermal growth factor receptor 2-negative (HER2-negative) or lymph node-negative early breast cancer have gene expression profiling and expanded immunohistochemistry tests.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- The statement should be amended to reflect the fact gene profiling is recommended people whose breast cancer is HER2 negative and lymph node negative rather than HER2 negative or lymph node negative.
- It should clearly outline that only Oncotype DX is recommended by NICE DG10 and this statement should only refer to gene expression profiling and not expanded immunohistochemistry tests.
- Should this statement only include people with an intermediate risk (people with a Nottingham Prognostic Index score of greater than 3.4) to be in line with NICE guidance?
- Further detail was requested over whether this genetic profiling should be conducted as part of trials or registration studies.
- Currently many breast cancer centres conduct gene testing under Oncotype guidelines and it was queried how this statement will be applied across cancer networks and whether it will impact on pathology reporting times.
- The statement is measurable as the hormone receptor status of a patient’s tumour is recorded. However what happens when a patient is offered tests but declines?

At consultation we also asked following specific question: Are there other areas of genetic testing for breast cancer that should be covered in this quality standard and if so, what is the supporting evidence for these?

Responses highlighted that there are several areas of genetic testing for familial breast cancer covered in CG164 that could be considered for inclusion in the quality standard. The following were outlined specifically:

- The need for people whose family history meets guidelines for genetic testing referral to be offered the opportunity to discuss genetic testing with a specialist genetic service
- Breast cancer patient who have a BRCA mutation identified as part of their cancer treatment should be referred to the clinical genetics service

5.4 Draft statement 4

People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of the tumour assessed.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Support for this statement although the need to define what is meant by ‘if clinically appropriate’ was identified.
- Evidence to support reassessment of ER and HER2 status in all people when their breast cancer reoccurs was highlighted.
- If there is a need for further biopsy to retest tumour status this must be discussed with the patient with the potential value of further biopsy clearly explained to them.
- For the measures to be measurable then invasive breast cancer would need to be defined. The date of breast cancer recurrence and the date the hormone receptor status was reassessed should also be recorded to ensure the tumour status recorded was not that of the original tumour. Furthermore it was suggested that two indicators may be required to record data on the recurrent tumour and tumour re-assessment. It was also highlighted that the collection of data on recurrent and secondary breast cancer is currently poor.

At consultation we also asked the following specific question: How should ‘if clinically appropriate’ be defined in terms of when the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of a tumour should be reassessed in people with recurrent breast cancer?

Responses suggested clinically appropriate should mean retesting is required if it is possible to carry out a biopsy in terms of the accessibility of the tumour. In additional clinically appropriate should also mean retesting should be carried out if the information gained from this informs treatment decisions as if the biology has changed from the original tumour this may require alternative treatment.

5.5 Draft statement 5

People with breast cancer who develop metastatic disease are assessed by a multidisciplinary team.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- General support for this statement was received with variation in practice highlighted.
- There is a lack of clarity within breast cancer services over systems in place to ensure clinicians refer all women with metastatic disease who have not already been assessed by an MDT to be referred back for assessment.
- It was highlighted that the data to support the measures for this statement should be covered in the Cancer Outcomes and Service Dataset (COSD).

5.6 Draft statement 6

People with locally advanced, metastatic or distant recurrent breast cancer are assigned a key worker.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- The statement should be expanded to include all people with breast cancer.
- The importance of not only having a key worker but seeing them regularly was highlighted.
- The role of specialist therapeutic radiographers should be outlined within the audience descriptors.
- The COSD already records whether a patient has a key worker assigned to them. However concerns over the reliability in data collection for secondary breast cancer were also raised.

At consultation we also asked the following specific question: Is there evidence to suggest that people with advanced breast cancer are not having a key worker assigned to them?

Responses provided evidence showing variation in people with advanced breast cancer having a key worker assigned to them. Attention was drawn specifically to the high level of variation in levels of access to secondary (metastatic) clinical nurse specialists across England. The following information was presented to show variation in people with advanced breast cancer having a key worker assigned to them:

- Just under a third of patients, who took part in a patient experience survey looking at access to key workers breast cancer patients across 10 hospitals in 2014 and 2015, reported not having ongoing support from a nurse who had knowledge and skills to support them with their secondary breast cancer
- Evidence from the National Cancer Intelligence Network 2012 metastatic breast cancer pilot showed only half of patients were referred to a clinical nurse specialist or other key worker at the time of breast cancer recurrence or

metastasis. In the same study significant variation was also seen in the number of patients who were referred to a clinical nurse specialist

5.7 Draft statement 7(Placeholder)

Exercise for people with breast cancer.

Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

- Exercise for people with breast cancer is an important issue and a number of sources for evidence based guidance were suggested (see appendix).
- Past experience has shown that health professionals telling patients to exercise has limited effect on patient behaviour. Asking healthcare professionals to give advice about excise may therefore result in a box ticking exercise that has no effect on patient behaviour or health outcomes.
- More detail is needed to be added to the current placeholder statement for it to be useful going forward. It was highlighted that exercise can be used to promote different outcomes at different stages in the breast cancer pathway. Improvements for a number of outcomes suggested including survival, risk of reoccurrence of symptoms and vasomotor symptoms.
- The need to be clear over in the use of the terms exercise and physical activity. Physical activity is a more general term but exercise can refer to very specific programmes.

5.8 Consultation question: chemoprevention

Is there any evidence to suggest that there is variation in offering chemoprevention to women who have an increased risk of breast cancer, and in the use of drugs such as tamoxifen in premenopausal women? If so, should a statement on these areas be included in this quality standard?

Stakeholders made the following comments:

- Qualitative evidence from 2013 along with evidence from case studies and anecdotal evidence showing variation in eligible patients being offered chemoprevention to reduce their risk of developing breast cancer was highlighted. A stakeholder also highlighted differences in chemoprevention drug prescribing within general practice. Testimony from several key clinicians working in this field was also offered to highlight to us such case studies and the challenges they are experiencing in trying to implement the treatment.
- Results from a qualitative investigation where semi-structured interviews with GPs and clinicians working in family history or clinical genetics settings (FHCG clinicians) was also highlighted. The results this study suggests the reason for variation in chemoprevention rates may be due to difficulties with interpreting NICE guidelines. These difficulties were focused on a perceived lack of benefit of preventive therapy in clinicians who felt poorly informed about preventive therapy which discouraged them from raising it with patients.
- It was commented that the variation is not in the offer of chemoprevention but in low uptake and low adherence rates. A statement was therefore suggested around ensuring there is adequate support for women eligible for chemoprevention to address concerns over side effects etc.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Prescription of biphosphates for postmenapausal women with early invasive breast cancer to reduce the risk of breast cancer spreading to the bone.
- Reducing the risk of breast cancer recurrence.
- Referring people with breast cancer to fertility specialists.
- Choice of surgery for patients requiring mastectomy
- Surgical techniques to reduce physical trauma for lymph node sampling.
- Breath hold for radiotherapy.
- Advising patients on a number of aspects of their breast cancer care including self-referral to breast cancer services, self- examination, prevention of lymphoedema and the importance of health living e.g. rest and exercise
- Primary prevention of lymphoedema, specifically perioperative treatment and advice.
- Provision of information for people with breast cancer on appropriate trials and opportunities to contribute to research which may benefit future patients.
- Opportunities to donate tissue.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	Association of Breast Surgery	General	The ABS would like to record that they support the quality measures in the document
2	Royal College of Obstetricians and Gynaecologists	General	Many thanks for inviting the RCOG Guidelines Committee to review this document. The document addresses an important and topical issue related to quality standards in 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. The document is well written, and overall raised no major comments from the guideline committee members. A minor comment was related to the ordering of the statements. One member suggested that statement 4 would be better to be statement 3 throughout the document for ease of flow. Another suggestion was to include the full wording of statement 7 rather than keeping it as a place holder. The final minor comment was suggesting the use of the term ‘routinely’ rather than ‘usually’ (page 10 paragraph 4) to read ‘are not routinely offered MRI’. Finally, the committee would like to thank the NICE committee for asking us to comment on the document and for all the work and effort put in preparing it.
3	UK Cancer Genetics Group	General	need to flag issues with trying to implement recommendations re: surveillance within the NHSBSP for women at increased risk when the NHSBSP use different criteria to assess risk.
4	Independent Cancer Patients’ Voice	General	• Ref: p 14 of briefing paper - ‘The preferred technique is axillary lymph node dissection (ALND) because it gives additional staging information’. Surely we don't do this just for the information about staging? Lymph node dissection/removal needs to be minimal and the consequent nerve damage, resulting pain and swelling which lasts for months, reduced as far as possible. Investigate better methods of detecting cancer in lymph nodes, before removal or sampling by any means. • Vacuum assisted biopsy (VAB) is not essential for all biopsies but should be available at all centres. • The need for further biopsy must be discussed with all patients with recurrence if the metastasis is accessible – biology may have changed may require alternative treatment. Also needs metastatic MDT and a CNS confident in the care needed. Patients need proper explanation re potential value of further biopsy.
5	Independent Cancer Patients’ Voice	General	ICPV very much supports the comments from Breast Cancer Now and Breast Cancer Care and Ursula Mann (the lay member)

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[1] PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments[1]
6	The Society and College of Radiographers	General	Please could the Society and College of Radiographers request that 'Therapeutic Radiographers' are specifically listed in the sub heading of Healthcare Professionals as they deliver core service delivery for a large amount of patients and appropriate key worker referral
7	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
8	Royal College of General Practitioners	General	As an example, having checked the management of a pre-menopausal patient with unsuspected breast cancer. Her care fulfilled all the QS. This would be a an interesting audit. (JA)
9	Royal College of Nursing	General	There are no further comments to make on this document on behalf of the Royal College of Nursing.
10	Breast cancer care	General	Two of the three primary development sources for this Quality Standard (QS) are the two NICE breast cancer guidelines, *Early and locally advanced breast cancer: diagnosis and treatment* (CG80) and *Advanced breast cancer: diagnosis and treatment* (CG81). We're aware that there are plans to update both these guidelines, which were last updated in 2009. We feel that using these guidelines as a primary source to develop this QS is a missed opportunity. While we appreciate that, in terms of the *Early & advanced breast cancer* guideline, an updated guideline is not expected to be published until July 2018, it feels inappropriate to base this draft update on the current, outdated guidelines. We are concerned that the breast cancer QS are not being based on the latest evidence and best practice. We are also aware that the NHS England breast cancer Clinical Reference Group is due to publish its service guidance shortly. This details best practice along the entire breast cancer pathway. As such, it would have been a valuable source to consider when developing this Standard.
11	Breast cancer care	General	We note that there are fewer statements in the draft updated Quality Standard (QS) than in the current QS. We feel there is potentially scope for adding additional statements. For example, our suggested statements around fertility discussions and bisphosphonates for post-menopausal women, as detailed in subsequent comments.
12	Breast cancer now	Data collection	Statement 1. People with suspected breast cancer referred to specialist services receive the triple diagnostic assessment in a single hospital visit [new 2016]. This statement could be measured by collecting the dates of the three tests performed and seeing whether they match. This may be possible to do via the Cancer Outcomes and Services Dataset (COSD). Statement 2. People with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS) are not offered a preoperative MRI scan without specific clinical indication [new 2016]. Whilst it may be possible to collect data on this quality statement, it may be of limited value. Invasive breast cancer would need to be defined, or a proxy chosen, such as stage at diagnosis. The same applies

ID	Stakeholder	Statement number	Comments[1]
			for DCIS. Data could also be collected on date of MRI and date of surgery to work out if an MRI was given before surgery. However, we know that some patients may undergo multiple surgeries, which will complicate data collection, and may produce inaccurate results. Moreover, it would be difficult to determine what success looks like when collecting ‘negative evidence’ i.e. evidence that something was not offered. Unless the ‘specific clinical indications’ in this statement could be well-defined and recorded, you wouldn’t know whether the number that underwent MRI before surgery was the ‘right’ number or not. Statement 3. People with oestrogen receptor-positive (ER-positive), human epidermal growth factor receptor 2-negative (HER2-negative) or lymph node-negative early breast cancer have gene expression profiling and expanded immunohistochemistry tests [new 2016]. It should be possible to collect data to assess compliance with this statement. The hormone and lymph node status should be recorded against a patient’s records. Whether this test is offered may already, or in future, be collected via COSD, and so it should be possible to juxtapose the two to see whether it is being offered appropriately. Some consideration will need to be given to how to deal with cases where tests were offered but not taken up by the patient. Statement 4. People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of the tumour assessed [2011, updated 2016]. Invasive breast cancer would need to be defined, possibly by stage of diagnosis. This could then be juxtaposed with the HER2 and ER status records for the patient. It should be possible to record the date of recurrence and the date the receptor status was (re)assessed – i.e. you would need to make sure that the receptor status recorded upon recurrence was not simply a re-entry of the assessment made at the time of the primary diagnosis. It may be more difficult to include data on recurrent breast cancer and the re-assessment of the hormonal status, in a single indicator. In our opinion, recurrent breast cancer and tumour re-assessment would require a separate indicator to be meaningful. Furthermore, we are aware that data on recurrent and secondary breast cancer is poorly collected. If the correct systems and processes were in place, we believe it should be possible to collect this data in future. Statement 5. People with breast cancer who develop metastatic disease are assessed by a multidisciplinary team [2011, updated 2016]. We are aware that data on secondary breast cancer is not being collected consistently. However, recurrence should already be collected via COSD, as are the dates of any MDT meetings, where a particular patient is discussed. Therefore, if the correct processes were in place, we believe that it should be possible to design an indicator for this statement. Statement 6. People with locally advanced, metastatic or distant recurrent breast cancer are assigned a key worker [2011, updated 2016]. We are aware that data on secondary breast cancer is not being collected consistently, so we do not have an

ID	Stakeholder	Statement number	Comments[1]
			accurate picture of the numbers of people living with secondary breast cancer. However, we believe that with a good definition and the right systems in place, the accuracy of this data could be improved. Whether a patient is assigned a key worker is already being recorded for all cancer patients via COSD, in the presence of a Clinical Nurse Specialist code. Statement 7 (Placeholder). Exercise for people with breast cancer [new 2016]. We cannot comment on this statement as it is not yet defined.
13	The Society and College of Radiographers	1	The standard for the prompt diagnosis of suspected breast cancer is very desirable. The Society and College of Radiographers recognise that the recommendations are only applicable to *suspected* cancer; however, some of our members have noted that the number of referrals for non-suspected cancer is resulting in a poorer experience for suspected cancers patients. They are also concerned that there may be an increased likelihood of errors occurring. It is difficult to see how this level of service is sustainable if all breast referrals continue to be treated as suspected cancer.
14	Breast cancer now	1	We have no specific comment on the evidence of overuse as this is not an area we currently specialise in, however we can confirm that this recommendation appears to be in harmony with forthcoming guidance from the NHS England Breast Cancer Clinical Reference Group (CRG). The CRG, chaired by Professor Ian Smith, has developed breast cancer service guidance, 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 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 guidance with NICE. This guidance will recommend that “standard triple assessment should be undertaken at a single visit to ensure the patient has a positive experience of their care and to save resources. MRI should not be used as routine imaging but reserved for specific indications and reasons documented in the notes”.
15	The Society and College of Radiographers	2	Some of the members of The Society and College of Radiographers have experienced that MRI usage has been increasing for evaluating the contralateral breast with a low level of positive results. It seems to be their experience that unnecessary delays can occur when a mastectomy is planned for the ipsilateral breast. Therefore this is a change The Society and College of Radiographers would support to prevent unnecessary delays and is more cost effective if the evidence supports this as reality.
16	All Wales Breast Cancer National Specialist Advisory Group	2	There is no mention of using MRI to assess response to NAC and plan surgery, but could be covered under clinical indications.
17	Newcastle upon Tyne Hospitals	2	Please could you review the indications for pre-operative MRI use as there is evidence that MRI use is not mandated in the management of lobular breast cancers treated with BCS.

ID	Stakeholder	Statement number	Comments[1]
18	UK Cancer Genetics Group	3	need to clarify what is meant by genetic testing and differentiate between somatic testing of tumours and germline testing in lymphocytic DNA/normal tissue
19	Independent Cancer Patients' Voice	3	This statement seems a bit vague, as it doesn't specify the type of gene-expression or IHC4 profiling or suggest this is done as part of trials or registration studies. Also the guideline talks about offering this to people with intermediate risk, NI greater than 3.4, whereas this seems to include everyone, but doesn't explain why. Sounds good but is there evidence?
20	NHS England	3	If following NICE guidance it isn't HER2 negative OR lymph node negative - it's both and then only intermediate risk patients need gene profiling.
21	NHS England	3	"People with oestrogen receptor-positive (ER-positive), human epidermal growth factor receptor 2-negative (HER2-negative) or lymph node-negative early breast cancer" should be "and", I suppose – otherwise it would allow gene-profiling for every node- negative patient, irrespective of ER and HER2 status. This is repeated several times through the draft.
22	The Society and College of Radiographers	3	Routine IHC4 testing. Currently many centres conduct gene testing under the Oncotype guidelines. Will this proposal increase pathology reporting times for MDT and how will the Oncotype testing be applied across the networks?
23	Genomic Health	3	Whilst the new Quality Statement to encourage uptake of the NICE DG10 guidance for gene expression profiling for eligible people with early breast cancer (Quality Statement 3) is very much needed and welcome, we would suggest that important changes be made to the wording of this draft Quality Statement to avoid it directly contradicting existing NICE guidance and to ensure that it has the desired positive impact on the quality of breast cancer care. The draft statement fails to specify that only tests which have been assessed and recommended for use in clinical practice by NICE (i.e. in this case, the NICE DG10 guidance) should be used in clinical practice. In fact, in the section titled 'Definitions of terms used in this quality statement', the current draft specifically indicates that the term 'Gene expression profiling and expanded immunohistochemistry tests' (and therefore the Quality Statement itself) refers to all of the tests included in the NICE DG10 assessment. However, only one specific test (the Onco*type* DX® breast cancer test) was recommended in the NICE DG10 guidance as an option for use in clinical practice. The remaining tests were specifically recommended for research only. Therefore, Quality Statement 3 should NOT apply generally to 'gene expression profiling and expanded immunohistochemistry tests' as a group, as this would directly contradict the existing recommendation in NICE DG10. NICE's Quality Standards and their corresponding Quality Statements to guide clinical practice should be based on and be supported by existing NICE guidance pertaining to that. The different gene expression tests are NOT interchangeable, as they provide different information. The tests have been shown to categorise patients differently according to risk of progression and the tests are supported by varying levels of evidence. Only the Onco*type* DX® breast cancer test is supported by the highest level of evidence and was

ID	Stakeholder	Statement number	Comments[1]
			found by NICE to be cost-effective to the NHS. The current draft of Quality Statement 3 would be a risk to all three of the dimensions of quality that are stated in the draft Quality Standard itself (patient safety, patient experience and clinical effectiveness). Furthermore, there is a real risk of patients being misguided by the section 'What the quality statement means for patients, service users and carers', in terms of patients' option to be tested with a NICE-recommended and NHSE-reimbursed gene expression profiling test. It is therefore crucial that the wording of Quality Statement 3 be updated to specify only gene expression profiling tests that have been recommended by NICE as an option for use in clinical practice. Furthermore, no expanded immunohistochemistry tests are recommended by NICE in this clinical setting and so we suggest that mention of this type of testing should be removed from the Quality Statement. Please see below specific proposed amendments to the text for Quality Statement 3.
24	Genomic Health	3	*(Specific Proposed Amendments)* People with oestrogen receptor-positive (ER-positive), human epidermal growth factor receptor 2-negative (HER2-negative) or lymph node-negative early breast cancer have a gene expression profiling test which has been recommended in NICE Diagnostics Guidance as an option for use in clinical practice ~~and expanded immunohistochemistry tests~~ [new 2016].
25	Genomic Health	3	*(Specific Proposed Amendments)* Gene expression profiling ~~and expanded immunohistochemistry~~ tests aim to identify certain genes ~~or proteins~~ found in breast cancer tumours. Testing for the levels of expression of these genes ~~or proteins~~ can give an indication of how a tumour might develop, and therefore help in planning treatment. Gene expression profiling ~~and expanded immunohistochemistry~~ tests have been shown to be effective in guiding adjuvant chemotherapy in people with ER-positive, HER2-negative or lymph node-negative early breast cancer.
26	Genomic Health	3	*(Specific Proposed Amendments)* Evidence of local arrangements to provide gene expression profiling ~~and expanded immunohistochemistry~~ tests recommended in NICE Diagnostics Guidance as an option for use in clinical practice for people with ER-positive, HER2-negative or lymph node-negative early breast cancer.
27	Genomic Health	3	*(Specific Proposed Amendments)* Proportion of people with ER-positive, HER2-negative or lymph node-negative early breast cancer who receive a gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ recommended in NICE Diagnostics Guidance

ID	Stakeholder	Statement number	Comments[1]
			as an option for use in clinical practice. Numerator – the number in the denominator who receive a gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ recommended in NICE Diagnostics Guidance as an option for use in clinical practice. Denominator – the number of people with ER-positive, HER2-negative or lymph node-negative early breast cancer.
28	Genomic Health	3	*(Specific Proposed Amendments)* Service providers (such as secondary care services/specialist breast cancer services) ensure that systems are in place for people with ER-positive, HER2-negative or lymph node-negative early breast cancer to have a gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ recommended in NICE Diagnostics Guidance as an option for use in clinical practice. Healthcare professionals (such as doctors, nurses and specialists) ensure that people with ER-positive, HER2-negative or lymph node-negative early breast cancer to have a gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ recommended in NICE Diagnostics Guidance as an option for use in clinical practice. Commissioners (such as clinical commissioning groups) ensure that they commission services that undertake gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ing recommended in NICE Diagnostics Guidance as an option for use in clinical practice for people with ER-positive, HER2-negative or lymph node-negative early breast cancer.
29	Genomic Health	3	*(Specific Proposed Amendments)* People diagnosed with a particular type of early breast cancer (called oestrogen receptor-positive, lymph node-negative or human epidermal growth factor receptor 2-negative early breast cancer) have a gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ which has received a positive recommendation (as an option for use in clinical practice and not research only) in National Institute for Health and Care Excellence (NICE) Diagnostics Guidance. The results of ~~these~~ such a test~~s~~ will help with the decision~~s~~ about the necessity for adjuvant chemotherapy treatment after surgery to remove the cancer.
30	Genomic Health	3	*(Specific Proposed Amendments)* Gene expression profiling ~~and expanded immunohistochemistry~~ test~~s~~ recommended in NICE Diagnostics Guidance

ID	Stakeholder	Statement number	Comments[1]
			as an option for use in clinical practice This refers to a gene expression profiling test, which has received a positive recommendation for use in clinical practice in relevant NICE diagnostics guidance, ~~with MammaPrint, Oncotype DX, IHC4 and Mammostrat~~ used to identify certain genes ~~or proteins~~ found in breast cancer tumours. [Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat (NICE diagnostics guidance DG10)]
31	Genomic Health	3	Gene expression profiling for early breast cancer, as is addressed in Quality Statement 3, is an example of genomic testing, NOT genetic testing. We suggest that, to avoid confusion, any genetic testing which may be identified for inclusion in the updated Breast Cancer Quality Standards should be addressed in a separate Quality Statement. Gene expression profiling for early breast cancer is a sufficiently important topic to merit its own Quality Statement so as not to lead to confusion or dilute the its impact. Genetic testing is a separate issue entirely which requires specific levels of support from dedicated professional able to interpret the genetic results and counsel the patient regarding the wider impact. The provision of genetic testing requires a very different approach provided by a very different group of professionals which in turn should require a totally different quality standard to ensure high a quality standard.
32	All Wales Breast Cancer National Specialist Advisory Group	3	This statement should be re-worded to clarify that gene profiling is only appropriate for patients with ER+ and HER2 negative and node negative breast cancer; also, it should be clarified whether the quality standard recommends testing of all such patients, or only those at intermediate risk of recurrence (as is currently the case in Wales, in line with current NICE guidance).
33	Manchester cancer	3	It is not clear exactly what group of patients it is referring to (e.g. are er+ her neg node neg patients included or not, are er neg her neg node neg patients included etc.) Genetic profiling is not currently used or funded for some of the patients (e.g. er pos her pos node neg) nor for patients with an excellent prognosis (e.g. grade 1 er pos her neg node neg) as it doesn't always inform the decision for chemotherapy. Also genetic testing could be omitted in patients with a performance score of over 2 or who refuse to consider chemotherapy.
34	Breast cancer now	3	Yes, there are several areas of genetic testing for familial breast cancer that could be considered for inclusion in the BCQS. 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. The 2016 NICE Familial Breast Cancer clinical guideline (CG 164) review will be considering what referral criteria are

ID	Stakeholder	Statement number	Comments[1]
			appropriate to decide referral to a specialist genetic clinic for patients with an isolated breast cancer and no family history. This is because evidence was identified that genetic testing should potentially be extended to those under 50 with triple negative breast cancer regardless of family history. The existing NICE Familial Breast Cancer clinical guideline also recommends that: People whose family history meets guidelines for genetic referral should be offered the opportunity to discuss genetic testing with a specialist genetic service. □ Breast cancer patients who have a BRCA gene mutation identified as part of their cancer treatment should be referred to the clinical genetics service
35	All Wales Breast Cancer National Specialist Advisory Group	4	Support this, would presume “clinically appropriate” to mean retesting if biopsy possible and if it would affect treatment decisions, sounds fine.
36	Breast cancer now	4	We provided an evidence breakdown to the technical analyst for the NICE Advanced Breast Cancer guideline on this point, given that this issue forms part of the 2016 review of this clinical guideline. However, we are not ourselves clinical experts and so we think it is not for us to answer this question. The NHS England Breast Cancer Clinical Reference Group (CRG), chaired by Professor Ian Smith, has developed breast cancer service guidance, 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 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 guidance with NICE. This guidance will recommend that “Re-biopsy with re-assessment of ER and HER2 markers on disease recurrence is strongly recommended. This is to confirm histology and determine whether markers (ER, HER2) have changed, altering treatment options.” Advice we have received from the Chair and Vice-Chair of the CRG on this point is that everyone should be re-biopsied as a starting point. However this is not always possible, for example when someone is clearly not fit for further treatment, or if it is considered too dangerous to biopsy.
37	Independent Cancer Patients’ Voice	5	This is excellent.
38	The Society and College of Radiographers	5	Some of our members note that within their service patients with metastatic cancer do appear to be assessed by the multi-disciplinary team and are included in discussions at the weekly MDT. However it is unclear how robust systems are to ensure all clinicians refer these women back to the breast team or what lines of communication are opened between different multi-disciplinary teams to ensure continuity of care and the appropriate sharing of relevant information. The Society and College of Radiographers would assume this is an integral part of the key workers role

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			as described in statement 6? Evidence could be obtained if the necessary resources were provided to interrogate the patient records. However data quality is often poor and some of our members report that collecting factual information regarding patient pathways and clinical activity is unpredictable.
39	Breast cancer care	5	Breast Cancer Care is pleased to see that this statement has been retained in the updated Quality Standard (QS). As stated in our response to the engagement exercise for this QS, we know from talking to people with secondary (metastatic) 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. Retaining this as a statement is a step towards ensuring that all patients with a secondary diagnosis benefit from consistent information and co-ordinated treatment from all those involved in their care. As noted in our response to the engagement exercise for this QS, the new Cancer Strategy* for England highlights the value of MDTs: '*They are seen as the 'gold standard' in terms of cancer patient management*'. It also recognises the need for MDTs to focus on the needs of those with more complex cases, such as those with metastatic breast cancer: *'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.'* *Recommendation 46: The Trust Development Authority, Monitor and NHS England should encourage MDTs to consider appropriate pathways of care for metastatic cancer patients. Clinical Reference Groups will need to play a key role in supporting these MDTs.* ----- *The Independent Cancer Taskforce (2015), *Achieving world-class cancer outcomes: A strategy for England 2015-2020*. Available at: http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf
40	Independent Cancer Patients' Voice	Question 6	Action is needed to ensure prescribing of Tamoxifen for prevention in high risk women despite off licence use and post patent.

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			ONCOTYPE DX is not the only biomarker/predictor available – some may be as/more appropriate and cheaper?
41	Independent Cancer Patients' Voice	6	This is excellent but all patients should have named CNS and prompt access when needed to psychological expertise and advice.
42	Royal College of General Practitioners	6	'Assigned a key worker'. It could be a good idea for people with advanced or advancing breast cancer to have a key worker, but it will make little or no difference to the patients' experience if they don't see the key workers regularly and develop a relationship with them. The risk of applying it as a quality standard is that it becomes a purely nominal exercise of making sure that someone's name appears in that box in the patients' records. If it is to mean anything then the measurement has to be by asking the patients 'Do you know who your key worker is?', and 'How often have you seen that person in your visits to the hospital?' (DJ)
43	Breast cancer care	6	Breast Cancer Care is pleased to see that this statement has been retained in the updated Quality Standard (QS). As stated in our response to the engagement exercise, there is still a great variation in levels of access to a secondary (metastatic) Clinical Nurse Specialist (CNS) across the country. In the current statement, it is specified that the 'key worker' is '*a clinical nurse specialist whose role is to provide continuity of care and support, offer referral to psychological services if required and liaise with other healthcare professionals, including the GP and specialist palliative care services'.* We are concerned that the removal of this from the updated version of the statement risks losing the clinical expertise that a CNS role provides, which a key worker may not have. The National Cancer Patient Experience Survey* has shown that the single most important factor associated with high patient scores, in every tumour group, is the patient being given the name of a CNS in charge of their care. This is also echoed in the new Cancer Strategy for England. ----- * NHS England (2014) Cancer Patient Experience Survey 2014 – National Report. Available 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).
44		6	There is strong evidence to suggest that there is significant variation in people with advanced breast cancer having a key worker assigned to them. Breast Cancer Now runs a hospital improvement programme called the Secondary Breast Cancer Pledge in partnership with Breast Cancer Care to improve care for people with secondary breast cancer. We compiled patient experience data on access to a key worker from the 2014 and 2015 Secondary Breast Cancer Pledge questionnaire – this covers 10 hospitals and 444 patients. The results are summarised in the table below.

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			The term ‘key worker’ isn’t used in the survey question because in our experience patients did not necessarily recognise this specific term which then skewed the results. Have you got ongoing support from a nurse who has knowledge and skills to support you with your secondary breast cancer? Answer Options Response Percent Response Count Yes 66.00% 293 No (please go to question 21) 29.00% 128 Don’t know (please go to question 21) 5.00% 23 answered question 444 skipped question 19 In addition, a report produced by Breast Cancer Campaign (one of the charities that merged to form Breast Cancer Now) in 2013 mapped results of the Cancer Patient Experience Survey against corresponding statements in the existing BCQS. It concluded that, while in general, women with breast cancer have relatively good access to a Clinical Nurse Specialist (CNS), there is evidence that they are not consistently available to women with secondary breast cancer. This report is included as an attachment. Evidence from the National Cancer Intelligence Network’s 2012 metastatic breast cancer pilot revealed that only half of patients were referred to a CNS or other key worker at the time of recurrence or metastasis. The pilot also identified significant variation in the proportion of secondary breast cancer patients for whom there was no referral to a CNS recorded. We are also aware that CNS’s do not always feel that they have the requisite skills to deliver specialist care specifically for metastatic breast cancer patients. For example, Reed et al (2010) conducted a survey of 276 breast cancer nurses which reported that 57% felt unable to adequately care for patients with metastatic breast cancer due to not having the time or the necessary skills. The importance of a key worker to patient experience and care Breast Cancer Now compiled patient experience data on access to a key worker from the 2014 and 2015 Secondary Breast Cancer Pledge questionnaire, which highlights the importance of having a nurse specialist to patient experience and care – again this data covers 10 hospitals and 444 patients. 94% of patients who had access to ongoing support from a nurse specialist agreed or strongly agreed that the nurse was able to provide them with information and support relating to secondary breast cancer, whenever they had concerns or questions 92% of patients who had access to ongoing support from a nurse specialist agreed or strongly agreed that their nurse has or will talk to their Oncologist, GP or other healthcare professionals on their behalf 79% of patients who had access to ongoing support from a nurse specialist agreed or strongly agreed that the nurse helped them coordinate care, including appointments, tests and results Some further qualitative comments help to illustrate the impact of the key worker on individual patients: “It is important to have support to enable individuals to deal with their emotions effectively.” (Secondary Breast Cancer Pledge, 2015 patient survey response) “I was referred to the psychologist and have access to further help from her if necessary, but initially I experienced emotional problems because of having no one to talk to when I was first diagnosed. A specialist nurse at this stage

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			could have been of great help.” (Secondary Breast Cancer Pledge, 2015 patient survey response) ☐ “I have already spoken with my specialist nurse. It was very helpful!” (Secondary Breast Cancer Pledge, 2015 patient survey response) ☐ In one hospital site, none of the patients had a named nurse – and they felt that this would be really beneficial as it had been invaluable when they had their primary diagnosis and secondary was comparatively much harder to deal with. (Secondary Breast Cancer Pledge, 2015 patient focus group) Finally, although it does not distinguish between primary and secondary patients, the 2014 Cancer Patient Experience Survey ‘key drivers’ analysis of the 2014 data shows that “the single most important factor associated with high patient scores, in every tumour group, is the patient being given the name of a clinical nurse specialist (CNS) in charge of their care”. Supporting information Finding the cures improving the care: Our recommendations for using the Breast cancer quality standard to achieve better care, Breast Cancer Campaign, 2013 (included as an attachment) National Cancer Intelligence Network, Recurrent and Metastatic Breast Cancer Data Collection Project: Pilot report, March 2012 28. Department of Health, Improving Outcomes: A Strategy for Cancer – Third Annual Report, December 2013 29. Available here: http://www.ncin.org.uk/publications/data_briefings/recurrent_and_metastatic_breast_cancer Reed E et al, A survey of provision of breast care nursing for patients with metastatic breast cancer, European Journal of Cancer Care, 19, 575–580, 2010. Available here: http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2354.2010.01213.x/abstract;jsessionid=AAA8CC2BA33101624133EDDEFD45C275.f01t04?userIsAuthenticated=false&deniedAccessCustomisedMessage=
45	The Society and College of Radiographers	6	The Society and College of Radiographers would request that this statement below be amended to include a ‘specialist Therapeutic Radiographer’ as role is in place in Radiotherapy departments fulfilling care. This support is delivered by both Palliative care specialist roles and Breast Cancer specialist Therapeutic Radiographer roles. ‘*What the quality statement means for patients, service users and carers* People with locally advanced, metastatic or distant recurrent breast cancer are assigned a healthcare professional (often a nurse who specialises in breast cancer) as their ‘key worker’. This ensures that they receive all the information and support they need throughout their care.’
46	Independent Cancer Patients’ Voice	7	This statement seems as if it is going to need a good deal of flesh on it to be useful, but it is an important topic.
47	NHS England	7	The American Cancer Society published few years ago a guidance about nutrition and exercise in cancer survivors. It is not specific for breast, however you may find it useful. Reference: Nutrition and Physical Activity Guidelines for

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			Cancer Survivors, April 26, 2012 in *CA: A Cancer Journal for Clinicians*.
48	Royal College of General Practitioners	7	I can well believe that exercise will have some positive effects (though whether this is via cancer deaths or ischaemic heart disease deaths is a question that the epidemiologists should look for when they assess the evidence). What we do know is that health professionals telling patients to exercise has very little influence on patients' behaviour. Just as above, the risk is that professionals are asked to give advice; it becomes a box to be ticked on the record; and has no effectiveness on patients' behaviour. (DJ)
49	UK Cancer Genetics Group	7	There is anecdotal evidence re variation in usage of chemoprevention, but confusion in the NICE guidelines (familial breast cancer) about who should provide information/prescriptions have contributed to this variation, along with GP reluctance (understandable) to prescribe a drug for an unlicensed use.
50	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	ACPOPC welcomes the opportunity to comment on this draft quality standard. We are pleased to see that NICE is including a quality statement on exercise for people with breast cancer.
51	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	ACPOPC welcomes the invitation to advise on evidence based guidance for this statement
52	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	ACPOPC believes greater specificity is required when defining outcomes. e.g. exercise has been shown to promote improvement in o shoulder function o survival o risk of re-occurrence of symptom o vasomotor symptoms Further clarification on this may be required.
53	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	ACPOPC would like to advise caution with terminology relating to exercise and to suggest there is a need to be clear on the difference between "physical activity" which tends to be more general and "exercise" which can be very specific.
54	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	Exercise may be used to promote different outcomes at different stages in a breast cancer pathway. If this Quality Statement is covering the whole treatment trajectory then the variety of exercise as treatment needs exploration. Or, as suggested, there may be scope for new evidence-based guidance relating to exercise and improved health

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			outcomes for people with breast cancer
55	Association of Chartered Physiotherapists in Oncology and Palliative Care	7	There is evidence around physical activity promotion and the benefit of that in improving people's activity levels following breast cancer diagnosis (for specific references see below). Evidence for Specific Shoulder Problems: Mcneely et al 2010 (systematic review); De Groef et al 2015 systematic review. Evidence for Vasomotor symptoms: Ibrahim et al 2010; Mutrie et al RCT Evidence for physical activity: Whitehead and Lavelle 2009; Chiefetz et al. 2015; Wu et al 2013; Schmitz et al. 2010; Bourke et al 2015; Irwin et al 2008; Daley et al 2007; Evidence specifically for decreased risk of re-occurrence and increased survival: Holmes et al 2005; Speck et al 2010. Evidence for psychological health: Penedo et al 2005 Evidence for reduced fatigue: Schwartz et al 2001; Cramp et al Evidence for improved quality of life both during and after treatment: Knols et al 2005 (systematic review); Courneya et al 2003 References BOURKE. L, H. K., THAHA. MA, STEED. L, ROSARIO. DJ, ROBB. K, SAXTON. J AND TAYLOR. SJC 2015. Interventions for Promoting Habitual Exercise in People Living with and Beyond Cancer. *The Cochrance Review* CHEIFETZ, O., DORSAY, J. P. & MACDERMID, J. C. 2015. Exercise facilitators and barriers following participation in a community-based exercise and education program for cancer survivors. *Journal of exercise rehabilitation,* 11, 20-9.

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			survivors during adjuvant treatment. Are there lasting effects? *Journal of Cancer Survivorship-Research and Practice,* 6, 420-430. Knols R, Aaronson NK, Uebelhart D, Fransen J, Aufdemkampe G. Physical exercise in cancer patients during and after medical treatment: a systematic review of randomized and controlled clinical trials. J Clin Oncol2005;23:3830-42. OGUNLEYE, A. A. & HOLMES, M. D. 2009. Physical activity and breast cancer survival.*Breast Cancer Research,* 11. PENEDO, F. J. & DAHN, J. R. 2005. Exercise and well-being: a review of mental and physical health benefits associated with physical activity. *Current Opinion in Psychiatry,* 18, 189-193. SCHMITZ, K. H., COURNEYA, K. S., MATTHEWS, C., DEMARK-WAHNEFRIED, W., GALVAO, D. A., PINTO, B. M., IRWIN, M. L., WOLIN, K. Y., SEGAL, R. J., LUCIA, A., SCHNEIDER, C. M., VON GRUENIGEN, V. E. & SCHWARTZ, A. L. 2010. American College of Sports Medicine Roundtable on Exercise Guidelines for Cancer Survivors.*Medicine and Science in Sports and Exercise,* 42, 1409-1426. SCHMITZ, K. H. & SPECK, R. M. 2010. Risks and benefits of physical activity among breast cancer survivors who have completed treatment. *Women's health (London, England),* 6, 221-38.
56	Breast cancer care	7	Breast Cancer Care welcomes the inclusion of a new quality statement on exercise for people with breast cancer. As stated in our response to the engagement exercise for this Quality Standard, 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. We would recommend a statement along the lines of: ‘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.’ ---- *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: http://annonc.oxfordjournals.org/content/25/7/1293.full.pdf+html
57	Breast cancer now	7	There is now clear evidence to show that patients who maintain a healthy weight and take the recommended exercise

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			can reduce the risk of breast cancer recurrence, sometimes to the same degree as adjuvant medical treatment (a reduction in risk of approximately 30 per cent). See in particular the following review: Association between physical activity and mortality among breast cancer and colorectal cancer survivors: a systematic review and meta-analysis The following may also be useful: World Cancer Research Fund International/American Institute for Cancer Research Continuous Update Project Report: Diet, Nutrition, Physical Activity, and Breast Cancer Survivors. 2014. The NHS England Breast Cancer Clinical Reference Group (CRG), chaired by Professor Ian Smith, has developed breast cancer service guidance, 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 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 guidance with NICE. This guidance will state that “Evidence shows that patients who maintain a healthy weight and take regular exercise can reduce the risk of recurrence in breast cancer, sometimes to the same degree as with adjuvant medical treatment. It is therefore mandatory that all patients are given advice on weight control and regular moderate exercise”. The 2015 Cancer Strategy puts a strong emphasis on lifestyle-based secondary prevention. It states that “with an increasing number of patients surviving their primary cancers, there is a growing need for the health service to tailor preventative approaches to reduce the chance of secondary cancer (metastasis)”. It argues that there is strong evidence for physical activity: “regular exercise has been shown through multiple observational studies to reduce the risk of a number of different types of cancer by 10-50% and also to reduce the risk of cancer-specific death. The majority of the evidence is in early breast cancer, but there is also evidence in early colorectal, prostate and ovarian cancers.” The strategy recommends that “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 include healthy eating, weight control, physical activity levels, smoking cessation and alcohol consumption, to help prevent secondary cancers.” The strategy also highlights research which has shown that people who have had cancer would like more information about how to approach lifestyle changes, and would also welcome support tailored to their individual needs. Breast Cancer Now has a key web-based resource about the role of physical activity in reducing breast cancer risk, called BRISK which is quality assured by the Information Standard, including a useful factsheet. This is primarily about reducing risk of primary breast cancer, however it could be a useful model for developing evidence-based guidance aimed at people with breast cancer. Breast Cancer Now is also funding ongoing research to expand knowledge and understanding in this area. For

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			example, we are currently funding a research project which aims to find the best exercise programme for people with breast cancer, in order to help people with breast cancer reduce their risk of recurrence.
58	Breast cancer care	Question 9	Regarding consultation question 9 on whether there evidence to suggest variation in offering chemoprevention to women who have an increased risk of breast cancer, and in the use of drugs such as tamoxifen in premenopausal women: We feel that the issue here may be less about variation in offering chemoprevention, and more about low uptake and low adherence rates. For example, Breast Cancer Care speaks to healthcare professionals who support younger women. We have seen evidence of extremely low uptake when patients are offered tamoxifen. Discussions about why this is the case focused on: • The impact of side-effects, which may be deterring women from taking up chemoprevention, and impacting on adherence rates for those who do take it up. • Many women opt for prophylactic breast surgery instead of chemoprevention, which has higher risk reduction success. Breast Cancer Care feels that there may be scope for including a statement in the Quality Standard around ensuring there is adequate support for women eligible for chemoprevention, so that side effects and other concerns can be addressed, to improve uptake and adherence rates.
59	Breast cancer now	Question 9	There is clear evidence to show that there is variation in eligible patients being offered chemoprevention to reduce their risk of developing breast cancer, despite the NICE Familial Breast Cancer clinical guideline recommending its use in 2013. Breast Cancer Now believes that a statement on this in the BCQS could really add value to the efforts to implement this treatment on the NHS. Breast Cancer Now has conducted qualitative research which clearly illustrates this variation. Highlights of this paper are included in appendix 2. The full paper is also included as an attachment. Although this research is now 16 months old, through our continued work on this issue, we are still coming across further case studies of the treatment either not being offered or not being prescribed. In particular, there are several key clinicians working in this field who continue to highlight to us such case studies and the challenges they are experiencing in trying to implement the treatment. These clinicians are happy to be contacted for further advice and to discuss this evidence: Anthony Howell, Professor of Medical Oncology; Research Director of the Genesis Breast Cancer Prevention Centre, University Hospital of South Manchester

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			T: 0161 291 4422/4408; E: tony.howell@ics.manchester.ac.uk □ Gareth Evans, Professor of Genomic Medicine and Cancer Epidemiology/ Honorary Consultant Clinical Geneticist, Manchester Centre for Genomic Medicine, University of Manchester. E: Gareth.Evans@cmft.nhs.uk □ Professor Jack Cuzick FMedSci FRCP(hon), John Snow Professor of Epidemiology; Head, Centre for Cancer Prevention; Director, Wolfson Institute of Preventive Medicine, Queen Mary University of London. E: j.cuzick@qmul.ac.uk Further qualitative research undertaken by the Pan-London Familial Breast Cancer Steering Group highlights variation in implementation across the London area, but unfortunately we are not at liberty to share it. For further information, please get in touch with Liz Jones, Programme Manager, Transforming Cancer Services Team, South East CSU. E: liz.jones9@nhs.net; T: 020 3049 4331 There is also some key research on this issue nearing completion, by Dr. Samuel Smith of the Centre for Cancer Prevention, Queen Mary University of London (T: +44 (0)20 7882 5698; E: Sam.smith@qmul.ac.uk), titled Clinician-reported barriers to implementing breast cancer chemoprevention in the UK: A qualitative investigation. Dr Smith conducted semi-structured interviews with GPs and clinicians working in family history or clinical genetics settings (FHCG clinicians). He found that FHCG clinicians reported difficulties interpreting the NICE guidelines, were focused on a perceived lack of benefit of preventive therapy, and felt poorly informed about preventive therapy which discouraged them from raising it with patients. With regards to GPs, he found that they were unfamiliar with the concept of preventive therapy, were not aware that they may be asked to prescribe it for high risk women, and were reluctant to initiate therapy because it is not licensed for that indication (however, they were willing to continue a prescription if it had been started in secondary or tertiary care). Dr Smith's research illustrates that barriers to implementing preventive therapy within routine clinical practice are common and arise from a combination of factors. Dr Smith also conducted a systematic review (published January 2016) of the factors affecting uptake and adherence to breast cancer chemoprevention. His finding that uptake is significantly lower outside of a controlled trial setting points strongly towards difficulties in implementing chemoprevention in routine care.
60	Breast cancer now	Question 9	A Evidence compiled by Breakthrough Breast Cancer in latter half of 2013 regarding prescribing chemoprevention treatments off-label Consultant Clinical Geneticist, Wales (Genetics Clinic) Anecdotally, I have found that some GPs, generally older ones, would be happy to prescribe chemoprevention but that in general, younger GPs are more reluctant. I think this might be because they are more protocol driven and would be reluctant to prescribe a drug for an unlicensed indication." Advanced Nurse Practitioner, Surrey (Family History Clinic) "In cases where I have discussed it with a patient and they've wanted to proceed, I've written a letter to the GP stating

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			that the patient is eligible under the NICE criteria, and enclosing a copy of the NICE guideline. However, some GPs have written back to say that they will not prescribe as the drugs are not licensed for preventative use." GP, Nottingham "One of the main issues for GPs is the lack of license for preventative use which is making some GPs uncomfortable about prescribing the drugs for this use." Breast Surgeon, Derby (Family History Clinic) "The drugs are unlicensed for preventative use which could pose problems in getting GPs to prescribe." Consultant Clinical Geneticist, London (Genetics Clinic) "Of three GPs I've written to asking them to prescribe chemoprevention for patients, two have refused to prescribe it and a third is still considering whether to do so." B Responses from a survey conducted by Breast Cancer Campaign in August-September 2014 We asked people if they knew of instances where they work in which women who were eligible for the chemoprevention drugs tamoxifen and raloxifene had been offered these drugs to lower their risk of developing breast cancer. Responses included: Breast surgeon, Yorkshire – "We have started to offer this but the FH [Family History] clinic is not structured yet so it is pot luck which patient sees the right doctor" Breast Clinician – "Capacity issues in family history service means not time to discuss with ladies" Associate Specialist Breast Clinician, Family History Breast Clinic Lead, Bath and Bristol – "I run a secondary referral centre family history breast clinic and as such this is occasionally raised by patients but not routinely discussed." Prescribing Adviser – "This is still a relatively new approach to managing these women. I am not aware that the appropriate national/regional supporting services are in place to support widespread routine adoption." Lead family history service, North West – "We have no agreed pathway for this to happen for either high or moderate risk women. For high risk women I mention chemoprevention. I use the leaflets from genetic alliance and give to patient and to GP. I explain we have no current pathway. I tell them to return to GP if they want them. I have no idea how many return." Advanced Breast Nurse Practitioner, Liverpool – "patients are offered this as a treatment option often when they themselves enquire about it as part of a family history consultation." We asked people who knew of instances where they work in which women could have benefitted from these drugs but were not offered them, the reasons why this was the case. Responses included: Consultant Breast Surgeon, East Midlands – "Active promotion [of chemoprevention drugs] is not current practice" Advanced Breast Nurse Practitioner, Liverpool – "Not sure who was going to be responsible to prescribe and oversee the patients' care following prescribing." Breast surgeon – "Lack of structure in clinic; too many locums and doctors without sufficient knowledge seeing patients in overbooked clinics with grossly insufficient time for FH [Family History] assessment or discussion."

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			Consultant breast surgeon, Mersey region – “we do not "case find" women who are at moderate risk but if they present we will be happy to discuss it with them” Clinical geneticist, North – “Not discussed” Where people had concerns about prescribing tamoxifen and raloxifene off-label for chemoprevention, we asked what these concerns were. Responses included: Consultant Breast Surgeon, East Midlands - “There is complete lack of clarity as to responsibility for prescribing and monitoring [chemoprevention drugs] on a national basis” Clinical Geneticist, Wales – “Although I am happy to recommend them if a woman has an increased risk because of her family history, I accept that we are asking a lot of GPs who are expected to prescribe them and monitor for side effects.” Prescribing Adviser – “There is a widespread lack of training and clinical support to implement the NICE recommendations.”
61	Independent Cancer Patients’ Voice	Additional statements	In aftercare programs we feel the following is important: • Advertise more the self-referral to breast screening services • Advise patients how to self-examine. (Some patients may prefer not to go for annual screening) • Teach patients how to manage care of the arm, to reduce the chance of lymphoedema, using massage techniques. (Not difficult, lots on YouTube) • Advise patients what symptoms may indicate spread or recurrence. • Advise patients re adequate sleep and rest, especially sleep. • Advise patients re healthy living, proper nutrition (10 veg and fruit a day) • Input via the NCRI Breast Sub Group originally chaired by Dr Adrienne Morgan from ICPV, emphasises the need for data collection on quality of life in short, but also long-term survival; encouragement re adherence to treatment; help with self-management and feedback of data when no longer in routine follow up
62	Independent Cancer Patients’ Voice	Additional statements	• Important to improve surgical techniques to reduce physical trauma of lymph node sampling. (Nerve damage, etc.) • Improve suturing to reduce scarring and have better cosmetic outcome, even with mastectomy. (Why have an ugly scar?) • Consider margins greater than 2mm. • All patients needing mastectomy should be given choice of type of surgery and referred to alternative centre for oncoplastic opinion if necessary
63	Independent Cancer Patients’ Voice	Additional statements	Lymphoedema – recommendations all seem to be about treating – should focus primarily on prevention. Huge costs to NHS in terms of long-term treatment but worse in physical and psychological costs to patients. Perioperative treatment and advice may increase initial costs but result in long term savings for NHS and patients

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64	Independent Cancer Patients' Voice	Additional statements	Low doses of Bisphosphonates should be considered for all patients prescribed AIs NB: If offering bisphosphonates, ensure oral medication given to reduce risk of osteonecrosis of the jaw.
65	Independent Cancer Patients' Voice	Additional statements	Breath Hold (heart spare) for RT is mentioned in information but doesn't appear in recommendations?
66	Independent Cancer Patients' Voice	Additional statements	ICPV would like to also highlight the following areas for quality improvement: • Research: this is extremely important to patients. It should be routine that all patients are given information about any appropriate trials and opportunities to contribute to research which may benefit future patients. • Tissue donation: as with research, extremely important to patients. All should be offered the opportunity to donate tissue where possible. Off-licence drugs – Urgent need for resolving issue of prescribing off licence – drugs which are now off patent but which research has shown to have alternative effective use. E.g. Use of Tamoxifen for prevention – GPs are likely to be reluctant to prescribe as now out of patent and not licenced for prevention?
67	Breast cancer care	Additional statements	Breast Cancer Care is disappointed that a statement around offering a prompt referral to a fertility specialist for people diagnosed with breast cancer is not included in this draft update. In our response to the engagement exercise, we suggested the following statement: '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, whether they have a partner or not, to discuss options for trying to preserve fertility before starting chemotherapy or hormone treatment.' In the NICE briefing paper for this Quality Standard (QS), the rationale for not including such a statement was given. The rationale was formed of two parts: 1) That this area is not contained in any of the development sources. 2) That this area is covered in the NICE Quality Standard for Fertility (QS73) We disagree with this rationale, for the reasons below: 1) As outlined in our first comment on this Quality Standard, the primary development sources for this guide include both of the current NICE guidelines for breast cancer (CG80 & CG81). Neither of theses guidelines have been updated since 2009. We therefore feel that it is not appropriate to decide against including a statement on offering prompt referrals to a fertility specialist in the QS based on this omission alone.

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			2a) The implication in point 2 is that breast healthcare professionals will consider the fertility QS when caring for a breast cancer patient. However, this clearly is not happening consistently. We know that breast healthcare professionals are unlikely to refer to the fertility QS, as this is not their specialism. There needs to be a prompt that encourages breast healthcare professionals to initiate a fertility discussion with their patients needing chemotherapy and/or hormone treatment and refer them on to a fertility specialist. We believe that having a dedicated statement in the QS will go some way to achieving this. As a minimum, this statement should cross-reference the fertility QS. 2b) The statement referred to in the fertility QS is focussed on access to cryopreservation - *‘People preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation.’* This does not adequately cover the fundamental aspect of our suggested statement, which is that patients should be offered a prompt referral to a fertility specialist, so that they can have the discussions that will enable them to make an informed decision about the options available to them before their cancer treatment commences. As highlighted in our response to the engagement exercise, Breast Cancer Care’s research* found that the majority (88%) of younger women with a breast cancer diagnosis are not being referred to a fertility clinic. This is leaving an estimated 5000 younger breast cancer patients across the UK missing out on fertility care. What people tell us As the only UK-wide breast cancer support charity, we speak with many younger women about the issue of the impact of treatment on fertility, through our services such as Younger Women Together, our Helpline and Ask the Nurse email service. A prompt referral to a fertility specialist is so important, as illustrated in the following quotes from younger women with breast cancer: *‘On the day I was told I had cancer I was also told I wouldn't have children…Being told this was just as devastating as being told I had cancer. When I questioned this no one seemed to know where to refer me too. No one had knowledge about fertility as obviously their main concern was my cancer.’* *‘I wasn't automatically given a referral to the fertility specialist pre treatment and now 5 years on I am still upset about this… I feel that discussions at earlier times would have left me in a much better place now’*

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			We know that the level of discussions had between patients and their healthcare team vary tremendously. One person told us that '*At diagnosis I was assured many times that I would be eligible for fertility treatment and not to worry.'* No further discussion was had and this person was later turned down for fertility treatment on the NHS, causing great distress. *'I do hope that NICE consider including fertility in their updated quality standard for breast cancer, as it may offer some hope to more young women that want a family in the future, but don't think to mention it when receiving their results in their consultation where their treatment plan is set. '* Positive stories really highlight the impact a prompt referral can have: *'I was one of the lucky ones. I was referred straight away and managed to get seven embryos in the freezer before chemo. It was hard, but I was well supported by my medical team at the time. I have heard on so many occasions that women didn't have time to undergo fertility preservation or that the options were not presented to them'.* *'My partner and I don't yet have any children, so I am very fortunate in that I was immediately referred to a fertility clinic to proceed with fertility preservation prior to starting chemotherapy. I know that not all hospitals make this initial referral, or even talk to women my age with this diagnosis, but I feel very strongly that this should be discussed as soon as possible.'* We would urge NICE to reconsider including a statement around prompt referrals to a fertility specialist in the updated Quality Standard. We are concerned that opportunities will be missed for people diagnosed with breast cancer to have these conversations. As survival rates continue to improve for breast cancer, the issue of fertility after a breast cancer diagnosis will only grow as an issue of importance to patients. ---- *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: http://www.touchoncology.com/system/files/private/articles/21608/pdf/bsmith_0.pdf
68	Breast cancer care	Additional statements	Breast Cancer Care is disappointed not to see a statement in the draft update about offering adjuvant bisphosphonate therapy to post-menopausal women with early breast cancer. We suggested a statement such as:

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			'Post-menopausal women with early breast cancer to be offered adjuvant bisphosphonate therapy to reduce the risk of bone metastases and breast cancer mortality.' As stated in our response to the engagement exercise, implementing this standard has great potential to reduce the number of post-menopausal women who experience a breast cancer recurrence and to reduce breast cancer mortality. The new Cancer Strategy for England has included the following recommendation: *Recommendation 47: NHS England should commission NICE to develop updated guidelines for adjuvant treatment for breast cancer. Updated guidelines should consider the use of bisphosphonates and aromatase inhibitors to prevent secondary cancers in women previously treated for early stage breast cancer. CCGs should ensure that GPs are appropriately prescribing these agents once these guidelines are published.* As the NICE guidelines for breast cancer (CG80 and CG81) are due to be updated, but will not be for some time, we would urge NICE to consider including a statement of this kind in the updated Quality Standard ahead of this update.
69	Breast cancer now	Additional statements	Dear Sir/Madam, Re: draft Breast Cancer Quality Standard I am writing concerning the consultation on the draft Breast Cancer Quality Standard. Breast Cancer Now is grateful for the opportunity to contribute to this consultation, and we plan to respond in the usual way using the comments form. However, there is a further issue that we feel warrants urgent attention in advance of the closure of the consultation. Bisphosphonates to reduce the risk of breast cancer spread In our response to the consultation on the scope of the Quality Standard, we suggested that a new quality statement should be included - that postmenopausal women with early invasive breast cancer are offered treatment with bisphosphonates to reduce the risk of breast cancer spreading to the bone. This is because significant new evidence was published in July 2015 which supports a change in clinical practice. 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%. The researchers estimated 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 if the treatment is implemented routinely.

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			The prevention of 1,000 cases of secondary breast cancer every year would also amount to significant cost-savings for the NHS. Rationale for inclusion in the new BCQS We believe there is a particularly strong rationale for this being included in the new Breast Cancer Quality Standard. 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 company is likely to act as an advocate for the drug(s) in its new indication. 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 to authorise companies to advertise it to health professionals, 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. Therefore, because there are likely to be particular challenges around getting this treatment into routine commissioning, despite very strong evidence to support a change in 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 new Quality Standard. NHS England guidance The NHS England Breast Cancer Clinical Reference Group (CRG), chaired by Professor Ian Smith, has developed breast cancer service guidance, 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 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 guidance with NICE. This guidance will recommend that postmenopausal women with early invasive breast cancer are offered treatment with bisphosphonates to reduce the risk of breast cancer spreading to the bone. However, there are potential limitations to the impact this guidance could have when it is published. In particular, without explicit support from NICE it could lack influence with commissioners. We have already heard of several cases where clinicians keen to start using the treatment have been refused by their CCG for lack of an approved local protocol and business case. Relationship to the Early and Locally Advanced clinical guideline update We are aware that NICE is considering the new evidence on bisphosphonates as part of the update to this guideline, and appreciate that NICE may want to wait for the outcome of the review of this evidence before including it as a quality statement in the new BCQS. We are delighted that NICE is reviewing this evidence as part of the update to the guideline. However, we would like to suggest respectfully that the timings of the two updates in relation to each other do not optimise the integration of

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			the latest research evidence into the new BCQS. Therefore, we are writing to ask if there is a possibility of delaying the update of the BCQS until after a decision has been made about the updating of the clinical guideline. Alternatively, would NICE consider putting a 'placeholder statement' (similar to that currently included for physical activity) into the BCQS for bisphosphonates to recognise that its inclusion would be contingent upon the review of the clinical guideline? It may be that there are other reasons why the decision was taken not to include bisphosphonates as a quality statement in the draft Quality Standard. If so, we would be very grateful if you were able to outline the rationale for not including it. I look forward to hearing from you. Please feel free to contact me using the following details: 0207 749 0883; jenny.goodare@breastcancernow.org Yours sincerely, Jenny
70	Breast cancer now	Additional statements	There are a number of key areas for quality improvement that we think are not sufficiently reflected in the draft Breast Cancer Quality Standard (BCQS). We have set these out below. a) Reducing risk of breast cancer recurrence Breast Cancer Now wrote to NICE on 1st February 2016 because we felt that there was an issue excluded from the draft BCQS that should be a key area for quality improvement. In our response to the consultation on the scope of the BCQS, we suggested that a new quality statement should be included - that postmenopausal women with early invasive breast cancer are offered treatment with bisphosphonates to reduce the risk of breast cancer spreading to the bone. If this treatment was implemented routinely, it could save around 1,000 lives every year, and by preventing 1,000 cases of secondary breast cancer every year it would also amount to significant cost-savings for the NHS. We believe there is a particularly strong rationale for this being included in the new BCQS. 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 company is likely to act as an advocate for the drug(s) in its new indication. Therefore, as there are likely to be (and already are) particular challenges around getting this treatment into routine commissioning, despite very strong evidence to support a change in 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. Our letter is included as appendix 1. b) Age equality (old Quality Statement 6): 'People with early invasive breast cancer, irrespective of age, are offered surgery, radiotherapy and appropriate systemic therapy, unless significant comorbidity precludes it'. We think it is imperative that a statement about older age and breast cancer is retained in the new BCQS. Background

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			People are now living longer than ever before, resulting in a worldwide increase in cancer diagnoses in older people. 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 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 percent, compared to 90 percent for women aged 60-69. By 2040, almost three-quarters of all women living with breast cancer in the UK will be aged over 65. The proportion of older women (aged 65 and older) living with breast cancer will increase from 59% today to 73% in 2040. In 2013, the All Party Parliamentary Group on Breast Cancer conducted an inquiry into older people and breast cancer. It reported that once diagnosed, older women are less likely to be assessed for HER2 status and less likely to receive active treatment. In 2015, the All Party Parliamentary Group on Breast Cancer produced a follow-up report which recommended that the requirements of older people are fully taken into account when developing and updating breast cancer guidelines: The National Institute for Health and Care Excellence (NICE) and the Association of Breast Surgery (ABS) should involve geriatricians when updating breast cancer guidelines to ensure that the needs and views of older breast cancer patients are taken into account. All bodies responsible for developing future guidelines that impact on breast cancer patients should ensure that the needs and views of older patients are taken into account. Why should there be a statement on this in the Breast Cancer Quality Standard? Awareness Amongst older women, awareness is lower that their risk increases with age, and awareness is lower of the signs and symptoms of breast cancer. In 2015 Breast Cancer Now commissioned a nationally representative online survey of 1,020. women across Great Britain to ask them about breast cancer symptoms and screening. We found that only 61% of women aged 55 and over knew that breast cancer risk increased with age. The National Cancer Intelligence Network’s report on Older People and Cancer (updated June 2015) concluded that “more needs to be done to encourage older people to recognise the signs and symptoms of cancer and seek appropriate help”. Screening Breast screening plays an important role in the early identification and diagnosis of breast cancer. Women between 50 and 70 years of age are routinely invited every three years for breast screening by the NHS Breast Screening Programme, but whilst breast screening is still available to women over 70, they are required to make their own appointments.

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			Poor knowledge of age-related risk for breast cancer is attributed in part to women incorrectly assuming they are no longer at risk of developing the disease after routine NHS breast screening invitations cease. Referral The National Cancer Intelligence Network (NCIN)'s report on Older People and Cancer (updated June 2015) showed that older women are referred from primary care for suspected breast cancer less often than younger women, even though their risk continues to increase with age. Surgery The NCIN report on Older People and Cancer concluded that, in breast cancer, 82% of patients aged 15-54 underwent a resection compared to 25% for those aged 85 and over. Chemotherapy The NCIN report on Older People and Cancer concluded that, for breast cancer patients in England, there is a notable reduction in the number of patients receiving chemotherapy from around the age of 70. The NCIN report concludes that whilst it is important to acknowledge that there may well be good clinical reasons why older people are less likely to be given chemotherapy, it may also be that the clinical decision about whether or not to give chemotherapy is sometimes being determined by chronological age rather than performance status ['biological age'] of the patient. Supporting information. The All Party Parliamentary Group on Breast Cancer conducted an inquiry into older people and breast cancer in 2013. This report can be found at: http://breastcancernow.org/sites/default/files/public/age-is-just-a-number-report.pdf. A follow-up report was produced in 2015. This can be found at: http://breastcancernow.org/sites/default/files/public/age-is-still-just-a-number-report.pdf The National Cancer Intelligence Network's report on Older People and Cancer (updated June 2015) is available here: http://www.ncin.org.uk/publications/older_people_and_cancer c) Patients involved in decisions about treatment (draft Quality Statement 3) We feel that draft Quality Statement 3 (QS3) could include more of the sentiment of old Quality Statement 8 about people being involved in decisions about adjuvant treatment. Tests like Oncotype DX are only intended to be used by a subset of patients to guide decision-making on chemotherapy, whilst all patients should be included in decisions about their treatment. Therefore, perhaps QS3 could also include a broader statement about patients being involved in decisions about adjuvant therapy. d) Personalised information and support (old Quality Statement 9): 'people having treatment for early breast cancer are offered personalised information and support, including a written follow-up care plan and details of how to contact a named healthcare professional'. Personalised information and support is vital to help women with breast cancer (both primary and secondary)

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			understand their condition, consider their treatment options and make informed decisions about their care. There is significant variation in patients being offered this, and we think it is imperative that a similar statement (perhaps broadened to include secondary breast cancer) is retained in the new BCQS. A report produced by Breast Cancer Campaign (one of the charities that merged to form Breast Cancer Now) in 2013 mapped results of the Cancer Patient Experience Survey against corresponding statements in the existing BCQS. This report is included as an attachment. It reported that less than a quarter (21%) of breast cancer respondents in 2013 could confirm that they had been offered a written assessment and care plan. The results varied widely between trusts, but according to the 2013 survey, even the highest-scoring trust in the country only offered written assessment and care plans to less than half (43.5 per cent) of patients. The lowest-scoring trust provided them to just 7.4 per cent. The 2013 CPES also showed that 1 in 10 breast cancer patients were not receiving clear written information before being discharged from hospital. The 2014 CPES report identified the offering of written assessment and care plans as an area for improvement, with only 22% of respondents being offered one. This was also identified as an area in which low scores have been stable over the period 2010-14. Breast Cancer Now runs a hospital improvement programme called the Secondary Breast Cancer Pledge in partnership with Breast Cancer Care to improve care for people with secondary breast cancer. We compiled some qualitative patient experience data on the issue of written information and care plans from patient focus groups that took place in 2015. Each bullet point is from a different hospital site: • There was a general feeling that there is not enough information available. Patients generally felt that having hard copies of this information was helpful as on the computer you can get lost in all the information that’s out there. • Patients reported that treatment plans were not always explained in terms of reasons or side effects. • The hospital was not good with giving letters and written information. One patient spoke about Patient Access which allows them to access their records; others felt that this needed to be publicised to the patients more. Patients also felt that there needed to be a separation of information between primary and secondary breast cancer. • The Breast Cancer Care Secondary Breast Cancer resource pack was given out to two thirds of the patients [present at the focus group]. e) Psychological support (old Quality Statement 12): ‘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 services.’ We think it is important that the detail of old Quality Statement 12 is included in the background to draft Quality Statement 6, particularly the reference to psychological support which is a crucial but often overlooked element of care for breast cancer.

Registered stakeholders who submitted comments at consultation

- All Wales Breast Cancer National Specialist Advisory Group
- Association of breast surgery
- Association of Chartered Physiotherapists in Oncology and Palliative Care
- Breast cancer care
- Breast Cancer CRG
- Breast cancer now
- Department of Health
- Genomic Health
- Independent Cancer Patients’ Voice
- Manchester cancer
- Newcastle upon Tyne Hospitals
- NHS England
- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists
- The Society and College of Radiographers
- UK Cancer Genetics Group