NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Early and locally advanced breast cancer: diagnosis and management

Draft for consultation, November 2023

This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences.

This guideline will update NICE guideline NG101 (published July 2018).

Who is it for?

- Healthcare professionals
- Commissioners and providers of breast cancer services
- People with early and locally advanced breast cancer, their families and carers

What does it include?

- new and updated recommendations on surgery to the breast
- the rationale and impact section that explains why the committee made the 2023 recommendations and how they might affect services.

Information about how the guideline was developed is on the guideline's webpage. This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

New and updated recommendations

We have reviewed the evidence on further surgery to the breast after breast-conserving surgery. You are invited to comment on these new recommendations only. These are marked as **[2023].**

Recommendations shaded in grey are not part of this update and are given for context only. We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification highlighted in yellow. Rationale sections for these recommendations have not been included.

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off‑label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.3 Surgery to the breast

1.3.1 Offer further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery if invasive cancer or DCIS is present at the radial margins ('tumour on ink'; 0 mm). **[2018]**

1.3.2 Consider further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery for invasive cancer with or without DCIS if tumour cells are present within 1 mm, but not at, the radial margins (greater than 0 mm and less than 1 mm). As part of the decision making:

- discuss the benefits and risks with the person

- take into account:
  - the person's preferences
  - any comorbidities
  - tumour characteristics and potential treatments, including the use of radiotherapy (also see radiotherapy after breast conserving surgery) and other adjuvant therapies **[2023]**

1.3.3 Consider further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery for DCIS without invasive cancer if tumour cells are present within 2 mm of, but not at, the radial margins (greater than 0 mm and less than 2 mm). As part of the decision making:

- discuss the benefits and risks with the person
- take into account:
  - the person's preferences
  - any comorbidities
  - tumour characteristics and potential treatments, including the use of radiotherapy (also see radiotherapy after breast conserving surgery) and other adjuvant therapies **[2023]**

1.3.4 When discussing the benefits and risks of further surgery, follow the recommendations on:

- enabling patients to actively participate in their care in the NICE guideline on patient experience in adult NHS services, and
- communicating risks, benefits and consequences in the NICE guideline on shared decision making. **[2023]**

1.3.5 All breast units should audit their local, regional and distant recurrence rates after treatment, including systematically collecting data on radial margins, and demographic information (such as socioeconomic status, age, ethnicity). **[2018, amended 2023]**

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Surgery to the breast

Recommendations 1.3.2 to 1.3.5

Why the committee made the recommendations

The committee agreed that the best choice for radial margin size would be a balance between the need for further surgery (to reduce the risk of local recurrence and maximise overall survival) against maintaining good levels of patient satisfaction. This balance also needs to take into account the potential harms of further surgery, and possible need for other treatments to take priority over further surgery. Because of the way the evidence was reported in the included studies, the committee discussed the evidence on radial margins after breast-conserving surgery for people who had invasive breast cancer with or without DCIS and for people who had DCIS only separately. Most of the data was for local recurrence, with some for distant recurrence and very limited data for overall survival or breast cancer specific survival. There was no evidence on patient reported outcomes or quality of life. Therefore, the committee based most of their discussion on the evidence for local recurrence, and used their personal and clinical experience to consider the perspective and preferences of people who have breast cancer.

The committee discussions focused on whether a radial margin of 1 mm or 2 mm should be the cut-off for further surgery. The committee agreed that where the tumour is at 0 mm, this balance is strongly in favour of further surgery to try to ensure the full tumour is removed and so the existing recommendation to offer further surgery was retained without reviewing the evidence. For people with invasive breast cancer with or without DCIS, the evidence showed that the risk of local recurrence was higher with radial margins of greater than 0 mm to less than 1 mm compared to greater than or equal to 1 mm. This was also the case for local recurrence when radial margins of greater than 0 mm to 2 mm were compared to greater than 2 mm. However, the evidence could not differentiate between greater

than 1 mm to 2 mm compared to greater than 2 mm. The committee also noted that the incidence of local recurrence has decreased because of advances in breast cancer care.

Taking this into account with the evidence for local recurrence, the committee did not think that recommending a margin of 1 mm, rather than 2 mm, would lead to a substantially increased risk of local recurrence. Additionally, they agreed that for many people, a margin of 1 mm is likely to be preferable over a more cautious approach with a margin of 2 mm because the smaller margin is likely to achieve better breast preservation and result in fewer additional surgeries. They noted that repeated surgeries negatively affect breast appearance, and can have negative effects on the person's self esteem and view of themselves. They are also traumatic for the person involved and can lead to stress, infections, pain, complications associated with recovery from the anaesthetic and operation, and negatively affect their everyday life. As a result, the committee agreed that further surgery should be considered for people who had breast-conserving surgery for invasive breast cancer with or without DCIS if tumour cells are present within 1 mm of the radial margins.

For DCIS only, the limited evidence was of very low quality, and it was not possible to combine the findings from the studies that were available in a meta-analysis. Therefore, the committee was not confident of the differences between a margin of less than, or greater than, 2 mm on local or distant recurrence. As a result, they decided to retain the threshold of 2 mm from the existing recommendation when considering further surgery for this population. The committee did not make a research recommendation for this group because they were aware new studies are already underway that could inform this decision in the future.

As well as thinking about the potential clinical benefits of further surgery, the committee acknowledged the importance of taking the person's preferences into account as part of the decision-making process. They recommended that there should be a discussion with the person about the benefits of surgery, such as reducing the risk of recurrence, as well as risks, such as infection and complications. The committee also agreed other clinical factors, such as tumour characteristics and potential treatments, should be taken into account as well as the person's

circumstances. They referred to the NICE guidelines on shared decision making and patient experience to help inform these discussions.

The committee noted that, in their experience, the existing recommendation about auditing recurrence is not uniformly applied and that the information recorded does not necessarily include the radial margin. They therefore expanded the recommendation to highlight factors that they thought should be recorded in addition to recurrence. The committee were also aware of a new National Audit of Primary Breast Cancer that may improve recording of this information.

The committee noted that there was no evidence for people receiving neoadjuvant hormone therapy or biological treatments and very little evidence for people receiving neoadjuvant chemotherapy, and that the quality of this evidence was very low. Therefore, they could not make a specific recommendation for this group. However, they agreed that the evidence for people who did not have neoadjuvant therapy could be extrapolated to this group and that the recommendation for people with invasive breast cancer with or without DCIS could apply to them as well until there is evidence to suggest that a different radial margin should be used.

How the recommendations might affect practice

It is not expected that the recommendation for people with invasive breast cancer will increase resource use, since it reinforces current best practice followed in some places, and it is likely that fewer people will have further surgery given the reduction in margin size. The recommendations should also encourage standardisation of practice in relation to radial margins for invasive breast cancer with or without DCIS across the UK. The recommendations for DCIS retain the existing radial margins and are therefore not expected to change practice or resource use.

Return to recommendations

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