Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer

NICE guideline: short version

Draft for consultation, November 2016

This guideline covers care for people with a family history of breast, ovarian or another related (prostate or pancreatic) cancer. It aims to improve the long-term health of these families by describing strategies to reduce the risk of and promote early detection of breast cancer (including genetic testing and mammography). It also includes advice on treatments for chemoprevention and risk-reducing surgery (mastectomy).

Who is it for?

- Healthcare professionals
- People with a family history of breast, ovarian or another related (prostate or pancreatic) cancer, and their carers

This guideline will update NICE clinical guideline CG164 (published June 2013).

We have updated recommendations on chemoprevention for women with no personal history of breast cancer and have added a new recommendation on genetic testing for women with triple negative breast cancer but no family history.

You are invited to comment on the new and updated recommendations in this guideline. These are marked as:

- **[new 2017]** if the evidence has been reviewed and the recommendation has been added or updated **or**

- **[2017]** if the evidence has been reviewed but no change has been made to the recommended action.

You are also invited to comment on recommendations that NICE proposes to delete from the 2013 guideline.

We have not updated recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See Update information for a full explanation of what is being updated.

This version of the guideline contains the draft recommendations, context and recommendations for research. Information about how the guideline was developed is on the guideline's page on the NICE website. This includes the guideline committee's discussion and the evidence reviews (in the full guideline), the scope, and details of the committee and any declarations of interest.

The supporting information and evidence for the 2017 recommendations is contained in the addenda.

Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in 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.

The recommendations in this guideline apply to women and men unless otherwise specified.

1.1 Clinical significance of a family history of breast cancer

Accuracy of family history

Family history-taking and initial assessment in primary care

1.1.1 When a person with no personal history of breast cancer presents with breast symptoms or has concerns about relatives with breast cancer, a first- and second-degree family history should be taken in primary care to assess risk, because this allows appropriate classification and care. **[2004]**

1.1.2 Healthcare professionals should respond to a person who presents with concerns but should not, in most instances, actively seek to identify people with a family history of breast cancer. **[2004]**

1.1.3 In some circumstances, it may also be clinically relevant to take a family history, for example, for women older than age 35 years using an oral contraceptive pill or for women being considered for long-term HRT use. **[2004]**

1.1.4 A person should be given the opportunity to discuss concerns about their family history of breast cancer if it is raised during a consultation. **[2004]**

1.1.5 A second-degree family history (that is, including aunts, uncles and grandparents) should be taken in primary care before explaining risks and options. **[2004]**

1.1.6 A second-degree family history needs to include paternal as well as maternal relatives. **[2004]**

1.1.7 Asking people to discuss their family history with relatives is useful in gathering the most accurate information. **[2004]**

1.1.8 Tools such as family history questionnaires and computer packages exist that can aid accurate collection of family history information and they should be made available. **[2004]**

1.1.9 For referral decisions, attempts should be made to gather as accurate information as possible on:

- age of diagnosis of any cancer in relatives
- site of tumours
- multiple cancers (including bilateral disease)
- Jewish ancestry[1]. **[2004]**

Family history-taking in secondary care

1.1.10 A family history should be taken when a person with no personal history of breast cancer presents with breast symptoms or has concerns about relatives with breast cancer. **[2004]**

1.1.11 A third-degree family history should be taken in secondary care where possible and appropriate. **[2004]**

[1] Women with Jewish ancestry are around 5–10 times more likely to carry *BRCA1* or *BRCA2* mutations than women in non-Jewish populations.

1.1.12 Tools such as family history questionnaires and computer packages exist that can aid accurate collection of family history information and risk assessment and they should be made available. **[2004]**

Family history-taking in a specialist genetic clinic

1.1.13 A third-degree family history should be taken in a specialist genetic clinic for a person with no personal history of breast cancer, if this has not been done previously. **[2004]**

1.1.14 For accurate risk estimation, the following are required:

- age of death of affected and unaffected relatives
- current age of unaffected relatives. **[2004]**

1.1.15 In general, it is not necessary to validate breast cancer-only histories (via medical records/cancer registry/death certificates). **[2004]**

1.1.16 If substantial management decisions, such as risk-reducing surgery, are being considered and no mutation has been identified, clinicians should seek confirmation of breast cancer-only histories (via medical records/cancer registry/death certificates). **[2004]**

1.1.17 Where no family history verification is possible, agreement by a multidisciplinary team should be sought before proceeding with risk-reducing surgery. **[2004]**

1.1.18 Abdominal malignancies at young ages and possible sarcomas should be confirmed in specialist care. **[2004]**

Family history and carrier probability

1.1.19 When available in secondary care, use a carrier probability calculation method with demonstrated acceptable performance (calibration and discrimination) as well as family history to determine who should be offered referral to a specialist genetic clinic. Examples of acceptable methods include BOADICEA and the Manchester scoring system. **[2013]**

1.1.20 In a specialist genetic clinic, use a carrier probability calculation method with demonstrated acceptable performance (calibration and discrimination) to assess the probability of a *BRCA1* or *BRCA2* mutation. Examples of acceptable methods include BOADICEA and the Manchester scoring system. **[2013]**

1.1.21 If there are problems with using or interpreting carrier probability calculation methods, use clinical judgement when deciding whether to offer genetic testing. **[2013]**

Communicating cancer risk and carrier probability

1.1.22 People should be offered a personal risk estimate but information should also be given about the uncertainties of the estimation. **[2004]**

1.1.23 When a personal risk value is requested, it should be presented in more than one way (for example, a numerical value, if calculated, and qualitative risk). **[2004]**

1.1.24 People should be sent a written summary of their consultation in a specialist genetic clinic, which includes their personal risk information. **[2004]**

1.2 Information and support

1.2.1 Effective care involves a balanced partnership between patients and healthcare professionals. Patients should have the opportunity to make informed choices about any treatment and care and to share in decision making. **[2004]**

1.2.2 To ensure a patient-professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organisations). **[2004]**

1.2.3 Tailoring of information should take into account format (including whether written or taped) as well as the actual content and form that should be provided (see box 1). **[2004]**

1.2.4 Standard information should be evidence based wherever possible, and agreed at a national level if possible (NICE's information for the public provides a good starting point). **[2004]**

1.2.5 Standard information should not contradict messages from other service providers, including commonly agreed information across localities. **[2004]**

Box 1 Information provision for people with concerns about familial breast cancer risk

Standard written information for all people

- Risk information about population level and family history levels of risk, including a definition of family history.
- The message that, if their family history alters, their risk may alter.
- Breast awareness information.
- Lifestyle advice regarding breast cancer risk, including information about:
  - HRT and oral contraceptives (women only)
  - lifestyle, including diet, alcohol, etc
  - breastfeeding, family size and timing (women only).

- Contact details of those providing support and information, including local and national support groups.
- People should be informed prior to appointments that they can bring a family member/friend with them to appointments.
- Details of any trials or studies that may be appropriate.

For people cared for in primary care

- Standard written information (as above).
- Advice to return to discuss any implications if there is a change in family history or breast symptoms develop.

For people being referred to secondary care

- Standard written information (as above).

- Information about the risk assessment exercise that will take place and advice about how to obtain a comprehensive family history if required.
- Information about potential outcomes, depending on the outcome of the risk assessment (including referral back to primary care, management within secondary care or referral to a specialist genetics service) and what may happen at each level.

For people being referred back to primary care

- Standard written information (as above).
- Detailed information about why secondary or a specialist genetics service are not needed.
- Advice to return to primary care to discuss any implications if there is a change in family history or breast symptoms develop.

For people being cared for in secondary care

- Standard written information (as above).
- Details of the risk assessment outcome, including why they are not being referred to a specialist genetics service.
- Details of surveillance options including risk and benefits.

For people being referred to a specialist genetic clinic

- Standard written information (as above).
- Details of the risk assessment outcome, including why they are being referred to a specialist genetics service.
- Details of surveillance options, including risk and benefits.
- Details of what should be expected in a specialist genetics service, including counselling and genetic testing.

For people being cared for in a specialist genetic clinic

- Standard written information (as above).
- Information about hereditary breast cancer.

- Information about genetic testing, both predictive testing and mutation finding, including details of what the tests mean and how informative they are likely to be, and the likely timescale of being given the results.
- Information about the risks and benefits of risk-reducing surgery when it is being considered, including both physical and psychological impact.

1.3 Care of people in primary care

Care and management in primary care

1.3.1 People without a personal history of breast cancer can be cared for in primary care if the family history shows only one first-degree or second-degree relative diagnosed with breast cancer at older than age 40 years[2], provided that none of the following are present in the family history:

- bilateral breast cancer
- male breast cancer
- ovarian cancer
- Jewish ancestry
- sarcoma in a relative younger than age 45 years
- glioma or childhood adrenal cortical carcinomas
- complicated patterns of multiple cancers at a young age
- paternal history of breast cancer (two or more relatives on the father's side of the family). **[2004]**

1.3.2 People who do not meet the criteria for referral should be cared for in primary care by giving standard written information. **[2004]**

Referral from primary care

1.3.3 People without a personal history of breast cancer who meet the following criteria should be offered referral to secondary care:

- one first-degree female relative diagnosed with breast cancer at younger than age 40 years **or**

[2] In most cases, this will equate to less than a 3% 10-year risk of breast cancer at age 40 years.

- one first-degree male relative diagnosed with breast cancer at any age **or**
- one first-degree relative with bilateral breast cancer where the first primary was diagnosed at younger than age 50 years **or**
- two first-degree relatives, or one first-degree and one second-degree relative, diagnosed with breast cancer at any age **or**
- one first-degree or second-degree relative diagnosed with breast cancer at any age and one first-degree or second-degree relative diagnosed with ovarian cancer at any age (one of these should be a first-degree relative) **or**
- three first-degree or second-degree relatives diagnosed with breast cancer at any age. **[2004]**

1.3.4 Advice should be sought from the designated secondary care contact if any of the following are present in the family history in addition to breast cancers in relatives not fulfilling the above criteria:

- bilateral breast cancer
- male breast cancer
- ovarian cancer
- Jewish ancestry
- sarcoma in a relative younger than age 45 years
- glioma or childhood adrenal cortical carcinomas
- complicated patterns of multiple cancers at a young age
- paternal history of breast cancer (two or more relatives on the father's side of the family). **[2004]**

1.3.5 Discussion with the designated secondary care contact should take place if the primary care health professional is uncertain about the appropriateness of referral because the family history presented is unusual or difficult to make clear decisions about, or where the person is not sufficiently reassured by the standard information provided. **[2004]**

1.3.6 Direct referral to a specialist genetics service should take place where a high-risk predisposing gene mutation has been identified (for example, *BRCA1*, *BRCA2* or *TP53*). **[2004]**

Patient education and information

Information for women who are being referred

1.3.7 Women who are being referred to secondary care or a specialist genetic clinic should be provided with written information about what happens at this stage. **[2004]**

Information and ongoing support for women who are not being referred

1.3.8 Support mechanisms (for example, risk counselling, psychological counselling and risk management advice) need to be identified, and should be offered to women not eligible for referral and/or surveillance on the basis of age or risk level who have ongoing concerns. **[2004]**

Support for primary care

1.3.9 Support is needed for primary care health professionals to care for women with a family history of breast cancer. Essential requirements for support for primary care are:

- a single point and locally agreed mechanism of referral for women identified as being at increased risk
- educational materials about familial breast cancer
- decision-support systems
- standardised patient information leaflets
- a designated secondary care contact to discuss management of 'uncertain' cases. **[2004]**

1.4 Care of people in secondary care and specialist genetic clinics

Care and management approach in secondary care

1.4.1 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 the following:

- written protocols for management
- central, standardised resources
- mammographic surveillance available to standard of the national breast screening programmes[3]
- access to surveillance **[2013]**
- access to a team offering risk-reducing surgery
- standardised written information
- designated/lead clinicians
- a designated contact for primary care
- a designated contact in a specialist genetic clinic
- audit
- clinical trials access
- access to psychological assessment and counselling
- information about support groups and voluntary organisations
- administrative support. **[2004]**

1.4.2 People who meet the following criteria should be offered secondary care and do not require referral to a specialist genetic clinic:

- one first-degree relative diagnosed with breast cancer at younger than age 40 years **or**
- two first-degree or second-degree relatives diagnosed with breast cancer at an average age of older than 50 years **or**
- three first-degree or second-degree relatives diagnosed with breast cancer at an average age of older than 60 years **or**

[3] National breast screening programmes: England – NHS Breast Screening Programme (NHSBSP); Wales – Breast Test Wales; Northern Ireland – NI Breast Screening Programme.

- a formal risk assessment (usually carried out in a specialist genetic clinic) or a family history pattern is likely to give risks of greater than 3–8% risk in the next 10 years for women aged 40 years, or a lifetime risk of 17% or greater but less than 30%[4]

provided that none of the following are present in the family history:

- bilateral breast cancer
- male breast cancer
- ovarian cancer
- Jewish ancestry
- sarcoma in a relative younger than 45 years of age
- glioma or childhood adrenal cortical carcinomas
- complicated patterns of multiple cancers at a young age
- very strong paternal history (four relatives diagnosed at younger than 60 years of age on the father's side of the family). **[2004]**

1.4.3 People whose risk does not meet the criteria for referral to secondary care (see recommendation 1.3.3) can be referred back to primary care:

- with appropriate information being offered **and**
- support mechanisms (for example, risk counselling, psychological counselling and risk management advice) need to be identified, and should be offered to people not eligible for referral and/or surveillance on the basis of age or risk level who have ongoing concerns. **[2004]**

Referral to a specialist genetic clinic

1.4.4 People who meet the following referral criteria should be offered a referral to a specialist genetic clinic.

- At least the following female breast cancers only in the family:
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 50 years (at least one must be a first-degree relative) **[2004] or**

[4] For the purpose of these calculations, a woman's age should be assumed to be 40 for a woman in her forties. A 10-year risk should be calculated for the age range 40–49.

  - three first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years (at least one must be a first-degree relative) **[2004] or**
  - four relatives diagnosed with breast cancer at any age (at least one must be a first-degree relative). **[2004] or**
- Families containing one relative with ovarian cancer at any age and, on the same side of the family:
  - one first-degree relative (including the relative with ovarian cancer) or second-degree relative diagnosed with breast cancer at younger than age 50 years **[2004] or**
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years **[2004] or**
  - another ovarian cancer at any age. **[2004] or**
- Families affected by bilateral cancer (each breast cancer has the same count value as one relative):
  - one first-degree relative with cancer diagnosed in both breasts at younger than an average age 50 years **[2004] or**
  - one first-degree or second-degree relative diagnosed with bilateral cancer and one first or second degree relative diagnosed with breast cancer at younger than an average age of 60 years. **[2004] or**
- Families containing male breast cancer at any age and, on the same side of the family, at least:
  - one first-degree or second-degree relative diagnosed with breast cancer at younger than age 50 years **[2004] or**
  - two first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years. **[2004] or**
- A formal risk assessment has given risk estimates of:
  - a 10% or greater chance of a gene mutation being harboured in the family (see recommendations 1.5.8–1.5.13) **[2013] or**
  - a greater than 8% risk of developing breast cancer in the next 10 years **[2004] or**
  - a 30% or greater lifetime risk of developing breast cancer. **[2004]**

1.4.5 Clinicians should seek further advice from a specialist genetics service for families containing any of the following, in addition to breast cancers:

- triple negative breast cancer under the age of 40 years **[2013]**
- Jewish ancestry **[2004]**
- sarcoma in a relative younger than age 45 years **[2004]**
- glioma or childhood adrenal cortical carcinomas **[2004]**
- complicated patterns of multiple cancers at a young age **[2004]**
- very strong paternal history (four relatives diagnosed at younger than 60 years of age on the father's side of the family). **[2004]**

1.4.6 The management of high-risk people may take place in secondary care if they do not want genetic testing or risk-reducing surgery and do not wish to be referred to a specialist genetics service. **[2004]**

1.4.7 Following initial consultation in secondary care, written information should be provided to reflect the outcomes of the consultation. **[2004]**

Care of people in a specialist genetic clinic

1.4.8 Care of people referred to a specialist genetic clinic should be undertaken by a multi-disciplinary team. In addition to having access to the components found in secondary care, it should also include the following:

- clinical genetic risk assessment
- verification for abdominal malignancies and possible sarcomas. **[2004]**

Genetic counselling for people with no personal history of breast cancer

1.4.9 Women with no personal history of breast cancer meeting criteria for referral to a specialist genetic clinic should be offered a referral for genetic counselling regarding their risks and options. **[2004]**

1.4.10 Women attending genetic counselling should receive standardised information beforehand describing the process of genetic counselling, information to obtain prior to the counselling session, the range of topics to be covered and brief educational material about hereditary breast cancer and genetic testing. **[2004]**

1.4.11 Predictive genetic testing should not be offered without adequate genetic counselling. **[2004]**

1.5 Genetic testing

1.5.1 All eligible people should have access to information on genetic tests aimed at mutation finding. **[2004]**

1.5.2 Pre-test counselling (preferably two sessions) should be undertaken. **[2004]**

1.5.3 Discussion of genetic testing (predictive and mutation finding) should be undertaken by a healthcare professional with appropriate training. **[2004]**

1.5.4 Eligible people and their affected relatives should be informed about the likely informativeness of the test (the meaning of a positive and a negative test) and the likely timescale of being given the results. **[2004]**

Mutation tests

1.5.5 Tests aimed at mutation finding should first be carried out on an affected family member where possible. **[2004]**

1.5.6 If possible, the development of a genetic test for a family should usually start with the testing of an affected individual (mutation searching/screening) to try to identify a mutation in the appropriate gene (such as *BRCA1*, *BRCA2* or *TP53*) (see recommendations 1.5.8–1.5.13). **[2004]**

1.5.7 A search/screen for a mutation in a gene (such as *BRCA1*, *BRCA2* or *TP53*) should aim for as close to 100% sensitivity as possible for detecting coding alterations and the whole gene(s) should be searched. **[2004]**

Carrier probability at which genetic testing should be offered

1.5.8 Discuss the potential risk and benefits of genetic testing. Include in the discussion the probability of finding a mutation, the implications for the individual and the family, and the implications of either a variant of uncertain significance or a null result (no mutation found). **[2013]**

1.5.9 Inform families with no clear genetic diagnosis that they can request review in the specialist genetic clinic at a future date. **[2013]**

1.5.10 Clinical genetics laboratories should record gene variants of uncertain significance and known pathogenic mutations in a searchable electronic database. **[2013]**

Genetic testing for a person with no personal history of breast cancer but with an available affected relative

1.5.11 Offer genetic testing in specialist genetic clinics to a relative with a personal history of breast and/or ovarian cancer if that relative has a combined *BRCA1* and *BRCA2* mutation carrier probability of 10% or more. **[2013]**

Genetic testing for a person with no personal history of breast cancer and no available affected relative to test

1.5.12 Offer genetic testing in specialist genetic clinics to a person with no personal history of breast or ovarian cancer if their combined *BRCA1* and *BRCA2* mutation carrier probability is 10% or more and an affected relative is unavailable for testing. **[2013]**

Genetic testing for a person with breast or ovarian cancer

1.5.13 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. **[2013]**

Genetic testing for *BRCA1*, *BRCA2* and *TP53* mutations within 4 weeks of diagnosis of breast cancer

1.5.14 Offer people eligible for referral to a specialist genetic clinic a choice of accessing genetic testing during initial management or at any time thereafter. **[2013]**

1.5.15 Offer fast-track genetic testing (within 4 weeks of a diagnosis of breast cancer) only as part of a clinical trial. **[2013]**

1.5.16 Discuss the individual needs of the person with the specialist genetics team as part of the multidisciplinary approach to care. **[2013]**

1.5.17 Offer detailed consultation with a clinical geneticist or genetics counsellor to all those with breast cancer who are offered genetic testing, regardless of the timeframe for testing. **[2013]**

Genetic testing for *BRCA1* and *BRCA2* mutations in women under 50 years with triple negative breast cancer but with no family history of breast or ovarian cancer

1.5.18 Offer genetic testing for *BRCA1* and *BRCA2* mutations to women under 50 years with triple negative breast cancer, but no family history of breast or ovarian cancer. **[new 2017]**

1.6 Surveillance and strategies for early detection of breast cancer

Breast awareness

1.6.1 Women at increased risk of breast cancer should be 'breast aware' in line with Department of Health advice for all women. **[2004]**

Surveillance for women with no personal history of breast cancer

Ultrasound surveillance

1.6.2 Do not routinely offer ultrasound surveillance to women at moderate or high risk of breast cancer but consider it:

- when MRI surveillance would normally be offered but is not suitable (for example, because of claustrophobia)
- when results of mammography or MRI are difficult to interpret. **[2013]**

Mammographic surveillance

1.6.3 Offer annual mammographic surveillance to women:

- aged 40–49 years at moderate risk of breast cancer

- aged 40–59 years at high risk of breast cancer but with a 30% or lower probability of being a *BRCA* or *TP53* carrier
- aged 40–59 years who have not had genetic testing but have a greater than 30% probability of being a *BRCA* carrier
- aged 40–69 years with a known *BRCA1* or *BRCA2* mutation. **[2013]**

1.6.4 Offer mammographic surveillance as part of the population screening programme to women:

- aged 50 years and over who have not had genetic testing but have a greater than 30% probability of being a *TP53* carrier
- aged 60 years and over at high risk of breast cancer but with a 30% or lower probability of being a *BRCA* or *TP53* carrier
- aged 60 years and over at moderate risk of breast cancer
- aged 60 years and over who have not had genetic testing but have a greater than 30% probability of being a *BRCA* carrier
- aged 70 years and over with a known *BRCA1* or *BRCA2* mutation. **[2013]**

1.6.5 Consider annual mammographic surveillance for women:

- aged 30–39 years at high risk of breast cancer but with a 30% or lower probability of being a *BRCA* or *TP53* carrier
- aged 30–39 years who have not had genetic testing but have a greater than 30% probability of being a *BRCA* carrier
- aged 30–39 years with a known *BRCA1* or *BRCA2* mutation
- aged 50–59 years at moderate risk of breast cancer. **[2013]**

1.6.6 Do not offer mammographic surveillance to women:

- aged 29 years and under
- aged 30–39 years at moderate risk of breast cancer
- aged 30–49 years who have not had genetic testing but have a greater than 30% probability of being a *TP53* carrier
- of any age with a known *TP53* mutation. **[2013]**

MRI surveillance

1.6.7 Offer annual MRI surveillance to women:

- aged 30–49 years who have not had genetic testing but have a greater than 30% probability of being a *BRCA* carrier
- aged 30–49 years with a known *BRCA1* or *BRCA2* mutation
- aged 20–49 years who have not had genetic testing but have a greater than 30% probability of being a *TP53* carrier
- aged 20–49 years with a known *TP53* mutation. **[2013]**

1.6.8 Consider annual MRI surveillance for women aged 50–69 years with a known *TP53* mutation. **[2013]**

1.6.9 Do not offer MRI to women:

- of any age at moderate risk of breast cancer
- of any age at high risk of breast cancer but with a 30% or lower probability of being a *BRCA* or *TP53* carrier
- aged 20–29 years who have not had genetic testing but have a greater than 30% probability of being a *BRCA* carrier
- aged 20–29 years with a known *BRCA1* or *BRCA2* mutation
- aged 50–69 years who have not had genetic testing but have a greater than 30% probability of being a *BRCA* or a *TP53* carrier, unless mammography has shown a dense breast pattern
- aged 50–69 years with a known *BRCA1* or *BRCA2* mutation, unless mammography has shown a dense breast pattern. **[2013]**

Also see Summary of recommendations on surveillance for women with no personal history of breast cancer.

Surveillance for women with a personal and family history of breast cancer

1.6.10 Ensure that all women with breast cancer are offered annual mammography for 5 years for follow-up imaging, in line with the NICE guideline on early and locally advanced breast cancer. In conjunction with follow-up, women who remain at high risk of breast cancer and have a

family history should receive surveillance as outlined in recommendations 1.6.11–16.15. **[2013]**

Mammographic surveillance

1.6.11 Offer annual mammographic surveillance to all women aged 50–69 years with a personal history of breast cancer who:

- remain at high risk of breast cancer (including those who have a *BRCA1* or *BRCA2* mutation), **and**
- do not have a *TP53* mutation. **[2013]**

1.6.12 Offer mammography as part of the population screening programme for all women aged 70 years and over with a personal history of breast cancer who:

- remain at high risk of breast cancer (including those who have a *BRCA1* or *BRCA2* mutation), **and**
- do not have a *TP53* mutation. **[2013]**

MRI surveillance

1.6.13 Offer annual MRI surveillance to all women aged 30–49 years with a personal history of breast cancer who remain at high risk of breast cancer, including those who have a *BRCA1* or *BRCA2* mutation. **[2013]**

1.6.14 Do not offer MRI surveillance to any women aged 50 years and over without a *TP53* mutation unless mammography has shown a dense breast pattern. **[2013]**

1.6.15 Consider annual MRI surveillance for women aged 20–69 years with a known *TP53* mutation or who have not had a genetic test but have a greater than 30% probability of being a *TP53* carrier. **[2013]**

Surveillance for women who remain at moderate risk of breast cancer

1.6.16 Ensure that surveillance for people with a personal history of breast cancer who remain at moderate risk of breast cancer is in line with the NICE guideline on early and locally advanced breast cancer. **[2013]**

Recommendations for all women having surveillance

1.6.17 Offer support (for example, risk counselling, psychological counselling and risk management advice) to women who have ongoing concerns but are not eligible for surveillance additional to that offered by the national breast screening programmes[5]. **[2004, amended 2013]**

1.6.18 Before decisions on surveillance are made, discuss and give written information on the benefits and risks of surveillance, including:

- the possibility that mammography might miss a cancer in women with dense breasts and the increased likelihood of further investigations **[2013]**
- possible over diagnosis
- the risk associated with exposure to radiation
- the possible psychological impact of a recall visit. **[2004, amended 2013]**

1.6.19 Review eligibility for surveillance if family history changes (for example, if another member of the family develops breast cancer or a mutation is identified). **[2013]**

1.6.20 At the start of a surveillance programme and when there is a transition or change to the surveillance plan, give women:

- information about the surveillance programme, including details of the tests, how often they will have them and the duration of the programme
- information about the risks and benefits of surveillance
- details of sources of support and further information. **[2006, amended 2013]**

1.6.21 Ensure that women know and understand the reasons for any changes to the surveillance plan. **[2006, amended 2013]**

[5] National breast screening programmes: England – NHS Breast Screening Programme (NHSBSP); Wales – Breast Test Wales; Northern Ireland – NI Breast Screening Programme

1.6.22 For women under 50 years who are having mammography, use digital mammography at centres providing digital mammography to national breast screening programme standards. **[2013]**

1.6.23 Ensure that individual strategies are developed for all women having mammographic surveillance and that surveillance is:

- to national breast screening programme standards
- audited
- only undertaken after written information is given about risks and benefits. **[2013]**

1.6.24 Ensure that MRI surveillance includes MRI of both breasts performed to national breast screening programme standards. **[2006, amended 2013]**

1.6.25 When women not known to have a genetic mutation are referred to a specialist genetic clinic, offer them assessment of their carrier probability using a carrier probability calculation method with acceptable performance (calibration and discrimination) to determine whether they meet or will meet the criteria for surveillance. (An example of an acceptable method is BOADICEA.) **[2013]**

1.6.26 Do not offer surveillance to women who have undergone a bilateral mastectomy. **[2013]**

1.7 Risk reduction and treatment strategies

Risk factors

1.7.1 People should be provided with standardised written information about risk, including age as a risk factor. **[2004]**

1.7.2 Modifiable risk factors should be discussed on an individual basis in the relevant care setting. **[2004]**

Menstrual and reproductive factors

1.7.3 Healthcare professionals should be able to provide information on the effects of hormonal and reproductive factors on breast cancer risk. **[2004]**

Hormonal contraceptives

1.7.4 Advice to women up to age 35 years with a family history of breast cancer should be in keeping with general health advice on the use of the oral contraceptive pill. **[2004]**

1.7.5 Women aged over 35 years with a family history of breast cancer should be informed of an increased risk of breast cancer associated with taking the oral contraceptive pill, given that their absolute risk increases with age. **[2004]**

1.7.6 For women with *BRCA1* mutations, the conflicting effects of a potential increased risk of breast cancer under the age of 40 years and the lifetime protection against ovarian cancer risk from taking the oral contraceptive pill should be discussed. **[2004]**

1.7.7 Women should not be prescribed the oral contraceptive pill purely for prevention of cancer, although in some situations reduction in ovarian cancer risk may outweigh any increase in risk of breast cancer. **[2004]**

1.7.8 If a woman has a *BRCA1* mutation and is considering a risk-reducing oophorectomy before the age of 40 years, the oral contraceptive pill should not be prescribed purely for the reduction in ovarian cancer risk. **[2004]**

Breastfeeding

1.7.9 Women should be advised to breastfeed if possible because this is likely to reduce their risk of breast cancer, and is in accordance with general health advice. **[2004]**

Hormone replacement therapy

1.7.10 Women with a family history of breast cancer who are considering taking, or already taking, HRT should be informed of the increase in breast cancer risk with type and duration of HRT. **[2004]**

1.7.11 Advice to individual women on the use of HRT should vary according to the individual clinical circumstances (such as asymptomatic menopausal

symptoms, age, severity of menopausal symptoms, or osteoporosis). **[2004]**

1.7.12 HRT usage in a woman at familial risk should be restricted to as short a duration and as low a dose as possible. Oestrogen-only HRT should be prescribed where possible. **[2004]**

1.7.13 A woman having an early (natural or artificial) menopause should be informed of the risks and benefits of HRT, but generally HRT usage should be confined to women younger than age 50 years if at moderate or high risk (see also recommendations 1.7.53 and 1.7.54). **[2004]**

1.7.14 Alternatives to HRT should be considered for specific symptoms such as osteoporosis or menopausal symptoms (see also recommendations 1.7.53 and 1.7.54). **[2004]**

1.7.15 Consideration should be given to the type of HRT if it is being considered for use in conjunction with risk-reducing gynaecological surgery. **[2004]**

Alcohol consumption

1.7.16 Women with a family history should be informed that alcohol may increase their risk of breast cancer slightly. However, this should be considered in conjunction with any potential benefit of moderate alcohol intake on other conditions (such as heart disease) and adverse effects associated with excessive alcohol intake. **[2004]**

Smoking

1.7.17 Women should be advised not to smoke, in line with current health advice. **[2004]**

Weight and physical activity

1.7.18 Women should be advised on the probable increased postmenopausal risk of breast cancer from being overweight. **[2004]**

1.7.19 Women should be advised about the potential benefits of physical exercise on breast cancer risk. **[2004]**

Chemoprevention for women with no personal history of breast cancer

1.7.20 Healthcare professionals within secondary care or specialist genetic clinics should discuss the absolute benefits and risks of options for chemoprevention with women at high or moderate risk of breast cancer. Discussion should include:

- the reduced risk of invasive breast cancer
- the lack of effect on mortality
- the side effects of the different options
- alternative approaches, such as surveillance alone and, for women at high risk, risk-reducing surgery.

Women should also be given information in an accessible format. **[2013, amended 2017]**

1.7.21 Offer tamoxifen[6] for 5 years to premenopausal women at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer. **[2017]**

1.7.22 Offer anastrozole[7] [8] for 5 years to postmenopausal women at high risk of breast cancer unless they have severe osteoporosis. **[new 2017]**

1.7.23 For postmenopausal women at high risk of breast cancer with severe osteoporosis, but no history or increased risk of thromboembolic disease or endometrial cancer:

[6] At the time of consultation (November 2016), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[7] At the time of consultation (November 2016), anastrozole did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[8] The summary of product characteristics for anastrozole indicates that women with osteoporosis or at risk of osteoporosis should have their bone mineral density assessed when starting treatment and then at regular intervals. Treatment or prophylaxis for osteoporosis should be started when needed and carefully monitored.

- offer tamoxifen[9] for 5 years, or
- consider raloxifene[10] for 5 years as an alternative to tamoxifen for women with a uterus. **[new 2017]**

1.7.24 Do not offer chemoprevention to women who were at high risk of breast cancer but have had bilateral risk-reducing mastectomy. **[2013, amended 2017]**

1.7.25 Consider tamoxifen[11] for 5 years for premenopausal women at moderate risk of breast cancer, unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer. **[2017]**

1.7.26 Consider anastrozole[12] [13] for 5 years for postmenopausal women at moderate risk of breast cancer unless they have severe osteoporosis. **[new 2017]**

1.7.27 For postmenopausal women at moderate risk of breast cancer with severe osteoporosis, but no history or increased risk of thromboembolic disease or endometrial cancer:

[9] At the time of consultation (November 2016), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[10] At the time of consultation (November 2016), raloxifene did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[11] At the time of consultation (November 2016), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[12] At the time of consultation (November 2016), anastrozole did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[13] The summary of product characteristics for anastrozole indicates that women with osteoporosis or at risk of osteoporosis should have their bone mineral density assessed when starting treatment and then at regular intervals. Treatment or prophylaxis for osteoporosis should be started when needed and carefully monitored.

- consider tamoxifen[14] for 5 years, or
- consider raloxifene[15] for 5 years as an alternative to tamoxifen for women with a uterus. **[new 2017]**

1.7.28 Do not continue chemoprevention beyond 5 years in women with no personal history of breast cancer. **[2013, amended 2017]**

1.7.29 Inform women that they should stop tamoxifen[16] at least:

- 2 months before trying to conceive
- 6 weeks before elective surgery. **[2013]**

Risk-reducing mastectomy for women with no personal history of breast cancer

1.7.30 Bilateral risk-reducing mastectomy is appropriate only for a small proportion of women who are from high-risk families and should be managed by a multidisciplinary team. **[2004]**

1.7.31 Bilateral mastectomy should be raised as a risk-reducing strategy option with all women at high risk. **[2004]**

1.7.32 Women considering bilateral risk-reducing mastectomy should have genetic counselling in a specialist cancer genetic clinic before a decision is made. **[2004]**

1.7.33 Discussion of individual breast cancer risk and its potential reduction by surgery should take place and take into account individual risk factors,

[14] At the time of consultation (November 2016), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[15] At the time of consultation (November 2016), raloxifene did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[16] At the time of consultation (November 2016), tamoxifen did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

including the woman's current age (especially at extremes of age ranges). **[2004]**

1.7.34 Family history should be verified where no mutation has been identified before bilateral risk-reducing mastectomy. **[2004]**

1.7.35 Where no family history verification is possible, agreement by a multidisciplinary team should be sought before proceeding with bilateral risk-reducing mastectomy. **[2004]**

1.7.36 Pre-operative counselling about psychosocial and sexual consequences of bilateral risk-reducing mastectomy should be undertaken. **[2004]**

1.7.37 The possibility of breast cancer being diagnosed histologically following a risk-reducing mastectomy should be discussed pre-operatively. **[2004]**

1.7.38 All women considering bilateral risk-reducing mastectomy should be able to discuss their breast reconstruction options (immediate and delayed) with a member of a surgical team with specialist oncoplastic or breast reconstructive skills. **[2004]**

1.7.39 A surgical team with specialist oncoplastic/breast reconstructive skills should carry out risk-reducing mastectomy and/or reconstruction. **[2004]**

1.7.40 Women considering bilateral risk-reducing mastectomy should be offered access to support groups and/or women who have undergone the procedure. **[2004]**

Risk-reducing oophorectomy for women with no personal history of breast cancer

1.7.41 Risk-reducing bilateral oophorectomy is appropriate only for a small proportion of women who are from high-risk families and should be managed by a multidisciplinary team. **[2004]**

1.7.42 Information about bilateral oophorectomy as a potential risk-reducing strategy should be made available to women who are classified as high risk. **[2004]**

1.7.43 Family history should be verified where no mutation has been identified before bilateral risk-reducing oophorectomy. **[2004]**

1.7.44 Where no family history verification is possible, agreement by a multidisciplinary team should be sought before proceeding with bilateral risk-reducing oophorectomy. **[2004]**

1.7.45 Any discussion of bilateral oophorectomy as a risk-reducing strategy should take fully into account factors such as anxiety levels on the part of the woman concerned. **[2004]**

1.7.46 Healthcare professionals should be aware that women being offered risk-reducing bilateral oophorectomy may not have been aware of their risks of ovarian cancer as well as breast cancer and should be able to discuss this. **[2004]**

1.7.47 The effects of early menopause should be discussed with any woman considering risk-reducing bilateral oophorectomy. **[2004]**

1.7.48 Options for management of early menopause should be discussed with any woman considering risk-reducing bilateral oophorectomy, including the advantages, disadvantages and risk impact of HRT. **[2004]**

1.7.49 Women considering risk-reducing bilateral oophorectomy should have access to support groups and/or women who have undergone the procedure. **[2004]**

1.7.50 Women considering risk-reducing bilateral oophorectomy should be informed of possible psychosocial and sexual consequences of the procedure and have the opportunity to discuss these issues. **[2004]**

1.7.51 Women not at high risk who raise the possibility of risk-reducing bilateral oophorectomy should be offered appropriate information, and if seriously considering this option should be offered referral to the team that deals with women at high risk. **[2004]**

1.7.52 Women undergoing bilateral risk-reducing oophorectomy should have their fallopian tubes removed as well. **[2004]**

HRT for women with no personal history of breast cancer who have a bilateral salpingo-oophorectomy before the natural menopause

1.7.53 When women with no personal history of breast cancer have either a *BRCA1* or *BRCA2* mutation or a family history of breast cancer and they have had a bilateral salpingo-oophorectomy before their natural menopause, offer them:

- combined HRT if they have a uterus
- oestrogen-only HRT if they don't have a uterus

up until the time they would have expected natural menopause (average age for natural menopause is 51–52 years). **[2013]**

1.7.54 Manage menopausal symptoms occurring when HRT is stopped in the same way as symptoms of natural menopause. **[2013]**

Risk-reducing breast or ovarian surgery for people with a personal history of breast cancer

Counselling

1.7.55 Refer women with a personal history of breast cancer who wish to consider risk-reducing surgery for appropriate genetic and psychological counselling before surgery. **[2013]**

Risk-reducing mastectomy

1.7.56 Discuss the risks and benefits of risk-reducing mastectomy with women with a known or suspected *BRCA1*, *BRCA2* or *TP53* mutation. **[2013]**

1.7.57 For a woman considering risk-reducing mastectomy, include in the discussion of risks and benefits:

- the likely prognosis of their breast cancer, including their risk of developing a distal recurrence of their previous breast cancer

- a clear quantification of the risk of developing breast cancer in the other breast
- the potential negative impact of mastectomy on body image and sexuality
- the very different appearance and feel of the breasts after reconstructive surgery
- the potential benefits of reducing the risk in the other breast and relieving the anxiety about developing breast cancer. **[2013]**

1.7.58 Give all women considering a risk-reducing mastectomy the opportunity to discuss their options for breast reconstruction (immediate and delayed) with a member of a surgical team with specialist skills in oncoplastic surgery or breast reconstruction. **[2013]**

1.7.59 Ensure that risk-reducing mastectomy and breast reconstruction are carried out by a surgical team with specialist skills in oncoplastic surgery and breast reconstruction. **[2013]**

1.7.60 Offer women who have *BRCA1*, *BRCA2* or *TP53* mutations but who decide against risk-reducing mastectomy, surveillance according to their level of risk. **[2013]**

Risk-reducing bilateral salpingo-oophorectomy

1.7.61 Discuss the risks and benefits of risk-reducing bilateral salpingo-oophorectomy with women with a known or suspected *BRCA1*, *BRCA2* or *TP53* mutation. Include in the discussion the positive effects of reducing the risk of breast and ovarian cancer and the negative effects of a surgically induced menopause. **[2013]**

1.7.62 Defer risk-reducing bilateral salpingo-oophorectomy until women have completed their family. **[2013]**

Contraindications to risk-reducing surgery for people with a personal history of breast cancer

1.7.63 Do not offer risk-reducing surgery to people with comorbidities that would considerably increase the risks of surgery. **[2013]**

1.7.64 Do not offer risk-reducing surgery to people who have a limited life expectancy from their cancer or other conditions. **[2013]**

Treatment options for people with a personal history of breast cancer who are *TP53* mutation carriers

1.7.65 When a person has invasive breast cancer or ductal carcinoma in situ and is known to have a *TP53* mutation or a 30% probability of a *TP53* mutation:

- inform them of all the possible treatment options
- make sure they know about the uncertainties associated with these treatment options
- inform them of the risks associated with each treatment (for example, the risk of recurrence, the risk of new primary breast cancer and the risks of malignancy associated with radiotherapy and chemotherapy). **[2013]**

1.7.66 Offer people with invasive breast cancer or ductal carcinoma in situ and a 30% probability of a *TP53* mutation, genetic testing to help determine their treatment options. **[2013]**

Summary of recommendations on surveillance for women with no personal history of breast cancer

	Moderate risk	**High risk**				
Age	**Moderate risk of breast cancer[1]**	**High risk of breast cancer (but with a 30% or lower probability of being a *BRCA* or**	**Untested but greater than 30% *BRCA* carrier probability [3]**	**Known *BRCA1* or *BRCA2* mutation**	**Untested but greater than 30% *TP53* carrier probability [4]**	**Known *TP53* mutation**

		TP53 **carrier)[2]**				
20-29	Do not offer mammography	Do not offer mammography	Do not offer mammography	Do not offer mammography	Do not offer mammography	Do not offer mammography
	Do not offer MRI	Do not offer MRI	Do not offer MRI	Do not offer MRI	Annual MRI	Annual MRI
30-39	Do not offer mammography	Consider annual mammography	Annual MRI and consider annual mammography	Annual MRI and consider annual mammography	Do not offer mammography	Do not offer mammography
	Do not offer MRI	Do not offer MRI			Annual MRI	Annual MRI
40-49	Annual mammography	Annual mammography	Annual mammography and annual MRI	Annual mammography and annual MRI	Do not offer mammography	Do not offer mammography
	Do not offer MRI	Do not offer MRI			Annual MRI	Annual MRI
50-59	Consider annual mammography	Annual mammography	Annual mammography	Annual mammography	Mammography as part of the population screening programme	Do not offer mammography

	Do not offer MRI	Do not offer MRI	Do not offer MRI unless dense breast pattern	Do not offer MRI unless dense breast pattern	Do not offer MRI unless dense breast pattern	Consider annual MRI
60-69	Mammography as part of the population screening programme	Mammography as part of the population screening programme	Mammography as part of the population screening programme	Annual mammography	Mammography as part of the population screening programme	Do not offer mammography
	Do not offer MRI	Do not offer MRI	Do not offer MRI unless dense breast pattern	Do not offer MRI unless dense breast pattern	Do not offer MRI unless dense breast pattern	Consider annual MRI
70+	Mammography as part of the population screenin	Mammography as part of the population screening programme	Mammography as part of the population screening programme	Mammography as part of the populatio n screenin	Mammography as part of the population screening programme	Do not offer mammography

	g program me			g program me		

[1] Lifetime risk of developing breast cancer is at least 17% but less than 30%.

[2] Lifetime risk of developing breast cancer is at least 30%. High risk group includes rare conditions that carry an increased risk of breast cancer, such as Peutz-Jegher syndrome, (*STK11*), Cowden (*PTEN*), familial diffuse gastric cancer (E-Cadherin).

[3] Surveillance recommendations for this group reflect the fact that women who at first assessment had a 30% or greater *BRCA* carrier probability and reach 60 years of age without developing breast or ovarian cancer will now have a lower than 30% carrier probability and should no longer be offered MRI surveillance.

[4] Surveillance recommendations for this group reflect the fact that women who at first assessment had a 30% or greater *TP53* carrier probability and reach 50 years of age without developing breast cancer or any other *TP53*-related malignancy will now have a lower than 30% carrier probability and should no longer be offered MRI surveillance.

Terms used in this guideline

Breast cancer risk category

	Breast cancer risk category		
	Near population risk	**Moderate risk**	**High risk[1]**
Lifetime risk from age 20	Less than 17%	Greater than 17% but less than 30%	30% or greater
Risk between ages 40 and 50	Less than 3%	3–8%	Greater than 8%

[1]This group includes known *BRCA1*, *BRCA2* and *TP53* mutations and rare conditions that carry an increased risk of breast cancer such as Peutz-Jegher syndrome (*STK11*), Cowden (*PTEN*) and familial diffuse gastric cancer (E-Cadherin).

First-degree relatives

Mother, father, daughter, son, sister, brother.

Second-degree relatives

Grandparent, grandchild, aunt, uncle, niece, nephew, half-sister, half-brother.

Severe osteoporosis

In this guideline severe osteoporosis is defined as having a T-score of at least – 2.5 SD as measured by DEXA (dual-energy X-ray absorptiometry). This definition is in line with that used in the NICE technology appraisal guidance on the primary prevention of osteoporotic fragility fractures in postmenopausal women (TA160) and by the World Health Organization. The T-score is a measure of how far a person's bone mineral density is below the mean value of young adults.

Third-degree relatives

Great grandparent, great aunt, great uncle, first cousin, great grandchild, grand nephew, grand niece.

Triple negative breast cancer

Oestrogen receptor, progesterone receptor, HER2 negative breast cancer.

Putting this guideline into practice

[This section will be completed after consultation]

NICE has produced tools and resources [link to tools and resources tab] to help you put this guideline into practice.

[Optional paragraph if issues raised] Some issues were highlighted that might need specific thought when implementing the recommendations. These were raised during the development of this guideline. They are:

- [add any issues specific to guideline here]
- [Use 'Bullet left 1 last' style for the final item in this list.]

Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed. Implementing change is most effective when aligned with local priorities.

[Clinical topics only] Changes recommended for clinical practice that can be done quickly – like changes in prescribing practice – should be shared quickly. This is because healthcare professionals should use guidelines to guide their work – as is required by professional regulating bodies such as the General Medical and Nursing and Midwifery Councils.

Changes should be implemented as soon as possible, unless there is a good reason for not doing so (for example, if it would be better value for money if a package of recommendations were all implemented at once).

Different organisations may need different approaches to implementation, depending on their size and function. Sometimes individual practitioners may be able to respond to recommendations to improve their practice more quickly than large organisations.

Here are some pointers to help organisations put NICE guidelines into practice:

1. **Raise awareness** through routine communication channels, such as email or newsletters, regular meetings, internal staff briefings and other communications with all relevant partner organisations. Identify things staff can include in their own practice straight away.

2. **Identify a lead** with an interest in the topic to champion the guideline and motivate others to support its use and make service changes, and to find out any significant issues locally.

3. **Carry out a baseline assessment** against the recommendations to find out whether there are gaps in current service provision.

4. **Think about what data you need to measure improvement** and plan how you will collect it. You may want to work with other health and social care organisations

and specialist groups to compare current practice with the recommendations. This may also help identify local issues that will slow or prevent implementation.

5. **Develop an action plan**, with the steps needed to put the guideline into practice, and make sure it is ready as soon as possible. Big, complex changes may take longer to implement, but some may be quick and easy to do. An action plan will help in both cases.

6. **For very big changes** include milestones and a business case, which will set out additional costs, savings and possible areas for disinvestment. A small project group could develop the action plan. The group might include the guideline champion, a senior organisational sponsor, staff involved in the associated services, finance and information professionals.

7. **Implement the action plan** with oversight from the lead and the project group. Big projects may also need project management support.

8. **Review and monitor** how well the guideline is being implemented through the project group. Share progress with those involved in making improvements, as well as relevant boards and local partners.

NICE provides a comprehensive programme of support and resources to maximise uptake and use of evidence and guidance. See our into practice pages for more information.

Also see Leng G, Moore V, Abraham S, editors (2014) Achieving high quality care – practical experience from NICE. Chichester: Wiley.

Context

Familial breast cancer typically occurs in people with an unusually high number of family members affected by breast, ovarian or a related cancer. If more cases of breast, ovarian or a related cancer are seen in a family than would be expected by chance alone, this can be a sign that genes have caused or contributed to its development. Breast cancer in people who have a family history of breast, ovarian or a related cancer may need different management from that in people without a family

history of these cancers. This is because of differences in the future risk of developing contralateral breast cancer.

The risk of developing breast cancer depends on the:

- nature of the family history
- number of relatives who have developed breast, ovarian or a related cancer
- age at which relatives developed breast cancer
- age of the person.

This guideline describes the classification and care of people at risk of familial breast cancer. It also covers people with a diagnosis of breast cancer and a family history of breast, ovarian or a related cancer. It includes recommendations on genetic testing thresholds, surveillance and risk reduction and treatment strategies. These areas are not covered by the NICE guideline on early and locally advanced breast cancer.

We have updated recommendations on chemoprevention for women with no personal history of breast cancer and have added a new recommendation on genetic testing for women with triple negative breast cancer but no family history.

More information

To find out what NICE has said on topics related to this guideline, see our web page on breast cancer.

Recommendations for research

The guideline committee has made the following recommendations for research. The committee's full set of research recommendations is detailed in the full guideline.

As part of the 2017 update, the standing committee made an additional research recommendation on *BRCA1* mutations in unselected basal phenotype and triple negative breast cancer. The committee also extended the research recommendation on chemoprevention to include the aromatase inhibitors exemestane and letrozole. Details can be found in the addenda.

1 Carrier probability calculation models

Further research is recommended into developing and validating models for calculating carrier probability, which incorporate additional data, such as the molecular pathology of tumours and the prevalence of mutations in different ethnic groups. **[2013]**

Why this is important

This guideline recommends offering genetic testing to people with a 10% likelihood of carrying a *BRCA1/2* mutation. Models to assess the likelihood of a *BRCA1/2* mutation need to be improved because their estimates still have wide confidence margins. Models are sensitive to population prevalence of mutations and need adjustment for pathological subtypes of breast and ovarian cancer, which are particularly associated with *BRCA1* mutations. Improving the predictive powers of these models will provide more cost-effective testing.

2 Rapid genetic testing

Research is recommended to determine the benefits and harms of creating rapid access to genetic testing for people with newly diagnosed breast cancer. This research should address the optimum model for service delivery and organisation, the clinical and cost effectiveness of such a change, uptake outcomes and patients' experience. **[2013]**

Why this is important

There is no clear evidence base for rapid genetic testing at the time of diagnosis of primary breast cancer. Knowledge of genetic status may increase uptake of risk-reducing mastectomy and in future guide first-line chemotherapy. To be useful for such decision-making, results of genetic tests are needed within 4 weeks of diagnosis. This creates logistic problems in providing enough information for considered decision-making and delivering results of genetic tests in a supportive environment. Some guideline committee members were of the opinion that people had enough to cope with shortly after diagnosis without additional worries about genetic testing. However, others thought that early knowledge of genetic status would help decisions about surgery thus avoiding the need to consider this at a future date. For example, initial treatment by wide local excision often necessitates

radiotherapy, which makes an acceptable cosmetic operation more challenging. Genetic counselling to facilitate such decisions soon after diagnosis would require reorganisation of current services.

3 Benefits of MRI surveillance in women over 50 years

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. **[2013]**

Why this is important

There have been at least 6 large trials of MRI surveillance in women at high risk of breast cancer. However, none of these contained enough women to assess the potential benefit of MRI over mammography alone in women over 50 years. After 50 years of age, mammography becomes more sensitive and the trade-off between sensitivity and specificity may make MRI less cost effective. Although breast density decreases with age, and particularly after the menopause, there is no sudden change at any particular age. For this reason breast density should be included as a confounding variable.

4 Chemoprevention to reduce incidence of breast cancer

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? **[new 2017]**

Why this is important

One randomised controlled trial (RCT) showed anastrozole to be effective for the primary prevention of breast cancer. However, there has been no RCT of other third-generation aromatase inhibitors, such as exemestane and letrozole. Exemestane is not strictly from the same class as anastrozole (and may therefore have different modes of action). More information on the efficacy of these other aromatase inhibitors may offer more options for chemoprevention for women at risk of breast cancer.

5 Impact of risk-reducing surgery

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. **[2013]**

Why this is important

Many women are happy with their decision to undergo risk-reducing surgery. However, some women do subsequently regret this choice. A greater understanding of the factors that predict satisfaction or regret will help to guide women's choices in the future. Studies show that risk-reducing surgery significantly reduces risk of breast cancer, but there is insufficient evidence to decide between, for example, skin-sparing mastectomy and total mastectomy. The pros and cons of risk-reducing surgery in women with a diagnosis of cancer also need further study.

6 Prevalence of BRCA1 mutations in unselected basal phenotype breast cancer compared with unselected triple negative breast cancer

What is the prevalence of *BRCA1* mutations in unselected basal phenotype breast cancer compared with unselected triple negative breast cancer? **[new 2017]**

Why this is important

The association of breast cancer with *BRCA1* mutations was originally with the basal phenotype. Although triple negative breast cancer has been used as a proxy for the basal phenotype, they do not fully overlap. Badve et al. (2010) found that 71% of triple negative breast cancers were basal-like and 77% of basal-like cancers were triple negative. Triple negative breast cancer has been adopted as a proxy for the basal phenotype because most pathology laboratories test for triple negative cancer as a standard. Rakha et al. (2009) found that the basal phenotype has a high positive predictive for the *BRCA1* mutation. A study of the prevalence of *BRCA1* mutations would be useful because we may be missing these in basal phenotype breast cancers that are not are not tested as standard. This information would indicate whether *BRCA1* testing is helpful for basal phenotype cancers.

Update information

We have updated recommendations on chemoprevention for women with no personal history of breast cancer and have added a new recommendation on genetic testing for women with triple negative breast cancer but no family history.

New and updated recommendations are marked as:

- **[new 2017]** if the evidence has been reviewed and the recommendation has been added or updated
- **[2017]** if the evidence has been reviewed but no change has been made to the recommended action.

NICE proposes to delete some recommendations from the guideline, because either the evidence has been reviewed and the recommendations have been updated, or NICE has updated other relevant guidance and has replaced the original recommendations. Recommendations that have been deleted or changed sets out these recommendations and includes details of replacement recommendations. Where there is no replacement recommendation, an explanation for the proposed deletion is given.

Where recommendations are shaded in grey the evidence has not been reviewed for the current update.

Where recommendations are shaded in grey and end **[2013, amended 2017]**, the evidence has not been reviewed but changes have been made to the recommendation wording that change the meaning (for example, because of equalities duties or a change in the availability of medicines, or incorporated guidance has been updated). These changes are marked with yellow shading, and explanations of the reasons for the changes are given in 'Recommendations that have been deleted or changed' for information.

See also the original NICE guideline and supporting documents.

Recommendations that have been deleted or changed

Recommendations to be deleted

Recommendation in 2013 guideline	Comment
Offer tamoxifen for 5 years to postmenopausal women without a uterus and at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or they have a past history of endometrial cancer. (1.7.22)	Replaced by: Offer anastrozole for 5 years to postmenopausal women at high risk of breast cancer unless they have severe osteoporosis. (1.7.22)
Offer either tamoxifen or raloxifene for 5 years to postmenopausal women with a uterus and at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer. (1.7.23)	Replaced by: For postmenopausal women at high risk of breast cancer with severe osteoporosis, but no history or increased risk of thromboembolic disease or endometrial cancer: • offer tamoxifen for 5 years, or • consider raloxifene for 5 years as an alternative to tamoxifen for women with a uterus. (1.7.23)
Consider prescribing tamoxifen for 5 years to postmenopausal women without a uterus and at moderate risk of developing breast cancer, unless they have a past history or may be at increased risk of thromboembolic disease or they have a past history of endometrial cancer. (1.7.26)	Replaced by: Consider anastrozole for 5 years for postmenopausal women at moderate risk of breast cancer unless they have severe osteoporosis. (1.7.26)
Consider prescribing either tamoxifen or raloxifene for 5 years to postmenopausal women with a uterus and at moderate risk of developing breast cancer, unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer. (1.7.27)	Replaced by: For postmenopausal women at moderate risk of breast cancer with severe osteoporosis, but no history or increased risk of thromboembolic disease or endometrial cancer: • consider tamoxifen for 5 years, or • consider raloxifene for 5 years as an alternative to tamoxifen for women with a uterus. (1.7.27)

Amended recommendation wording (change to meaning)

Recommendation in 2013 guideline	Recommendation in current guideline	Reason for change
Healthcare professionals within a specialist genetic clinic should discuss and give written information on the absolute risks and benefits of all options for chemoprevention to women at high risk or moderate risk of breast cancer. Discussion and information should include the side effects of drugs, the extent of risk reduction, and the risks and benefits of alternative approaches, such risk-reducing surgery and surveillance. (1.7.20)	Healthcare professionals within secondary care or specialist genetic clinics should discuss the absolute benefits and risks of options for chemoprevention with women at high or moderate risk of breast cancer. Discussion should include: • the reduced risk of invasive breast cancer • the lack of effect on mortality • the side effects of the different options • alternative approaches, such as surveillance alone and, for women at high risk, risk-reducing surgery. Women should also be given information in an accessible format. (1.7.20)	Recommendation amended so that discussion includes the lack of effect on mortality and to clarify that risk-reducing surgery is an option only for some women at high risk.
Do not offer tamoxifen or raloxifene to women who were at high risk of breast cancer but have had a bilateral mastectomy. (1.7.24)	Do not offer chemoprevention to women who were at high risk of breast cancer but have had a bilateral risk-reducing mastectomy. (1.7.24)	Recommendation amended to cover all types of chemoprevention and to clarify that mastectomy is risk reducing
Do not continue treatment with tamoxifen or raloxifene beyond 5 years for chemoprevention in women with no personal history of breast cancer. (1.7.28)	Do not continue chemoprevention beyond 5 years in women with no personal history of breast cancer. (1.7.28)	Recommendation amended to cover all types of chemoprevention

Changes after publication

In August 2015, we amended recommendation 1.7.28 to clarify that it applies only to women with no personal history of breast cancer.

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