NICE National Institute for Health and Care Excellence

Surveillance report 2018 – 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

Surveillance report

Published: 18 January 2018

www.nice.org.uk

Contents

Surveillance decision

We will not update the guideline on familial breast cancer at this time.

During surveillance editorial or factual corrections were identified. Details are included in appendix A: summary of evidence from surveillance.

Reason for the decision

Assessing the evidence

We found 30 studies through surveillance of this guideline.

This included evidence that supports current recommendations in the following areas:

- the accuracy of family history
- the optimal methods for assessing the carrier probability of people at different thresholds for genetic testing in those at risk of familial breast cancer
- patient information and support
- the effectiveness of chemoprevention for the reduction of the incidence of breast cancer in people with a family history of breast, ovarian or related (prostate/ pancreatic) cancer
- risk-reducing mastectomy for women with no personal history of breast cancer
- risk-reducing oophorectomy for women with no personal history of breast cancer.

We also identified evidence that was not consistent with current recommendations on: BRCA testing of women with epithelial ovarian cancer; mammographic surveillance of women under 40 years; and the efficacy of MRI screening compared to mammography and ultrasound. On further consideration, this evidence was deemed not to impact current recommendations (for further details see appendix A).

We found evidence on the following areas not covered in the guideline:

- use of a brief screening tool to identify low income women at high risk of breast cancer and to aid referral from primary care
- telephone-based genetic counselling
- rapid genetic counselling and testing
- clinical nurse specialist-led breast self-examination education intervention as part of a surveillance programme
- associations between breast cancer risk and dietary linoleic acid intake or serum linoleic acid level.

This evidence was considered to be insufficient in volume and conclusive results to add new recommendations in these areas at this time.

We did not find any evidence related to the following areas:

- communicating cancer risk and carrier probability
- care and management in primary care
- patient education and information
- care and management approach in secondary care
- the carrier probability at which genetic testing should be offered to people who are (a) unaffected but with a family history of breast, ovarian or related cancer; (b) unaffected with a family history and no living relative; (c) affected patients
- who should discuss the implications of genetic testing with the patient and when the most appropriate time is for such a discussion to occur
- the risks and benefits of hormone replacement therapy for women under the age of 50, with a BRCA1 or BRCA2 mutation who have undergone a bilateral salpingo-oophorectomy
- the level of risk which indicates that risk reducing surgery is a viable option
- the factors that indicate that offering risk reducing surgery is not appropriate

- the effectiveness of mastectomy compared with breast conserving surgery plus radiotherapy for people with newly diagnosed breast cancer or high grade ductal carcinoma in situ (DCIS) with a TP53 mutation or at high risk of TP53 mutation.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the evidence and views of topic experts and stakeholders, we decided not to update this guideline.

See how we made the decision for further information.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 4 years after the publication of NICE's guideline on familial breast cancer (NICE guideline CG164) in 2013.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Previous surveillance update decisions for the guideline are on our website.

Evidence

We found 20 studies in a search for systematic reviews, randomised controlled trials and diagnostic studies published between 26 January 2015 and 13 June 2017. We also included 1 relevant study identified by members of the guideline committee who originally worked on this guideline.

We also considered evidence identified in previous surveillance 2 years after publication of the guideline. This included 9 studies identified by the search.

From all sources, we considered 30 studies to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of evidence from surveillance for details of all evidence considered, and references.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline. Most topic experts felt that the guideline should be updated, mainly due to the increasing popularity of multigene panel tests now available to identify people at risk of breast cancer. It was agreed that this is a rapidly growing area of research and it was felt it sits best in the remit of the Diagnostic Assessment Programme at NICE. However, without

a defined intervention to assess, such as a specific gene panel product, and because of 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.

Topic experts also highlighted a need for ultrasound to be considered in women with dense breasts who are not eligible for MRI. No evidence was identified in this area so it is unlikely that the recommendations will change, however we will log this issue and review the area again at the next surveillance point.

Views of stakeholders

Stakeholders commented on the decision not to update the guideline. Responses were limited in number and content, therefore a targeted consultation was undertaken for a further two weeks with stakeholders specifically involved in this area. Overall, 7 stakeholders commented. See appendix B for stakeholders' comments and our responses.

Seven stakeholders including Public Health England, Royal College of General Practitioners, Royal College of Radiologists, Ovarian Cancer Action, UK Cancer Genetics Group, National Hereditary Breast Cancer Helpline, and CancerCare North Lancashire and South Cumbria commented on the proposal to not update the guideline: 3 stakeholders agreed and 4 disagreed with the proposal.

One stakeholder highlighted that the NHS breast screening programme (NHSBSP) are currently revising their guidance on screening women at high risk of breast cancer. The new guidance will provide more clarity about the distinction between those at high risk eligible for NHSBSP surveillance and those who are not eligible but still classed by NICE as high risk. It was suggested that the new guidance be acknowledged in CG164. We will consider the new guidance once it is published and the impact on CG164 will be determined at that point.

Three stakeholders commented on the growing evidence base around multigene panel tests and the use of SNPs, requesting that this be reviewed and included in the guideline. This was also an issue raised by topic experts (see views of topic experts for further details). It was agreed that this is a rapidly growing area of research and it was felt it sits best in the remit of the Diagnostic Assessment Programme at NICE. However, without a defined intervention to assess, such as a specific gene panel product, and because of 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.

Many stakeholders disagreed with the proposal to withdraw the priority research recommendations 3, 4, 5, and 6 from the NICE version of the guideline and the NICE research recommendations database. The majority of feedback indicated that the research questions are still valid, therefore these research recommendations will remain in the guideline.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

NICE Surveillance programme project team

Kay Nolan
Associate Director

Martin Allaby
Consultant Clinical Adviser

Emma McFarlane
Technical Adviser

Alice Murray
Technical Analyst

The NICE project team would like to thank the topic experts who participated in the surveillance process.

ISBN: 978-1-4731-2786-9