NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Clinical Practice – Surveillance Programme

Recommendation for Guidance Executive (post-consultation)

Clinical guideline
CSGBC: Improving outcomes in breast cancer

Publication date
August 2002

Surveillance report for GE (post-consultation)
December 2014

Surveillance recommendation
GE is asked to consider the following proposal which was consulted on for two weeks:

- The Improving outcomes in breast cancer service guidance should not be considered for an update at this time.

- The guidance should be transferred to the static list as it meets the following criteria:
    - No evidence was identified that would impact on the current guidance and no major ongoing studies or research has been identified as due to be published in the near future (that is, within the next 3-5 years).

- The recommendations in the guidance which have been covered by subsequent guidelines including, referral for suspected cancer, metastatic spinal cord compression, early and locally advanced breast cancer, advanced breast cancer and familial breast cancer, should be withdrawn.

Key findings

			Potential impact on guidance	
			Yes	**No**
Evidence identified from literature search				✓
Feedback from Guideline Development Group				✓
Anti-discrimination and equalities considerations				✓
No update	CGUT update	Standard update	**Transfer to static list**	Change review cycle
✓			✓	

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Clinical Practice – Surveillance Programme

Surveillance review of CSGBC: Improving outcomes in breast cancer

Recommendation for Guidance Executive (post consultation)

Background information

Guideline issue date: 2002
12 year review: 2014

Twelve year surveillance review

1. For this 12 year surveillance review, a focused search to identify new evidence was carried out for articles published between 16 February 2001 and 9 July 2014 and the relevant abstracts were assessed. The focus of the search was to identify studies evaluating the impact of surgeon volumes on quality of decision making and outcomes. Due to the nature of the potential evidence sought, the search strategy included observational studies in addition to randomised controlled trials (RCTs) and systematic reviews. Clinical feedback was also obtained from members of the guideline development group (GDG) through a questionnaire. The GDG highlighted evidence and ongoing trials relating to different breast cancer treatments, and two members felt that the guideline needed to be updated to reflect these new developments. However, the recommendations relating to the areas identified have been superseded by more recent NICE guidelines.

2. Through the surveillance review it was identified that a number of recommendations within the Improving outcomes in breast cancer service guidance have been superseded by recommendations in a number of related NICE guidelines including CG27: Referral for suspected cancer (update in development); CG75: Metastatic spinal cord compression; CG80: Early and locally advanced breast cancer; CG81: Advanced breast cancer; CG164: Familial breast cancer and TA112: Hormonal therapies for the adjuvant treatment of early oestrogen-receptor positive breast cancer. In light of this, it is proposed that the recommendations within the Improving outcomes in breast cancer service guidance related to the following clinical areas should be withdrawn:
   - Referral for suspected breast cancer
   - Genetic advice and support
   - Genetic testing
   - Prophylactic treatment

- Chemoprevention
- Patient information
- Diagnostic, staging and pathological investigations
- Surgical management
- Radiotherapy, chemotherapy and hormone therapy
- Prevention and treatment of lymphoedema
- Adjuvant systemic therapy
- Follow-up
- Bone metastases
- Metastatic spinal cord compression

3. No new evidence was identified through the literature search which would invalidate the guideline recommendations.

Ongoing research

4. None identified.

Anti-discrimination and equalities considerations

5. None identified.

Implications for other NICE programmes

6. This guideline relates to the Breast cancer quality standard (QS12).

7. None of the quality statements are likely to be affected by the decision not to update the guidance or to add the guidance to the static list as the guidance was not used as a development source for the Quality Standard.

Summary of stakeholder feedback

8. Stakeholders were consulted on the following proposal over a two week consultation period:

- The Breast cancer service guidance should not be considered for an update at this time.

- The guidance should be transferred to the static guidance list because it fulfils the following criteria:
  - No evidence was identified that would impact on the current guidance and no major ongoing studies or research has been identified as due to be published in the near future (that is, within the next 3-5 years).

- The recommendations in the guidance which have been covered by subsequent guidelines including, referral for suspected cancer, metastatic spinal cord compression, early and locally advanced breast cancer, advanced breast cancer and familial breast cancer, should be withdrawn.

9. In total, 16 stakeholders responded to the surveillance review proposal recommendation during the two week consultation period. 14 stakeholders provided comments on the proposal and the remaining 2 stakeholders stated that they had no substantive comments to make. The table of stakeholder comments can be viewed in Appendix 1.

10. Of the 14 stakeholders that provided comments on the surveillance review proposal, 11 stakeholders agreed with the proposal to not update the guidance at this time and 3 stakeholders disagreed.

11. 11 stakeholders agreed with the surveillance review proposal to transfer the guidance to the static list although one stakeholder stated that this should be only be for a year or two, and 3 stakeholders disagreed.

12. No comments were provided by any stakeholders suggesting any areas that have been excluded from the original scope.

13. The following is a summary of the general comments made by the stakeholders:

    Breast cancer treatment

    Several stakeholders suggested that there is new evidence as well as several ongoing studies relating to different aspects of breast cancer treatment, including, hormone therapy, adjuvant bisphosphonates, trastuzumab (Herceptin) therapy, chemotherapy, radiotherapy, management of the axilla, and adjuvant therapy for secondary breast cancer. It was felt that the guidance should be updated to reflect this evidence. However, the recommendations relating to breast cancer treatment in the Improving outcomes in breast cancer guidance have been superseded by recommendations in a number of related NICE guidelines including CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer and CG164: Familial breast cancer. It is therefore proposed that these recommendations are withdrawn. The new evidence and ongoing studies identified by stakeholders will be considered through the surveillance reviews of CG80, CG81 and CG164.

    Organisation of services

    One stakeholder indicated that changes to the structure of the NHS in April 2013 resulted in replacement of the 28 Cancer Networks with 12 Strategic Clinical Networks which cover cancer as well as several other major conditions. The stakeholder felt that the guidance should be updated to reflect the fact that Cancer Networks no longer exist, and to set out how the functions they performed will be taken up by the new Strategic Clinical Networks. Many of the recommendations relating to Cancer Networks in the guidance have been superseded by recommendations in more recent NICE guidelines. In addition, as the terminology is a small aspect of the guidance, it wasn't considered

significant enough to warrant updating the guidance at this point. The terminology will be amended if the guidance is considered to require an update in the future.

Assessment of services

It was identified by two stakeholders that some of the recommendations in the guidance are assessed though the National Cancer Peer Review Programme which is currently paused pending the outcome of an internal review. One stakeholder stated that an update should take into account the outcome of this review and that the guidance should set out how health bodies should monitor data on compliance with national standards and quality metrics. It was considered that setting out how health bodies should monitor data on compliance with national standards and quality metrics is beyond the remit of the guidance. However, the NICE Quality Standard for Breast cancer (QS12) provides statements, with accompanying metrics, aimed at driving improvements within this area.

Implementation

One stakeholder indicated that implementation of certain recommendations, such as the provision of psychosocial support and counselling and lymphoedema/physiotherapy services, has been variable. However, failure to follow the guidance recommendations is a local implementation issue.

Equality and Diversity issues

Two stakeholders stated that that they would be interested in data regarding whether breast conserving surgery is the preferred option in units where there is higher Black and Minority Ethnic (BME) population. In addition, they felt that there is need for information to be more readily available in common south Asian languages.

Conclusion

14. Through the 12 year surveillance review of the Improving outcomes in breast cancer service guidance and subsequent consultation with stakeholders no new evidence was identified which may potentially change the direction of current recommendations. The proposal is not to update the guidance at this time and to move this guidance onto the static list because it fulfils the following criteria:
    - No evidence was identified that would impact on the current guidance and no major ongoing studies or research has been identified as due to be published in the near future (that is, within the next 3-5 years).

15. A number of areas of this guidance have been covered by subsequent guidelines including referral for suspected cancer, metastatic spinal cord compression, early and locally advanced breast cancer, advanced breast cancer and familial breast cancer, and the relevant recommendations should be withdrawn.

Mark Baker – Centre Director
Sarah Willett – Associate Director

Diana O'Rourke – Technical Analyst

Centre for Clinical Practice
December 2014

Appendix 1 Surveillance review consultation

Surveillance review consultation comments table
4 November 2014 – 18 November 2014

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
The Royal College of Nursing				This is to inform you that the Royal College of Nursing have no comments to submit to inform on the surveillance review proposal for the Improving outcomes in breast cancer guidelines.	Thank you.
The Royal College of Pathologists				The Royal College of Pathologists does not have comments on the Improving outcomes in breast cancer guideline.	Thank you.
Robin Wilson				I think this is a reasonable conclusion.	Thank you.
The Royal College of Radiologists	Agree	Agree		The Royal College of Radiologists agrees that a review of this Guidance is not required at this time. However, the RCR notes that a review before five years may be appropriate, bearing in mind the potential for change in breast cancer treatments in the coming years (including – for example - the outcomes from the Fast Forward and IMPORT trials, greater follow-up through survivorship programmes and developments in systemic treatments (in particular in HER-2 positive breast cancers).	Thank you for your comments. A number of recommendations within the Improving outcomes in breast cancer service guidance have been superseded by recommendations in a number of related NICE guidelines. It is therefore recommended that the relevant recommendations in the Improving outcomes in breast cancer service guidance are withdrawn. New evidence relating to these areas, including evidence related to breast cancer treatments will be assessed at future surveillance reviews of other related guidelines. However, if stakeholders become aware of any new evidence or information that is likely to impact on the Improving outcomes in breast cancer service guidance, we ask them to contact NICE with the

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
					appropriate details.
Breast Cancer Care	Agree	Agree		While we agree that this guideline has been mostly superseded by newer NICE guidelines and Quality Standards, we would like to highlight the points below for consideration: 1) To assist those accessing the guideline, we feel that it should be made very clear that much of the information contained in it is now out of date and/or superseded by other guidance. For example, the Background section of the guideline is aimed at providing a broad overview of breast cancer for non-clinicians and contains out of date statistics on incidence, mortality and prevalence. Those accessing the guideline could be signposted to sources of more recent statistics. 2) To help ensure that patients with both primary and secondary breast cancer receive the best standards of treatment and care, it is crucial that the superseding guidelines are appropriately updated to ensure that guidance continues to recommend the best practice and reflect the most up-to-date evidence. Neither the early and locally advanced or advanced breast cancer guidelines have been thoroughly updated since their publication in 2009 and both have content which is out of date given current practice. 3) The work of the newly established	Thank you for your comments. Unfortunately reviewing the background section of a guideline is beyond the scope of the surveillance process. However, more up to date statistics relating to breast cancer incidence and mortality are available via CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer and the Quality Standard for breast cancer (QS12) on the NICE website. A formal check to assess the need to update a guideline is undertaken through our surveillance process every two years. CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer and CG164: Familial breast cancer will all undergo this process in 2015/16. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. Assessment of the delivery of recommendations through the National Cancer Peer Review Programme is beyond the remit of NICE. Clinical guidelines placed on the static list will be reviewed every 5 years to determine if they should remain on the static list. However, if you become aware of any new evidence or

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
				Breast Cancer Clinical Reference Group will also build on the guidance in 'Improving Outcomes…' and should be taken into consideration. The group are developing a breast cancer Service Specification, which sets out the essential services for patients with early, recurrent and metastatic breast cancer. However, 'Improving Outcomes …' covers both England and Wales. The work of the new Breast Cancer CRG only covers England, so we are keen to see equitable minimum standards across the UK. 4) Some of the recommendations in 'Improving Outcomes…' are now assessed via the Breast Measures in the National Cancer Peer Review Programme. However, we understand that the Peer Review Programme is currently under threat.	information that is likely to impact on the guideline recommendations, please contact NICE with the appropriate details.
Dr Adrian Harnett	Agree	Agree – it has been superseded by subsequent guidelines		Agree from P.2 of surveillance review recommendation that: "It is therefore unlikely that the new evidence will impact on the current recommendations in the guideline which state: All breast referrals should be to specialist breast teams working in units which deal with at least 100 new cases of breast cancer per year" P.4 - One retrospective study17 (n=2,094) reported that the rate of radiation	Thank you for your comments. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. Failure to follow the guidance recommendations is a local implementation issue. With regards to the link between breast cancer and menopausal symptoms, this area is now covered by CG80: Early and locally advanced breast cancer and

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				therapy use following breast-conserving surgery was significantly higher in high-volume hospitals compared to low-volume hospitals. Comment – less variation now The original document included the importance of breast cancer specialist nurses – there remains under provision particularly in Oncology departments dealing with patients with metastatic or advanced breast cancer. Similarly, the importance of psychological and psychosocial counselling was covered (P.27, 28 & 30) but is often not provided. Patients don't always have access to a lymphoedema / physiotherapy service (P.59 & 60). Both have been a serious concern of patient representatives on the GDGs. Finally, can there be a reference to breast cancer and menopause symptoms which is in the Menopause guideline due to be issued by NICE 2014/15?	its associated pathway Early and locally advanced breast cancer.
Royal College of Obstetricians	the guideline should not be updated	yes, the guidance should be put on the static list	we have no comments to make on equality issues or		Thank you.

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
and Gynaecologists			areas excluded from the original scope.		
Association for Palliative Medicine of Great Britain & Ireland	yes	yes	N/A		Thank you.
Ursula Van Mann	YES I AGREE	YES I AGREE	NONE		Thank you.
South Asian Health Foundation	Agree	Agree	I couldn't find any equality issues or areas excluded from the original scope and agree with the findings in the guidelines regarding high volume surgeons and units producing better outcomes. However, it would be interesting to know whether any data exists in units where there is higher population of BME groups and whether breast conserving surgery still appears to be the preferred option in these groups in such units. Also I feel there is need for information to be readily available in	None	Thank you for your comments. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. NICE considers all aspects of equality and diversity in developing and assessing the need for an update of a guideline. No data or evidence was identified through the surveillance review relating to BME groups. However, if you become aware of any new evidence or information that is likely to impact on the guideline recommendations, please contact NICE with the appropriate details.

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
			common south Asian languages.		
Muslim Doctors & Dentist Association (MDDA)	Agree	Agree	I couldn't find any equality issues or areas excluded from the original scope and agree with the findings in the guidelines regarding high volume surgeons and units producing better outcomes. However, it would be interesting to know whether any data exists in units where there is higher population of BME groups and whether breast conserving surgery still appears to be the preferred option in these groups in such units. Also I feel there is need for information to be readily available in common south Asian languages	None	Thank you for your comments. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. NICE considers all aspects of equality and diversity in developing and assessing the need for an update of a guideline. No data or evidence was identified through the surveillance review relating to BME groups. However, if you become aware of any new evidence or information that is likely to impact on the guideline recommendations, please contact NICE with the appropriate details.
The Royal College of Surgeons of Edinburgh	Agree	Agree – for a year or two.			Thank you. Please note that clinical guidelines placed on the static list will be reviewed every 5 years to determine if they should remain on the static list. However, if you become aware of any new evidence or information that is

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
					likely to impact on the guideline recommendations, please contact NICE with the appropriate details.
Roche Products Ltd	Agree	Agree			Thank you.
NCRI/RCP/RCR/ACP	Disagree	Disagree	None	The clinical guideline SGBC Improving outcomes in breast cancers is a complex document that covers many aspects of breast cancer management. We acknowledge that keeping this current is challenging. Whilst we recognise aspects of the guidance have been superseded many times with individual NICE appraisals we strongly believe that there remains a value to a comprehensive review document. However, for this to be useful there are multiple areas where the guidance needs to be updated. There is in addition a substantial range of research studies that are expected to report in the next five years many of which are expected to have significant implications for breast cancer management. There is some concern that the proposal to place the guidance on the static list may represent a desire to discontinue any future update. It may be that, for the future, the topic is too large to be covered in a single document and that keeping this contemporary as a single document may be an ineffective exercise. Perhaps NICE remit may be confined to more manageable sized topics and single technology appraisals? We would recommend clarification in this area as the intention	Thank you for your comments. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. A number of recommendations in the guidance, including those related to surgical management, radiotherapy, chemotherapy, hormone therapy and adjuvant systemic therapy, have since been covered by more recent NICE guidelines. It is therefore proposed that these recommendations should be withdrawn. The NICE Pathways for CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer, and CG164: Familial breast cancer bring together all the key recommendations relating to breast cancer care and treatment. A formal check to assess the need to update a guideline is undertaken through our surveillance process every two years. The new evidence highlighted by the consultee would therefore be assessed at future surveillance reviews of the guidelines to which they are related. CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer and

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				is not apparent from the consultation, as stands. We wish to highlight, for illustration, six specific areas for review. We would stress that this is not a comprehensive list of aspects of the guidance that might benefit from review within the IOG guidelines or a more focused review. Optimal duration of adjuvant endocrine therapy (ATLAS trial Davies et al Lancet. Mar 9, 2013; 381(9869): 805–816.) and (attom trial definitive publication due 2015) have demonstrated advantage to extended adjuvant tamoxifen to ten years. There are multiple ongoing studies of extended aromatase inhibition expected to report over next five years Adjuvant bisphosphonates for postmenopausal women with early breast cancer. A recent meta-analysis shows a clear benefit in outcome in this subgroup (Coleman et al SABCS December 2013) Duration of adjuvant trastuzumab is the subject of three major phase III trials expected to report within the next five years. The addition of dual targeted anti HER-2 agent the subject of two International trials while the first trial has reported negative results the second trial using pertusumab is anticipated to be positive (will likely require a single technology appraisal)	CG164: Familial breast cancer will all undergo this process in 2015/16. Please note that guidelines placed on the static list will continue to be reviewed every 5 years to determine if they should remain on the static list. However, if you become aware of any new evidence or information that is likely to impact on the guidance, please contact NICE with the appropriate details.

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				Platinum chemotherapy agents in advanced and early triple negative breast cancer. Neoadjuvant data suggests these agents may have a role in early breast cancer in this subgroup. Potentially practice changing Phase III Metastatic data will be presented to SABCS December 2014 Modified adjuvant radiotherapy techniques are emerging with published data on IMRT (JCO 2013), Partial breast radiotherapy and heart sparing technique publications all due over next 2 years. The literature on the management of the axilla has become increasingly complex and guidance requires review particularly management after positive sentinel node biopsy, management of micrometasatic nodal involvement. Radiation to the positive axilla	
Breast Cancer Campaign	Disagree	Disagree	N/a	Breast Cancer Campaign believes that the clinical guideline CSGBC Improving outcomes in breast cancer ('the guideline') should be considered for an update, and should not be moved to the static list. This is because since 2002, the year of its publication, there has been a substantial amount of new evidence published and there have been significant changes to the structure of the health system, which could impact many areas of the	Thank you for your comments. A number of recommendations within the Improving outcomes in breast cancer service guidance have been superseded by recommendations in a number of related NICE guidelines, including recommendations related to chemoprevention, surgical management, radiotherapy, chemotherapy, hormone therapy, and adjuvant systemic therapy. It is therefore proposed that these

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				guideline. We believe that 14 days is not sufficient time to prepare and present an in-depth evidence review which covers all topics that are included in this lengthy manual, so in this response we will set out a brief overview of some of the issues we believe to be explored in more depth, using selected examples to demonstrate this point. However we would be happy to consult further with NICE on a future update for this guideline, which we believe is necessary. Changes to the health structure The guideline was last updated in 2002, when cancer services were planned and coordinated locally by 28 Cancer Networks. Each of these networks had a dedicated staff of up to 30 people working solely on cancer in the area, and all supported a Breast Network Site Specific Group to undertake specialist monitoring and improvement work for this tumour site in the area. These groups would have been regulated through the Cancer Peer Review programme, which included measures for NSSGs. In line with this, the guideline makes very frequent reference to the role of Cancer Networks in implementing many aspects of the guideline, and also to the role of NSSGs and peer review. For example, p.46 includes the	recommendations are withdrawn. However, those recommendations which have not been covered elsewhere, for example, aspects of service delivery (e.g. staffing, local service planning, hospital facilities) will remain within the Improving outcomes for breast cancer guidance. New evidence relating to breast cancer treatment (e.g. trastuzumab (Herceptin), radiotherapy, aromatase inhibitors, bisphosphonates etc.) would be considered within the context of a review of the relevant guideline or technology appraisal. A formal check to assess the need to update a clinical guideline is undertaken through our surveillance process every two years. CG80: Early and locally advanced breast cancer, CG81: Advanced breast cancer and CG164: Familial breast cancer will all undergo this process in 2015/16. The purpose of the Improving outcomes in breast cancer guidance is to provide evidence-based recommendations on the organisation and delivery of services for women with breast cancer. We recognise that there have been substantial changes to the organisation of the NHS since the guideline was published and that many aspects of the terminology used in the guidance may now be outdated. However, many of the recommendations relating to Cancer

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				recommendation 'Breast cancer site-specific groups should produce network-wide guidelines on the appropriate use of radiotherapy for patients with invasive or in-situ disease.' Also p. 8 includes the recommendation 'Each cancer network should review its arrangements for breast screening, with the goal of bringing services for screened and symptomatic patients into closer alignment.' Also p.51 includes the recommendation 'Networks should agree, and regularly revise, evidence-based guidelines for the use of systemic treatments for breast cancer.' Finally p.5 states 'Recommendations from the original breast guidance were incorporated into the NHS cancer standards for both England and Wales. These standards have in turn been used to help improve services in various ways (including national peer review in England).' Since April 2013 the structure of the NHS nationally and locally has changed substantially. There are now no longer 28 Cancer Networks but 12 Strategic Clinical Networks which cover cancer along with several other major condition areas. Local compliance with Cancer Peer Review has declined since these changes came into place, and the Peer	networks highlighted by the consultee have been superseded by recommendations in more recent NICE guidelines. In addition, as no evidence was identified that would change the direction of the recommendations, and considering that the terminology is a small aspect of the guidance, this is not significant enough to warrant updating the guideline at this point. The terminology will be amended if the guidance is considered to require an update in the future. Setting out how health bodies should monitor data on compliance with national standards and quality metrics is beyond the remit of the guideline. However, the NICE Quality Standard for Breast cancer (QS12) provides statements, with accompanying metrics, aimed at driving improvements within this area.

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				Review programme is currently paused pending the outcome of an internal review – which may conclude that it should be discontinued permanently. Related to this, there has been a decline in the number of Breast NSSGs, from 28 areas having a fully operational group in 2012 to just 4 out of 25 areas having one in the most recent 2014 peer review cycle. We believe it is important that this guidance is updated to reflect that fact that Cancer Networks no longer exist, and to set out how the functions they performed (such as agreeing evidence based guidelines for the network area, as above) will be taken up by the new SCNs. It is also important for the guideline to be updated to make clear what the current expected role of Breast NSSGs is to be – if these groups are to continue and be run by SCNs in the absence of Cancer Networks, or if they are no longer required. If the latter, then the guideline should set out how the functions they performed will be taken up by the new SCNs or local commissioners. A guideline update should take into account the outcome of the review of Cancer Peer Review, and set out how new local health bodies should monitor data on compliance with national standards and quality metrics in the absence of this programme. New evidence on treatments	

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				In the past decade substantial new evidence has been published on many aspects of breast cancer treatment. We feel it is incorrect to state that no evidence has been published since 2002 which would impact on the current guidance in the 12 areas listed in the Surveillance Review consultation document. We agree that a number of recommendations within the guidelines have been superseded by recommendations in a number of NICE related guidelines, however these other guidelines combined do not adequately replace the full scope of the 2002 guidance. We have outlined one key example of this, however as previously stated we have not undertaken a full evidence review. Radiotherapy: For example, the section on radiotherapy in the guideline covers 5 full pages, including issues relating to staffing, local service planning, hospital facilities, anticipated benefits and impact on survival rates, and machine replacement planning. Radiotherapy is mentioned in several of the more recent NICE guidelines indicated, however only very briefly and with specific reference to the subject of the guideline (e.g. 'metastatic spinal cord compression'). These brief mentions are not a sufficient replacement for the detailed and wide-ranging section on radiotherapy in the	

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				2002 guideline, which arguably needs to be updated. For example, the guideline includes no mention of Intensity Modulated Radiotherapy. Since 2002 this advanced form of radiotherapy has been established as a highly beneficial treatment, and has become a standard practice option in some areas for breast cancer patients as it has been found to improve the cosmetic outcome of treatment. In 2012 the Government announced a £15 million Radiotherapy Innovation Fund alongside a pledge to enable all 50 NHS radiotherapy centres to deliver a minimum of 24% of all treatments with IMRT by April 2013. Key developments such as the advent of IMRT, the initial sizable investment in the Radiotherapy Innovation Fund (and the subsequent further investment to bring the fund up to £23 million), have had a significant impact on the current status of radiotherapy services in England and current clinical best practice. This should be reflected in the guideline if it is to remain a current source of information for clinicians. Hormone therapy: The use of aromatase inhibitors as a first line adjuvant endocrine therapy is now standard practice for most post-menopausal women with oestrogen receptor positive breast cancer. This follows the results of several clinical trials. However, the guideline states on	

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				p.54: "Tamoxifen is normally used in this situation but early trial results for aromatase inhibitors show promise. Their effectiveness remains to be confirmed and trials are continuing." This information is clearly out of date and therefore misleading when compared with current best practice in breast cancer treatment. Herceptin: The use of Herceptin for treating HER2 positive breast cancer is not mentioned in the guideline. The use of Herceptin for HER2 positive breast cancer is now standard practice and therefore having a guideline still available, although static, which makes no mention of Herceptin has the potential to mislead people looking for information on breast cancer treatment. Secondary breast cancer Secondary breast cancer unfortunately remains incurable, however it is nevertheless treatable and in many cases women are able to live – with good quality of life – for years following their secondary diagnosis. Stopping women dying from breast cancer is a major focus of breast cancer treatment and support, however it is vital to ensure that the treatments and services made available to patients whose cancer has	

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				spread are of the best quality, and that patients are supported to live as long as they can while managing their disease. Since the guideline was produced in 2002, 5-year survival rates have improved, and more women are being supported to live with a secondary diagnosis for longer. In light of this the way metastatic breast cancer is presented in the guideline should be updated to reflect different attitudes towards secondary breast cancer, including the provision of secondary breast cancer clinical nurse specialists in some areas, – for example p. 66 states: 'Metastatic breast cancer is incurable. Systemic treatment with chemotherapeutic and/or hormone-modifying agents may produce modest improvements in survival time, but the primary aim of any form of treatment at this stage should be to relieve symptoms and optimise quality of life.' Since 2002 new ways of preventing and treating secondary breast cancer, including some drugs that have been found to add on average six months of life, have started being made available to patients. The guideline should be updated to include these pioneering new developments to reflect a different outlook for secondary breast cancer	

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
				patients. Bisphosphonates: For example, the guideline explores the use of bisphosphonates to treat bone fractures in secondary breast cancer patients in detail. However it states on p. 69: 'It is not clear whether bisphosphonates can delay the development of bone metastases or related skeletal events in women with breast cancer… relevant trials are only just beginning and will not report for some years.' Since 2002 clear evidence has started to emerge that these drugs can be very effective in preventing the spread of breast cancer to the bone. Within the next few months, we anticipate that major new research will be published that provides evidence that bisphosphonates are effective in early breast cancer in reducing the risk of the disease spreading to the bone in post-menopausal women. This meta-analysis of clinical trials is likely to show that in post-menopausal women with early breast cancer, bisphosphonate therapy reduced the 10-year risk of breast cancer spreading to the bone by 34% and the risk of dying from breast cancer by 17%. This is a key example of the type of	

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
				pioneering new evidence that has begun to emerge since 2002, which should be included in an update of the guideline. Conclusion We feel these selected 'case study' examples demonstrate the extent to which the 2002 guideline is now out of date. It is incorrect in many cases to say that no new evidence has come to light which impacts the content of this guideline, and we feel that this guideline must be either withdrawn from use by clinicians and planners or updated fully to reflect the wealth of new evidence available since 2002, as well as substantial recent changes to the health structure.	
Royal College of surgeons cancer committee	No	No		There is new data on the management of the axilla in 2 randomised trials (ACSOG Z-11 and AMAROS), which will be and are currently practice changing. These reduce the extent of surgical treatments of the axilla in node positive patients. A recent consensus document published by ASCO (and agreed by 3 other major breast cancer speciality societies), based on the new data, has changed the management of these patients and if NICE does not look at the new data, the UK will be out of step with the rest of the breast cancer world, and more importantly UK patients will suffer by having more extensive	Thank you for your comments. The recommendations relating to the management of the axilla in the Improving outcomes in breast cancer service guidance have been superseded by recommendations in CG80: Early and locally advanced breast cancer. It is therefore recommended that the relevant recommendations in the Improving outcomes in breast cancer service guidance are withdrawn. New evidence relating to this area will be assessed as part of a future surveillance review of CG80 which will be scheduled in 2015/16.

Stakeholder	Do you agree that the guidance should not be updated?	Do you agree that the guidance should be put on the static list	Comments on equality issues or areas excluded from the original scope	Comments If you disagree please explain why	Response
				treatments than they require.	

Appendix 2 Decision matrix

The table below provides summaries of the evidence for key questions for which studies were identified.

Is there any new evidence/intelligence identified during this 12-year surveillance review (2014) that may change this conclusion?	Clinical feedback from the GDG	Conclusion of this 12-year surveillance review (2014)
Primary Care and the Management of Women at High Risk		
CSGBC-01: What is the role of routine physical breast examination for self-presenting well women (i.e. asymptomatic) in the primary care setting?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-02: Is there any evidence to establish what level of genetic advice and support should best be offered in primary care or specialist cancer genetic services? • **Who should have access to a hereditary cancer clinic and on what basis should referral from primary care be made?** • **Who should be offered genetic testing?** • **What counselling, surveillance, prevention, and prophylactic treatment options should be available for women carrying breast cancer associated gene mutations?** • **Is there any evidence on risk-benefit and cost-benefit of genetic testing?**		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-03: Does tamoxifen, raloxifene or retinoic acid derivatives provide effective chemoprevention against invasive breast cancer among high risk women, and what impact do they have on quality of life?		
No new evidence was considered. .	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Patient-centred care		
CSGBC-04: What methods of information giving have been proposed to improve communication with cancer patients, and how effective are they? **CSGBC-05: What training should senior health professionals be given to improve communication with cancer patients?**		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Rapid and Accurate Diagnosis		
CSGBC-06: Is there any evidence relating to patient experience regarding one-stop clinics, in terms of surroundings, location and other aspects of using facilities on one site or at multiple sites?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-07: Should women be informed of their diagnosis on the same day at a one-stop clinic, or is a two-stage procedure better for women?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.

CSGBC-08: Does diagnostic ultrasound of mammography-detected breast lesions assist in the differentiation of benign from malignant disease in newly-presenting breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-09: Is core biopsy an effective and safe alternative, and is it more acceptable to women, than fine needle aspiration (FNA) in the context of triple assessment diagnosis of primary breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-10: Is ultrasound necessary for women with small breast lesions undergoing core biopsy or FNA?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-11: Is MRI more reliable than mammography or US to assess whether disease is multifocal or multicentric (rather than a single tumour)?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-12: If there is still doubt about the presence of recurrent disease following triple-assessment (including FNAC or CB) does MRI accurately predict the absence of recurrent disease (local recurrence of breast cancer within the breast or chest wall or axilla)?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-13: For which women with DCIS should mastectomy be considered?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-14: What evidence exists to support the need to excise breast tumours with negative margins, and is there any evidence as to what distance constitutes a clear margin (non-invasive DCIS, as well as invasive cancer)?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-15: What are women's information needs on breast reconstruction surgery?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-16: How do immediate and delayed reconstruction compare in terms of surgical complications, cosmesis and psychosocial outcomes; and do breast surgeons and plastic surgeons get equivalent results?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-17: Does axillary node sampling as an alternative to axillary clearance provide accurate stage determination, result in better informed treatment decisions, reduce recurrence in axillary lymph nodes and improve survival?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-18: What evidence is there to inform whether axillary node dissection should entail removal of all axillary lymph nodes, removal of level I and II nodes, or axillary sampling in invasive breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.

CSGBC-19: Is axillary node sampling plus radiotherapy better than axillary clearance without radiotherapy in terms of local recurrence and quality of life?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-20: Does sentinel lymph node biopsy provide accurate staging of the axilla in patients with breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-21: Does sentinel lymph node biopsy avoid the morbidity associated with more extensive axillary dissection?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Radiotherapy		
CSGBC-22: Has good radiotherapy practice in the delivery of locoregional treatment been defined in national guidelines, if so is this based on expert opinion or research/audit evidence?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-23: Does radiotherapy after breast conserving surgery for DCIS reduce the incidence of recurrence compared with local excision alone?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-24: For which patients with DCIS should radiotherapy after conservative surgery be recommended?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-25: What is the effect on long-term survival and local recurrence of radiotherapy following mastectomy or conserving surgery for primary breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-26: What is the optimum sequencing of chemotherapy and radiotherapy in the adjuvant treatment of early breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Systemic Therapy		
CSGBC-27: What evidence is there for primary neoadjuvant systemic therapy to down-stage tumour status in terms of the need for mastectomy, quality of life and survival?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-28: Is there evidence from randomised trials that anthracycline containing multiple-agent adjuvant treatment improves quality of life and survival in women with breast cancer compared to CMF? • **CMF versus AC** • **CMF versus FEC/FAC** • **CMF versus ECF** • **FEC versus ECF**		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.

CSGBC-29: Does measurement of oestrogen and progesterone receptor status inform prescribing and improve the outcome of adjuvant chemotherapy?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-30: Is there a role for high dose chemotherapy with CMF in breast cancer treatment?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-31: What is the role for taxanes in the adjuvant treatment of breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-32: What is the role of tamoxifen in the management of DCIS?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-33: What is the evidence from randomised trials to support aromatase inhibitors as part of adjuvant treatment regimens for newly diagnosed breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-34: In pre-menopausal women with early breast cancer and ER+ tumours, does adjuvant therapy with a lutenising hormone-releasing hormone (LHRH) agonist (goserelin or buserelin) improve survival compared to CMF?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-35: In pre-menopausal women with early breast cancer and ER+ tumours who have maintained ovarian function following chemotherapy and tamoxifen therapy, does the addition of LHRH agonist therapy reduce the risk of recurrence?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Follow-up after Treatment for Early Breast Cancer		
CSGBC-36: What are the treatment related factors that predispose women with breast cancer to lymphoedema?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-37: How does lymphoedema following treatment for breast cancer (mastectomy, breast conserving surgery, axillary dissection, radiotherapy) affect quality of life?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-38: Is lymphoedema still a problem for women treated for breast cancer in the UK?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-39: What information on lifestyle do women need to minimise the impact of lymphoedema?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-40: What impact do different treatment options for management of lymphoedema have on quality of life, and when is the best time to start treatment?		

No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-41: Should women with a history of breast cancer be offered HRT?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-42: Is routine (single-shot) mammography effective for early detection of breast cancer in women under the age of 50 years prior to HRT?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
Management of Advanced, Recurrent, and Metastatic Disease		
CSGBC-43: Is there evidence from randomised trials that aromatase inhibitors or progestins are better than tamoxifen for first line treatment of metastatic breast cancer in terms of survival and quality of life? • **Tamoxifen versus anastrozole or letrozole** • **Tamoxifen versus exemestane or formestane** • **Tamoxifen versus megestrol acetate or medroxyprogesterone acetate**		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-44: Is there evidence from randomised trials that aromatase inhibitors are safe and effective for second line treatment of hormone-dependent (ER+) metastatic breast cancer in post-menopausal women failing tamoxifen therapy?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-45: Is there evidence that routine combined measurement of oestrogen and progesterone receptor status influences decisions about endocrine therapy, and improves outcomes in metastatic breast cancer (ER+ and ER-)?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-46: Is there evidence that determining HER-2/neu (c-erb-B2) receptor status can improve patient outcome in advanced breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-47: Is there a reliable test for HER-2/neu (c-erb-B2) receptor status in advanced breast cancer?		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-48: Palliative care		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-49: The Breast Care Team		
<u>Survival/Risk of death</u> 12 studies were identified which examined the impact of surgeon and hospital case volume on risk of death and survival time. One retrospective study[1] showed that there was an increased risk of death in patients treated by	No GDG feedback was provided through the questionnaire.	The new evidence suggests that high volume hospitals and surgeons lead to improved outcomes for breast cancer patients in terms of improved survival/reduced risk of death, lower rates of unplanned readmission or re-operation following surgery, fewer complications, and increased frequency of breast conserving surgery.

low-volume surgeons (<29 cases per annum) compared to high volume surgeons (>50 cases). The results of a systematic review[2] and two cohort studies[3,4] indicated that survival times were improved in patients managed by high volume surgeons or at hospitals with higher surgical caseloads compared to lower volume surgeons/hospitals. A further six studies[5-10] found that patients treated at higher volume hospitals or by higher volume surgeons had increased 4, 5 and 10 year survival rates. Where reported, high volumes ranged from 20 or more cases up to over 200 cases per year. The results of a cohort study[11] showed that treatment by a high volume surgeon was associated with various factors including age, ethnicity, and socioeconomic status. After taking these factors into account, the study found that there were no differences in the risk of death from breast cancer between high-volume and low-volume surgeons. However, risk of death from other causes was significantly lower in patients treated by high-volume surgeons. A further study[12] also indicated that there were no differences in the risk of long-term death between patients who underwent resection of the breast in low volume hospitals compared to high-volume hospitals. <u>Readmission</u> A study[13] was identified which found that the rate of unplanned readmission within 30 days of breast cancer surgery was significantly higher for low-volume hospitals (<50 cases per year) compared to high-volume hospitals (> or =100 case per year). However, the findings were based on just 17 unplanned readmission cases from a sample of 1351 patients. Another study[14] of women who underwent breast-		This is consistent with the evidence presented in the guideline linking higher patient volumes and better surgical care and lower mortality rates. Whilst the new evidence is consistent with the guideline regarding high patient volumes and improved outcomes, there is considerable variation across the new evidence relating to the number of cases per surgeon/hospital that is considered as 'high' volume. Where reported, high volumes ranged from 20 to 200 or more cases per year. It is therefore unlikely that the new evidence will impact on the current recommendations in the guideline which state: All breast referrals should be to specialist breast teams working in units which deal with at least 100 new cases of breast cancer per year (a level which may be anticipated from a population of around 200,000 people). The figure of 100 was acknowledged in the guideline to be arbitrary although was based on research evidence, including evidence of benefit from a case-load above 30 new breast cancer patients per surgeon.

conserving surgery (n=8,318) found that there was an increased risk of re-operation and total mastectomy in patients treated by low-volume surgeons compared to those treated by a higher-volume surgeon. Complications Two studies were identified which found an association between hospital volume and surgical complications. One study[15] found that hospitals performing fewer than 9 cases a year were more likely to have perioperative complications following breast reconstruction compared to high-volume hospitals which performed over 44 cases per year. Another study[16] reported that patients operated on at low-volume hospitals (<30 cases/year) had a higher risk of death following breast-conserving therapy and postoperative complications compared with high-volume hospitals (> or =70 cases per year). Non-surgical treatment One retrospective study[17] (n=2,094) reported that the rate of radiation therapy use following breast-conserving surgery was significantly higher in high-volume hospitals compared to low-volume hospitals. Breast conserving treatment Three studies were identified[18-20] which found that patients treated by high volume surgeons/hospitals were more likely to receive breast conserving surgery than those treated by low volume surgeons/hospitals.		
CSGBC-50: Interprofessional communication		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-51: Clinical guidelines, up-to-date practice and continuing professional development		
No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.
CSGBC-52: Environment and facilities		

No new evidence was considered.	No GDG feedback was provided through the questionnaire.	No new evidence was considered.

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