

Appendix B: stakeholder consultation comments table

2018 surveillance – Advanced breast cancer: diagnosis and treatment (2009) NICE guideline CG81

Consultation dates: 20.10.17 – 03.11.17

Do you agree with the proposal not to update the guideline?			
Stakeholder	Overall response	Comments	NICE response
Breast Cancer Care	No	<p>This guideline was published in 2009. Since then, there have been only minor updates to the guideline.</p> <p>In contrast, there have been a number of changes to clinical practice since this time.</p> <p>Unfortunately, the levels of care and support received by people living with metastatic breast cancer are still poor compared to those with primary breast cancer, making improved and updated guidance vital.</p> <p>We are therefore disappointed that NICE has decided not to update this guideline at this time.</p> <p>Many areas of this guideline, especially the information and support areas, could be strengthened and updated with current best practice.</p> <p>We have detailed these points below in separate rows.</p>	Thank you for your comments. We have addressed these individually as detailed below.
Breast Cancer Care	No	<p>Section 1.2 Providing information and support for decision making and 1.4 Supportive Care</p> <p>We believe that these sections should be updated to strengthen and add to the recommendations.</p>	Thank you for your comments. Regarding the provision of information and support, NICE guideline CG81 recommends (1.4.1) compliance with NICE cancer service guideline CSG1 (2002) and NICE cancer service guideline CSG4 (2004). Recommendations within these

	<p>Providing information & support The guideline currently recommends:</p> <p><i>'1.2.1 Assess the patient's individual preference for the level and type of information. Reassess this as circumstances change. [2009]'</i></p> <p><i>'1.2.2 On the basis of this assessment, offer patients consistent, relevant information and clear explanations, and provide opportunities for patients to discuss issues and ask questions. [2009]'</i></p> <p>And also:</p> <p><i>'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'</i> [Section 1.4]</p> <p>A key recommendation (recommendation 65) in the Cancer Strategy for England is for every patient to have access to the elements of the Recovery Package by 2020¹. As set out in the Cancer Strategy, this recommendation is aimed at those who have finished treatment for primary cancers. Breast Cancer Care recommends that the Recovery Package is adapted to meet the unique needs of patients with metastatic breast cancer and should include:</p> <ul style="list-style-type: none"> • Referral to specific metastatic breast cancer support services • A bespoke Holistic Needs Assessment (HNA) at the point of diagnosis and as treatment changes and care planning for metastatic breast cancer that considers palliative care needs • A Treatment Summary and Cancer Care Review which meets the specific needs of patients with metastatic breast cancer and improves communication between secondary, primary, and palliative care, as well as patients. <p>We suggest strengthening these sections in line with this recommendation.</p>	<p>guidelines outline the need for every patient with advanced breast cancer to be treated by a multidisciplinary team containing specialists. This is also advised in the NICE quality standard on breast cancer (QS12). Recommendation 1.4.1 also highlights the need for a holistic assessment and provides details on the specific areas to be discussed and assessed with the patient.</p> <p>Recommendation 1.4.1 identifies the role of a key worker for individual patients. This role is detailed in the cancer services guidelines to include effective collaboration between services and promote continuity of care.</p> <p>The cancer services guidelines highlight the need for clinical nurse specialists to be involved throughout the treatment process and during follow-up. It is also recommended that nurse specialists receive appropriate training in follow-up of treated breast cancer patients.</p> <p>Current NICE guidance relating to advanced breast cancer is in line with the Cancer Strategy for England recommendations as highlighted in your comments. For this reason, we do not propose to update the recommendations in NICE guideline CG81. All these recommendations and related NICE guidelines are brought together in the NICE pathway of care for advanced breast cancer.</p>
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¹ Achieving World-Class Cancer Outcomes – A Strategy for England 2015-2020 (2015), available at http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf [accessed 26/10/2017]

	<p>Nursing</p> <p>There is currently no recommendation in the guideline addressing the need for people with metastatic breast cancer to have access to a designated clinical nurse specialist.</p> <p>In the surveillance review document, it is noted that topic experts highlighted the need for designated breast care nurses (p.25).</p> <p>Access to a CNS is the single most important factor associated with high patient satisfaction, according to the Cancer Patient Experience Survey².</p> <p>However, research by Breast Cancer Care³ has found that only 21% of organisations (NHS Trusts of Health Boards) across the UK had one or more Clinical Nurse Specialist dedicated to metastatic breast cancer.</p> <p>In comparison, we know that the majority of patients with a diagnosis of primary breast cancer are given the name of a CNS to support them through treatment⁴.</p> <p>The recommendation that patients with a diagnosis of metastatic breast cancer have access to a clinical nurse specialist with the right skills, knowledge and experience to support them is supported in other guidelines. For example:</p> <p>Clinical Advice to Cancer Alliances for the Provision of Breast Cancer Services</p> <p>The NHSE Breast Cancer Clinical Expert Group has recently published its clinical advice to cancer alliances. The advice represents current best practice, as agreed by a multidisciplinary group of professionals involved in delivering breast cancer services.</p> <p>The advice recommends:</p> <p><i>'5.2.9 All patients must have access to a clinical nurse specialist at all stages in their treatment pathway. This specifically includes</i></p>	
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² National Cancer Patient Experience Survey, 2015, available at www.ncpes.co.uk/index.php [accessed 26/10/2017]

³ Breast Cancer Care (2017), Secondary. Not Second Rate - Secondary breast cancer Part four: Nursing care, available at <https://www.breastcancercare.org.uk/sites/default/files/secondary-nursing-report.pdf> [accessed 26/10/2017]

⁴ National Cancer Patient Experience Survey 2015, available at www.ncpes.co.uk/index.php [accessed 26/10/2017]

		<p><i>patients with recurrent/metastatic disease. This should be recorded in the notes and the name and contact details given to the patient.'</i></p> <p>And</p> <p><i>'5.2.52 It is particularly important that all patients with recurrent or metastatic breast cancer have access to a clinical nurse specialist with specialist knowledge of secondary disease. They should be available to give information and psychological support to patients and their families'</i></p> <p>Access to a CNS for all patients is also a key recommendation of the NHS's 2015 Cancer Strategy for England⁵:</p> <p><i>'Recommendation 61: NHS England and the Trust Development Authority should encourage providers to ensure that all patients have access to a CNS or other key worker from diagnosis onwards, to guide them through treatment options and ensure they receive appropriate information and support.'</i></p> <p>Breast Cancer Care therefore suggests mirroring the recommendation included in the NICE Early and Locally Advanced Breast Cancer Guideline (CG80):</p> <p><i>'1.2.2 All patients with breast cancer should be assigned to a named breast care nurse specialist who will support them throughout diagnosis, treatment and follow-up.'</i></p> <p>For example:</p> <p><i>'All patients with metastatic breast cancer should be assigned a named breast care nurse specialist, with the right skills, knowledge and experience, as well as allocated time and resource, to support them throughout diagnosis, treatment and follow-up'</i></p>	
Breast Cancer Care	No	<p>Multidisciplinary Team (MDT) discussions of patients with metastatic breast cancer</p> <p>We believe the guideline should be updated to recommend that at presentation patients with metastatic breast cancer are discussed at an MDT meeting.</p>	<p>Thank you for your comments. NICE guideline CG81 recommends (1.4.1) compliance with NICE cancer service guideline CSG1 (2002) and NICE cancer service guideline CSG4 (2004). Recommendations within these guidelines outline the need for every patient with advanced breast cancer to be treated by a multidisciplinary team</p>

⁵ Achieving World-Class Cancer Outcomes – A Strategy for England 2015-2020 (2015), p. 53, available at http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf [accessed 26/10/2017]

	<p>This point was also noted by a topic expert during NICE's surveillance review (p.32 of the review document).</p> <p>People living with metastatic breast cancer often tell us that they feel lost in the system, and are not given the information or referred to the support that they need:</p> <p><i>'You need to tell your story so many times to so many different doctors. You have to become an expert in your own condition to ensure you are getting the treatment you need.'</i></p> <p>In a recent study of over 800 people living with metastatic breast cancer conducted by Breast Cancer Care⁶, it was found that:</p> <ul style="list-style-type: none"> • Only 27% of people were told about a palliative and supportive care organisation • Only 36% were made aware of counselling • Levels of information given to patients from diagnosis and as their disease progressed drastically waned. <p>An MDT is considered the 'gold standard' in planning treatment and care for patients living with metastatic breast cancer. However, we know that many MDT meetings do not specifically discuss metastatic cancers and often do not discuss people with metastatic breast cancer at all.</p> <p>Breast Cancer Care believes this omission leads to ineffective treatment planning for people living with metastatic breast cancer and for healthcare professionals.</p> <p>MDT discussion of people with metastatic breast cancer is currently supported by other guidelines, standards and strategies, including:</p> <p>1) NICE Breast Cancer Quality Standard⁷</p> <p><i>'People with breast cancer who develop metastatic disease have their treatment and care managed by a multidisciplinary team'</i></p>	<p>containing specialists. This is also advised in the NICE quality standard on breast cancer (QS12). All these recommendations and related NICE guidelines are brought together in the NICE pathway of care for advanced breast cancer.</p>
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⁶ Breast Cancer Care, Secondary. Not Second Rate - Secondary breast cancer Part three: support and impact (2017), available at https://www.breastcancercare.org.uk/sites/default/files/sbc_report_3_2017_final.pdf [accessed 26/10/2017]

⁷ NICE Breast Cancer Quality Standard (2011), available at <https://www.nice.org.uk/guidance/qs12/chapter/Quality-statement-5-Multidisciplinary-team-management-of-metastatic-breast-cancer> [accessed 26/10/2017]

		<p>2) 3rd ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 3)⁸</p> <p><i>‘The management of ABC is complex and, therefore, involvement of all appropriate specialties in a multidisciplinary team (including but not restricted to medical, radiation, surgical oncologists, imaging experts, pathologists, gynecologists, psycho-oncologists, social workers, nurses and palliative care specialists), is crucial.’</i></p> <p>3) Clinical Advice to Cancer Alliances for the Provision of Breast Cancer Services⁹</p> <p><i>‘5.2.51 Patients with recurrent/metastatic disease should be re-discussed at a dedicated metastatic MDT slot if they develop local and/or metastatic disease. A record of this discussion must be filed in the notes and relevant fields in the COSD completed.’</i></p> <p>4) Cancer Strategy for England¹⁰</p> <p><i>‘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.’</i></p> <p><i>‘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.’</i></p> <p>The advanced breast cancer guideline should mirror these more up-to-date documents.</p>	
Breast Cancer Care	No	Biological therapy 1.3.12	Thank you for your comments. The recommendation is to discontinue trastuzumab if there is disease progression outside the central nervous system. This recommendation is based on the evidence that the drug

⁸ 3rd ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 3), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378224/pdf/mdw544.pdf> [accessed 26/10/2017]

⁹ NHS England Breast Cancer Clinical Expert Group Clinical Advice to Cancer Alliances for the Provision of Breast Cancer Services (2017), available at http://breastcancernow.org/sites/default/files/public/clinical_advice_for_the_provision_of_breast_cancer_services_aug_2017.pdf [accessed 26/10/2017]

¹⁰ Achieving World-Class Cancer Outcomes – A Strategy for England 2015-2020 (2015), available at http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf [accessed 26/10/2017]

		<p>The recommendation to discontinue trastuzumab at disease progression no longer mirrors clinical practice, with many oncologists continuing to treat patients with trastuzumab after this point. This is particularly the case if accompanying treatment with another HER2 drug.</p>	<p>does not cross the blood-brain barrier and is therefore not effective in treating metastatic disease of the central nervous system and progression outside the central nervous system is an indication that the treatment is no longer effective. Guidance on the use of trastuzumab for the treatment of advanced breast cancer is covered in NICE technology appraisal TA34. Clinical practice should follow NICE recommendations and any use of trastuzumab outside the summary of product characteristics would be off-label and the responsibility of the prescribing clinician.</p>
Breast Cancer Care	No	<p>Brain metastases 1.5.18 – 1.5.21</p> <p>The surveillance review concluded that no new evidence was identified which would impact on current recommendations for this section.</p> <p>However, Breast Cancer Care suggests that consideration is given to recommending the use of stereotactic radiotherapy where possible for those with brain metastases, to minimise the toxicity of treatment.^{11 12}</p> <p>This is currently recommended in the 3rd ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 3)¹³:</p> <p><i>‘Because patients with HER2+ MBC and brain metastases can live for several years, consideration of long-term toxicity is important and less toxic local therapy options (e.g. stereotactic RT) should be preferred to whole brain RT, when available and appropriate (e.g. in the setting of a limited number of brain metastases)’</i></p>	<p>Thank you for your comments. We have considered the references provided regarding the use of stereotactic radiotherapy for brain metastases.</p> <p>The Soliman (2016) study is not included in the surveillance review as there is insufficient data in the abstract to draw conclusions from the results. The process to determine whether a study is included in the surveillance review only considers evidence at the abstract level.</p> <p>The Lippitz (2014) study is not included in the surveillance review as it does not meet the review criteria for randomised controlled trials or systematic reviews, and the abstract does not contain sufficient statistical data for the relevant breast cancer population.</p> <p>We note the recommendation in the 3rd ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer.</p> <p>NICE guideline CG81 contains a research recommendation calling for the need to compare stereotactic radiotherapy with whole brain radiotherapy in a randomised controlled trial.</p> <p>The management of brain metastases is being covered in a NICE guideline currently in development. If appropriate, the NICE pathway on advanced breast cancer will cross-refer to the guideline on brain metastases when it publishes.</p>

¹¹ 2016 Mar 15; 7(11): 12318–12330. Stereotactic radiosurgery (SRS) in the modern management of patients with brain metastases. Soliman H et al Oncotarget.

¹² Cancer Treatment Reviews. Volume 40, Issue 1, February 2014, Pages 48-59. Stereotactic radiosurgery in the treatment of brain metastases: The current evidence. Lippitz B et al.

¹³ 3rd ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 3), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378224/pdf/mdw544.pdf> [accessed 26/10/2017]

Breast Cancer Care	No	<p>Bone metastases</p> <p>1.5.14 Consider offering bisphosphonates to patients newly diagnosed with bone metastases to prevent skeletal-related events and reduce pain. [2009]</p> <p>We believe that this recommendation should be updated. It is now current practice for all patients with bone metastases to be offered bisphosphonates.</p> <p>Additionally, it is becoming more common for people with primary breast cancer to take bisphosphates to prevent recurrence. Guidance is needed on whether these patients should continue to be treated with bisphosphonates should they go on to develop metastatic disease.</p>	<p>Thank you for your comments. Evidence identified at the surveillance review supports the current recommendations to offer bisphosphonates to patients newly diagnosed with bone metastases. NICE guideline CG81 does not cover the management of primary or early breast cancer as this population is covered in NICE guideline CG80.</p>
Novartis Pharmaceuticals Ltd	Yes	<p>We feel that given the treatment paradigm for advanced/metastatic breast cancer is rapidly changing and with the development of new class of therapies (e.g. CDK 4/6 inhibitors, PI3K inhibitors) there are a number of Technology Appraisals ongoing that would not be captured in the guideline if updated at this time. However, we feel that the clinical guideline should be updated to incorporate new published Technology Appraisals at the earliest time point possible</p>	<p>Thank you for your comments. The surveillance review decision is to amend the relevant sections of the guideline to cross-refer to the relevant published NICE technology appraisals related to the treatment of advanced breast cancer. A statement will be added to the guideline noting that this is a clinical area in which new technologies are developed and assessed frequently and for clinicians to refer to the NICE pathway on advanced breast cancer in conjunction with the guideline.</p>
Royal College of Nursing	Yes	<p>Under 'Surveillance decision': We are pleased to see further recommendations for studies to update lymphoedema management and psychological care and note that this will be considered again at the next surveillance point</p>	<p>Thank you for your comments. The next surveillance review will consider any new evidence in the areas of lymphoedema management and psychological care.</p>
<p>Do you have any comments on areas excluded from the scope of the guideline?</p>			
Stakeholder	Overall response	Comments	NICE response
Breast Cancer Care		<p>Early diagnosis of metastatic breast cancer</p>	<p>Thank you for your comments. We will note the concerns you raise regarding the scope of other guidelines. We will log this information for the surveillance of those topics. These will be considered when these guidelines next undergo a surveillance review.</p>

		<p>Breast Cancer Care is aware that many people with metastatic breast cancer experienced delays in receiving their diagnosis¹⁴. Our recent research found that this was broadly due to two factors: patients' lack of awareness of the signs and symptoms of metastatic breast cancer and not having concerns about symptoms taken seriously by healthcare professionals. These issues must be addressed in order to improve the quality of life of those living with the disease. Unfortunately, other relevant NICE guidelines do not address this issue:</p> <p>Early breast cancer guidance Breast Cancer Care believes that the NICE Early and Locally Advanced Breast Cancer Guideline (CG80) does not go far enough in its recommendations around informing patients of the signs and symptoms of potential metastatic disease. This is something we raised in our response to the scope consultation for this guideline in 2016.</p> <p>Suspected cancer guidance NICE Guideline 12, Suspected Cancer: Recognition and Referral, which was published in 2015 and aimed at helping healthcare professionals to identify potential cancers, does not include identifying potential metastatic cancers in its scope. Breast Cancer Care believes this was a missed opportunity and believes that symptoms of potential metastatic disease should be incorporated into this guideline.</p> <p>With this current lack of guidance in other NICE guidelines, we suggest reflecting the importance of early diagnosis of metastatic breast cancer in the advanced breast cancer guideline.</p>	
Novartis Pharmaceuticals Ltd	No	No comment	Thank you for your response.
Royal College of Nursing	No	No comment	Thank you for your response.
<p>Do you have any comments on equalities issues?</p>			

¹⁴ Breast Cancer Care, Secondary. Not Second Rate – Secondary Breast Cancer Part One: Diagnosis (2016), available at <https://www.breastcancercare.org.uk/sites/default/files/secondary-breast-cancer-report-part-1.pdf> [accessed 26/10/2017]

Stakeholder	Overall response	Comments	NICE response
Breast Cancer Care	No	No comment	Thank you for your response.
Novartis Pharmaceuticals Ltd	No	No comment	Thank you for your response.
Royal College of Nursing	No	No comment	Thank you for your response.