2017 surveillance – Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer (2013) NICE guideline CG164

Appendix B: stakeholder consultation comments table

Consultation dates: October – November 2017

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No	We strongly recommend the guidelines be reviewed, for reasons detailed in question 6.	Thank you. Please see our response to your comment on page 6.
UK Cancer Genetics Group	No	No comments provided	Thank you.
Royal College of General Practitioners	Yes		Thank you.
Public Health England	No	The NHSBSP are currently revising their guidance on screening women at high risk. High risk is likely to be reclassified as "very high risk" due to the NICE guidance where some women who are deemed high risk include both those proven to be BRCA carriers and some are not proven. The NICE cut off for high risk is 30%. The new draft revised NHSBSP guidance is likely to be 45% (proven BRCA carriers and equivalent mutations which will be documented) and these will be "very high risk". It would be helpful if NICE could acknowledge this in their guidance. The new NHSBSP guidance should be published in the new year. Section 1.6.4 is not what is offered currently by the national screening programme. I note that you mention "Many topic experts noted the increasing popularity of multigene panel tests now available. This information has been passed onto the Diagnostics Assessment Programme at NICE to consider drafting guidance in this area". It would be very helpful to the	Thank you for your comments. Please see our response to each comment below: 1) Thank you for letting us know that the NHSBSP are revising their guidance on the screen of women at high risk of breast cancer. We will take this into consideration once the new guidance is published and any impact on CG164 will be determined then. 2) Thank you for the information regarding recommendation 1.6.4. It has not been possible to action any change without further information on where the discrepancies between the different guidance occur. We did not encounter any issues in the previous surveillance review and update in 2013 to indicate that this recommendation was not in line with the

		NHSBSP if we could be informed about decisions by the Diagnostics assessment programme within NICE as it could help inform further who we consider as “equivalent risk” to proven BRCA carriers.	National Screening Programme. Therefore we are unable to make any changes at this point without more information. 3) Thank you for your comment regarding multigene panel tests. Any plans for guidance in this area will be published on the ‘guidance in development’ page here.
CancerCare North Lancashire and South Cumbria	Yes	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No	The current guideline applies only to testing BRACA1: BRACA2: and TP53. A large number of other genes are now included in gene panels. There is currently no guidance on this, yet this is essential.	Thank you for your comment. As stated in Appendix A of the consultation document, we acknowledge that there are now a wide range of genes that could be included in panel tests. We referred this information to the Diagnostics Assessment Programme at NICE for consideration to develop guidance in this area. However, without a defined intervention to assess, such as a specific gene panel product, and because there is a lack of evidence indicating the benefit of testing for other high risk genes in this population, it is not possible to pursue diagnostic guidance further at this time. If there is further information available to identify a specific technology, please notify the medical technologies evaluation programme.
The Royal College of Radiologists	Yes	The Royal College of Radiologists (RCR) is happy for no change to be made in the guidance.	Thank you for your comment.

Do you agree with the proposal to remove the research recommendation?

Do you agree with the proposal to remove the research recommendation:
RR-03 Research is recommended to establish the risk and benefits of MRI surveillance compared with mammography in women over 50 years with a personal history of breast cancer. Studies should include sub-analysis for breast density.

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No comment	No comments provided	Thank you.

UK Cancer Genetics Group	No	We would like the breast density data reviewed	Thank you for your comment. After considering all stakeholder responses, we have decided to keep this research recommendation.
Royal College of General Practitioners	Yes	No comments provided	Thank you.
Public Health England	No comment	Cannot comment	Thank you.
CancerCare North Lancashire and South Cumbria	Yes	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No	This has not been verified by research.	Thank you for your comment. After considering all stakeholder responses, we have decided to keep this research recommendation.
The Royal College of Radiologists	Yes	No comments provided	Thank you.

Do you agree with the proposal to remove the research recommendation?

RR-04 What is the clinical and cost effectiveness of aromatase inhibitors (particularly exemestane and letrozole) compared with tamoxifen and raloxifene for reducing the incidence of breast cancer in women with a family history of breast or ovarian cancer?

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No comment	No comments provided	Thank you.
UK Cancer Genetics Group	No comment	No comments provided	Thank you.
Royal College of General Practitioners	Yes	No comments provided	Thank you.
Public Health England	No comment	Cannot comment	Thank you.

CancerCare North Lancashire and South Cumbria	Yes	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No	This has not been verified by research.	Thank you for your comment. After considering all stakeholder responses, we have decided to keep this research recommendation.
The Royal College of Radiologists	Yes	No comments provided	Thank you.

Do you agree with the proposal to remove the research recommendation?

RR-05 Further research is recommended to compare psychosocial and clinical outcomes in women who choose and women who do not choose to have risk-reducing surgery.

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No	Risk-reducing surgery is not for everyone. Patients should be able to access to up to date, accurate information about the impact of the decision on whether or not to have both breast and gynaecological risk reducing surgery so as to make informed decisions. In order to provide this, it is essential that further research on clinical and psychosocial outcomes is undertaken. As such we do not agree with the proposal to remove research recommendation into outcomes for women who do or do not choose risk reducing surgery.	Thank you. After considering all stakeholder responses, we have decided to keep this research recommendation.
UK Cancer Genetics Group	No	We would like to see further research in this area	Thank you. After considering all stakeholder responses, we have decided to keep this research recommendation.
Royal College of General Practitioners	Yes	No comments provided	Thank you.
Public Health England	No comment	Cannot comment	Thank you.

CancerCare North Lancashire and South Cumbria	Yes	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No	This has not been verified by research.	Thank you. After considering all stake holder responses, we have decided to keep this research recommendation.
The Royal College of Radiologists	Yes	No comments provided	Thank you.

Do you agree with the proposal to remove the research recommendation:

RR-06 What is the prevalence of BRCA1 mutations in unselected basal phenotype breast cancer compared with unselected triple negative breast cancer?

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No comment	No comments provided	Thank you.
UK Cancer Genetics Group	No comment	No comments provided	Thank you.
Royal College of General Practitioners	No	No comments provided	Thank you.
Public Health England	No comment	Cannot comment	Thank you.
CancerCare North Lancashire and South Cumbria	No	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No	This has not been verified by research.	Thank you. After considering all stake holder responses, we have decided to keep this research recommendation.

The Royal College of Radiologists	Yes	No comments provided	Thank you.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	Yes	As part of our recently published policy paper "Acting on BRCA: Breaking down barriers to save lives" (http://ovarian.org.uk/documents/88/Acting_on_BRCA_Policy_Paper.pdf) Ovarian Cancer Action made several recommendations directly relating to NICE guidelines CG164: 1) NHS England Clinical Commissioning Policy E01/pb (https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/10/e01pb-brca-ovariancancer-oct15.pdf) recommends that women with ovarian cancer be offered genetic testing at the point of diagnosis as standard. **We therefore recommend that NICE guideline 1.5.13 which states "Offer genetic testing in specialist genetic clinics to a person with breast or ovarian cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more" should be amended to be in line with NHS England's policy, so that it reflects that women diagnosed with ovarian cancer should be offered BRCA testing as standard regardless of their family history.** This will help ensure patients and families at high risk of cancer be fully informed of their cancer treatment prevention options. 2) The testing eligibility threshold should be lowered from 10% to 5% combined BRCA1 and BRCA2 mutation carrier probability. NHS England's own economic analysis has shown that a 5% carrier probability threshold would be cost-effective. **As such we suggest recommendations 1.4.4, 1.5.11 and 1.5.12 be amended from 10% to 5%.** 3) We support the current recommendation that patients should be provided with standard written information. **However, we recommend that Box 1 "Information provision for people with concerns about familial breast cancer risk" also include the following:**	Thank you for your comments and for highlighting your recently published policy paper. Please see our response to each comment below: 1) Thank you for requesting that women diagnosed with ovarian cancer should be offered BRCA testing as standard regardless of their family history. NICE Guideline CG164 is currently in line with the NHS England Clinical Commissioning Policy on this matter, which states on page 19 that "*Genetic testing will be offered in specialist genetic clinics to a person with breast or ovarian cancer if their combined BRCA1 and BRCA2 mutation carrier probability is 10% or more.*" Therefore we will not be changing the recommendation during this time. 2) Thank you for your comment regarding the eligibility threshold for genetic testing. We acknowledge that the economic analysis presented in the NHS England Clinical Commissioning Policy does support a level of genetic testing at both the 5% and 10% carrier probability. However, NHS England note that using the 5% threshold would substantially increase the number of people being eligible for testing. Furthermore, they state that "*this increase in numbers being able to access the test may not only cause an overload onto the existing infrastructure and services but is also out of line with the threshold offered by most other countries (10%). Therefore a level of 10% has been recommended as benefits at this level are perceived*

		a. Information about fertility options and their availability (e.g. PGD) b. Specific information for males, including the provision of separate materials where necessary c. Advice for contacting family members at risk d. Rights regarding financial concerns e.g. insurance/ mortgage/ sick leave from work 4) We support recommendation 1.2.4 that "Standard information should be evidence based wherever possible, and agreed at a national level if possible" and **further recommend that a central, standardised resource be set up and kept up to date so that all patients may access the same resources across the UK.** 5) We support guideline 1.4.1 stating "Care of people in secondary care (such as a breast care team, family history clinic or breast clinic) should be undertaken by a multidisciplinary team. It should include…access to psychological assessment and counselling." **We do however recommend that this should explicitly state that support should be ongoing.** Those with a BRCA gene mutation should have access to relevant mental health services adequately trained to support those with a genetic mutation at any point in their BRCA journey, whether pre or post testing, at the time of considering or undergoing risk-reducing surgery or at any point beyond this. 6) Currently the guideline's title references breast cancer only. We strongly recommend that guidelines about genetic testing for BRCA mutations not sit under those for breast cancer family history, but instead as standalone guidelines in order to make it clearer for both medical professionals and the layman that risks also include ovarian cancer, prostate and pancreatic cancer, and that family history of these cancers should be a red flag. Evidence and international practice for all the above points can be found in our policy paper (link above).	*to be reduced morbidity and mortality, reduced variation in practice, increased patient choice, improvement in informed decision making and a reduction in unnecessary surgery/treatment.*" Therefore we will not be changing the recommendations at this time. 3) Thank you for your comments regarding Box 1 "*Information provision for people with concerns about familial breast cancer risk*". Please find a separate response to each point below: a. Lifestyle advice is already listed as a component of the standard written information for all people, this includes advice on breastfeeding, family size and timing. NICE also have a separate guideline on Fertility problems: assessment and treatment (CG156) which has recommendations for people with cancer who wish to preserve their fertility (see section 1.16). b. Unless otherwise specified, the information in box 1 applies to males as well as females. Recommendation 1.2.2. states that "*patients should be offered individually tailored information*" and recommendation 1.2.3 states that "*tailoring of information should take into account format (including whether written or taped) as well as the actual content*". c. The scope of the guideline does not cover offering specific advice for contacting family members at risk. However Box 1 does contain advice on providing details of those who can offer further support. d. The scope of the guideline does not cover advice on financial concerns. However Box 1 does contain advice on providing details of those who can offer further support. Specific guidance relating to sick leave can be found in NICE guideline PH19 (Workplace health: long-term sickness absence and incapacity to work).

			For each of the reasons outlined above, we will not be making any changes to Box 1 at this time. 4) Thank you for your comment regarding recommendation 1.2.4, requesting that a central, standardised resource be set up and kept up to date. The setting up of a national resource is not within the remit of NICE, however we have noted your comment for consideration at the next surveillance point should any evidence be found in this area. 5) Thank you for your comment regarding recommendation 1.4.1. We found no evidence at any surveillance review that suggests ongoing psychological support would improve outcomes in this population so we will not be expanding this recommendation at this point. However we will note your comment for consideration at the next surveillance point. 6) Thank you for your comment regarding the guideline title and the suggestion for a separate guideline for BRCA mutations. NICE is required to fulfil the remit set out by the Department of Health in 2010, which asks for a guideline on the diagnosis and management of affected women with hereditary cancer. We therefore cannot make any changes at this point.
UK Cancer Genetics Group	Yes	(1) we would like NICE to consider when gene panels should be used and what should these include. (2) we would like the SNP18 panels reviewed as well as their implications for risk assesssment. (3) we would like a recommendation regarding blood and/or tumour testing in patients particularly with regard to therapeutic choices. (4) we would like the threshold for offering RRSO reviewed in the light of new health economic data	Thank you for your comment regarding gene panels and SNP18 panels. As stated in Appendix A of the consultation document, we acknowledge that there are now a wide range of genes that could be included in panel tests. We referred this information to the Diagnostics Assessment Programme at NICE for consideration to develop guidance in this area. However, without a defined intervention to assess, such as a specific gene panel product, and because there is a lack of evidence indicating the benefit of testing for other high risk genes in this population, it is not possible to pursue diagnostic guidance further at this time. If there is further information available to identify a specific technology, please notify the medical technologies evaluation programme. Thank you for your comment regarding the threshold for risk-reducing salpingo-oophorectomy. We did not identify any evidence

			in this area at any surveillance point so we are unaware of the new health economic data that you mention. We would consider the evidence accordingly if you are able to provide a reference. For each of the reasons outlined above, we will not be making any changes to CG164 during this time.
Royal College of General Practitioners		Would be interested to learn on how genomics will be included	Thank you for your comment regarding genomics. Any plans for guidance in this area will be published on the 'guidance in development' page here.
Public Health England	No	No comments provided	Thank you.
CancerCare North Lancashire and South Cumbria	No	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No comment	No comments provided	Thank you.
The Royal College of Radiologists	Yes	The role of tomosynthesis should be added to the evidence review.	Thank you for your comment regarding the role of tomosynthesis. We did not find any evidence on tomosynthesis in the recent surveillance review. This area was recently considered by the Interventional Procedures Team at NICE but was decided to be out of remit due to it being a minor modification of an existing procedure.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Ovarian Cancer Action	No comment	No comments provided	Thank you.
UK Cancer Genetics Group	No	No comments provided	Thank you.

Royal College of General Practitioners	No	No comments provided	Thank you.
Public Health England	No	No comments provided	Thank you.
CancerCare North Lancashire and South Cumbria	No	No comments provided	Thank you.
National Hereditary Breast Cancer Helpline	No comment	No comments provided	Thank you.
The Royal College of Radiologists	No	No comments provided	Thank you.

Comments:

This is to inform you that the Royal College of Nursing has no comments to submit to inform on the Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer NICE Surveillance consultation at this time.

Breast Cancer Care- We won't be submitting any comments this time.