ABS
ASSOCIATION OF
BREAST SURGERY

Association of Breast Surgery Summary Statement

OVERVIEW OF THE IMPLICATIONS AND IMPLEMENTATION OF NICE GUIDELINES ON FAMILIAL BREAST CANCER

1. INTRODUCTION

Breast cancer rates continue to rise with approximately 50,000 women and 400 men diagnosed each year in the UK[1]. The rate of breast cancer is also increasing in women under 50, who would not normally be offered screening. Up to 1 in 5 women under the age of 50 in the general population has a family member who has had breast cancer. The NICE Familial Breast Cancer Guidelines were produced to help identify both women and men who are at significantly increased risk of diagnosis of a future breast cancer due to their family history, and how to help healthcare workers better organise their care so as to detect breast cancer at an earlier stage or to reduce the chances of it occurring.

The aim of this guideline is to provide outline advice on the implications and implementation of the new NICE CG164 Familial Breast Cancer Guideline published in June 2013[2]. A quick reference guide for use in clinics is provided in the Appendices.

Readers of this guideline should be familiar with the full version of NICE CG164, the previous versions CG14 (2004), CG41 (2006), and the 'Guidelines for the management of women at increased familial risk of breast cancer' (2004)[3].

2. IMPLICATIONS

The NICE guideline makes recommendations on risk assessment, thresholds for genetic testing, screening, surveillance, risk reduction and treatment strategies for women with a FH of breast cancer or women diagnosed with breast cancer. The implications are substantial and affect primary, secondary and tertiary care.

For many units there will be significant resource needs: activity and financial modelling is complicated by the inherent variability in the existing structure of breast and genetic services, local referral patterns and protocols. Funding of an expanded FH service is likely to be complicated by the multiple commissioners involved (CCGs and NHS England). Some units may absorb the new changes into their existing established FH clinics. Breast units without a structured service may need to work with commissioners to secure funding for such a service. It is beyond the scope of this guideline to provide detailed directives on the best approach to commissioners. However, an essential first step is to understand the numbers of patients within your hospital's catchment area that may be eligible for FH referral.

3. CAPACITY PLANNING

Many breast units lack accurate data as to the number of FH patients they see. There are differing pathways through which FH patients access services, are assessed and screened. This can present difficulties in defining the existing costs of the service and in predicting the increase in capacity and the resource required to meet the needs introduced by the adoption of CG164.

It is very likely that from a FH aspect most moderate to high-risk women in the community remain unaware of their breast cancer risk and do not currently seek access to FH services or are aware but chose not to seek specialist care. As awareness and familiarity with CG164 increases, it is likely that standardised assessment of FH in primary and secondary care settings will identify a considerably greater number of women who are eligible for risk assessment, additional breast screening and chemoprevention.

More accurate estimates can be made by looking at census data of the number of women in a catchment area in the age group of interest and calculating eligible numbers from prevalence data of moderate and high risk patients in the community. The paper by Evans et al provides some of the most interesting data to date[4]. They were able to show that among women entering the PROCAS population based screening cohort study in Greater Manchester, 0.7% met high and 3.0% moderate-risk FH criteria. This would equate to approximately 35,000 women between age 30 and 50 years and 18,500 women between 40 and 50 in a catchment area of 1,000,000 general population. Only one sixth of women at moderate or high risk were shown to have accessed the FH service in Greater Manchester[4].

4. IMPLEMENTATION IN SECONDARY CARE

ACTION NEEDED:
- Develop a locally agreed mechanism and a single point for referral from primary care
- Identify a Secondary Care Contact to discuss management of uncertain cases
- Care should be undertaken by an identifiable comprehensive multidisciplinary team
- The service must include administrative support, clinical trials access, audit, a designated lead clinician, and a designated contact in a Specialist Genetics Clinic
- Develop standardised patient information sheets and written protocols

We recommend that each unit has a nominated consultant breast surgeon to act as the secondary care lead in their Trust. The structure of FH clinics will vary according to throughput and resources. Many units have established nurse led clinics. We recommend that a formal structure, protocol and written pathway are identified for the management of FH referrals. Due to the more variable commitments and turnover of trainee doctors we recommend that permanent staff are involved in the running of the FH clinic, the risk assessment process and management of these patients.

You should establish links and agree protocols with the Regional Genetics Unit. We recommend that a programme of awareness raising and education across the region should be delivered through the GP cancer leads to ensure appropriate referrals and develop the comprehensive resource of written supporting information as required by CG164. The Guideline recommends this for patients at population level risk, moderate, high and very high risk groups. Similar standards should exist.

Referrals to the service may come from sources other than primary care, for example: Genetics, the breast MDT, and from conventional breast clinics. Encourage all GP referrals to include a FH. Any patient with breast symptoms should be referred via the 2WW pathway.

Significant medical, administrative and IT support is required to run a dedicated FH clinic which will be required in most breast units. They should be run by a member of the breast MDT (it is often a nurse led service) who has received adequate training and has access to triple assessment. It should be run in conjunction with the Regional Genetics Unit. Referrals are triaged and those women who don't fulfil at least moderate risk criteria are reassured and discharged back to primary care. Those at moderate risk are usually seen at a clinic and may be entered into a local screening programme according to NICE criteria with appropriate written advice. High risk women are usually seen at a family history clinic and referred to the Regional Genetics Unit as per NICE guidelines. Increasing activity levels will be expected as the FH service develops and support requirements will need to be reviewed accordingly. A robust database and imaging recall system is essential along with written protocols for patient management. It should be understood that as well as receiving new patients, patients will gradually accrue in the service year on year.

A pathway should be established for patients wishing to discuss risk-reducing surgery, patients who are gene positive, and patients suitable for referral to gynaecology services. The pathway should include support groups and access to psychological counselling. Those women with identified BRCA mutations or who are untested but at 50% risk should be referred to the NHSBSP high risk pathway.

FH should be verified where no mutation has been identified before bilateral risk-reducing mastectomy. Where no family history verification is possible, agreement by a multidisciplinary team should be sought before proceeding with bilateral risk-reducing mastectomy. A second consultation with the surgical team after an interval of time before proceeding with the surgery is usually appropriate.

Standardised written information is required for many aspects of this guideline (appendix 6).

SUMMARY STATEMENT:

OVERVIEW OF THE IMPLICATIONS AND IMPLEMENTATION OF NICE GUIDELINES ON FAMILIAL BREAST CANCER

5. RISK ASSESSMENT IN SECONDARY CARE

ACTION NEEDED:
- Risk assess using the NICE algorithms. Use risk calculators where the algorithm is unclear
- Population risk patients can be referred back to their GP
- All high risk patients should be referred to the Regional Genetics Unit for further assessment
- Use the Manchester score to assess BRCA carrier probability. All 'affected' patients with score of 15 or above, and 'unaffected' patients with a score of 17 and above should also be referred to Genetics as eligible for BRCA testing.

Patients disclosing breast symptoms should be referred to the symptomatic service. The formal risk assessment should take place in secondary care. The vast majority of patients should be risk assessed by using the NICE algorithms (Appendix 2 and 3). Some less clear cut cases may require the use of a recognised risk-assessment calculator. The purpose of the risk assessment is primarily to enable one to classify the patient into their risk category (eg: population level, moderate and high risk groups), and to establish the probability of carrying a pathogenic BRCA mutation. This enables provision of an individualised lifetime risk assessment, to provide advice on any need for screening, chemoprevention, surgery and to determine who should be referred to a specialist Genetics clinic for consideration of genetic testing.

NICE guidelines allow NHS mutation screening if the likelihood of a BRCA mutation is 10% or over in affected individuals. It may also be offered 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. We recommend use of the Manchester scoring system to determine if a patient is eligible. It takes less than 60 seconds to carry out. A Manchester score of 15 or more is equivalent to a 10% or greater risk. A score of 17 or more is equivalent to a risk of 20% or more.

There should be a limited number of health professionals involved in secondary care family history assessment to maintain optimal standards and consistency. They should seek guidance from their Genetics service about risk assessment and ensure they are adequately trained. Risk determinations and management recommendations already given to other family members should be considered. The clinician should avoid working in isolation, and it is useful to have a contact in Genetics to discuss unusual cases.

Presentation of family information should be in the form of an easily readable chart. Pedigree drafting uses a standardized set of symbols: squares represent males; circles represent females (appendix one)

Different methods of risk assessment will not provide the same result. It is important that you agree with your Genetics Department as to which method you will use. Patients should be informed of their risk value in more than one format (numerical and qualitative) and of the uncertainties over risk estimates.

SOME EXAMPLES OF COMMONLY USED METHODS:

NICE ALGORITHMS (APPENDIX 2 AND 3)
This is the simplest and quickest method. Quite simply, if a patient meets the algorithm criteria for referral to secondary care they are at least 'moderate risk'. If they also meet the algorithm criteria for referral to tertiary care they will likely be 'moderate' or 'high' risk, but all should be referred to Genetics where this will be accurately determined.

IBIS RISK CALCULATOR[8]
The IBIS breast cancer risk evaluation tool (Tyrer Cuzick) is available for download from the internet: http://www.ems-trials.org/riskevaluator/

This software is periodically updated and users should check that they have the most up to date version. Version 7.02 was released on 13th June 2013. It has the advantage that it can be launched from a desktop icon, so is quick to use. It also includes 'hormonal history', weight, hyperplasia/LCIS. This risk calculator is already widely used in

secondary care although not used much by Genetics services. There are some limitations e.g. prostate/pancreas cancer is not included, and you are not able to record an index case with breast cancer. 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 then be calculated for the age range 40–49. Women with a 10-year risk of 3–8% for women aged 40–49 or a lifetime risk of 17% or greater but less than 30% would be managed in secondary care as 'Moderate risk'. Women who have a 10-year risk at age 40–49 years of greater than 8% or a lifetime risk of 30% or greater, should be referred to Genetics. Please be aware that inputting hormonal data and parity probably leads to over estimation of BRCA mutation carrier risk.

BOADICEA
This software estimates the likelihood of detecting BRCA1/2 mutation. BOADICEA is available from: http://ccge.medschi.cam.ac.uk/boadicea

It is an online software tool, which requires you to create a new pedigree each time or upload a pedigree file. It is possibly the most comprehensive tool for calculating familial risk but also the most time consuming and is more complicated to store as a record. It is more commonly used in Genetics.

MANCHESTER SCORE (APPENDIX 4)
This is an empirical scoring system that was developed in 2003. It estimates the chance of identifying a mutation in BRCA1 or BRCA2 genes. The score can be refined further by using the pathology adjustment of the index case if it is known. Doing so will further increase the accuracy of the risk assessment.

6. WHAT TO DO IN PRACTICE:

- Use NICE algorithms +/- a risk assessment tool
- Identify patients clearly at low risk → Primary care
- Identify patients clearly at moderate risk → Secondary care
- Identify patients meeting criteria (high/high-moderate risk) → Genetics. Gene testing if eligible & check risk

Other considerations:

- Predictive genetic testing for family members if a pathogenic mutation is identified
- Risk Reducing surgery
- Rare syndromes:
  - Li Fraumeni – v. young breast Ca, sarcomas, leukaemia, brain tumours, adrenal cancer
  - Peutz-Jeghers – mucosal freckling, intussusception, breast cancer, GI/gynae cancers
  - Cowden – Large headsize, facial/oral papules, breast cancer, thyroid (esp follicular), endometrial, renal cancer

7. SURVEILLANCE OF WOMEN WITH NO PRIOR PERSONAL HISTORY OF BREAST CANCER

(See Appendix 5)

Only undertaken after written information is given about risks and benefits.

UNDERSTANDING THE WORD 'CONSIDER' IN THE NICE GUIDELINES.
It is important to note the definition of the word "consider" provided in the NICE Guidelines. For all recommendations, it is expected that a discussion will take place with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion should help the patient reach a fully informed decision. "Consider" relates to where "an intervention will do more good than harm for most patients" and "the choice of intervention and whether to have the intervention or not is more likely to depend on the patient's values and preferences"..."the healthcare profession should spend more time considering and discussing the options with the patient".

Therefore, taking into account the 'consider group', and the 'offer group', annual mammographic surveillance should be available to all women who choose it if they are:

- at moderate risk from age 40-59
- at high risk from 30-59
- if known BRCA mutation from 30-69

Followed by 3 yearly mammography through the NHSBSP

Don't use mammographic surveillance in these circumstances:
- If age 29 or under
- If 30-39 and moderate risk
- At any age with a TP53 mutation
- At 30-49 with no genetic testing but > 30% chance of having a TP53 mutation

MRI Surveillance
Annually:
- Age 30-49 with a known BRCA mutation (or >30% chance of being a BRCA carrier)
  - Extend annually up to age 69 if mammography shows a dense breast pattern
- Age 20-49 with a known TP53 mutation (or >30% chance of being a BRCA carrier)
- Consider to age 69 with a known TP53 mutation

Don't use MRI surveillance in these circumstances (unless recommended due to high breast density):
- At any age if at moderate risk
- At any age if high risk but < 30% chance of having BRCA or TP53 mutation
- At age 20-29 even with a known BRCA mutation except TP53 mutation group

USS Surveillance
Don't routinely offer USS surveillance to women at moderate or high risk.

Other recommendations
- Do not offer surveillance to women who have undergone a bilateral mastectomy.
- Give written information on the advantages and disadvantages of surveillance.
- Review eligibility for surveillance if the family history changes (e.g. where additional members of a family report breast cancer or a mutation is identified).
- Give information on surveillance programme being provided; duration, frequency and method.

8. Screening for women who DO have a personal history of breast cancer
(See Appendix 5)

All women after breast cancer excision should be offered annual mammography of residual breast tissue for 5-years in line with NICE CG80. Women who remain at increased risk of development of a future breast cancer and have a high risk* family history should receive prolonged surveillance.

- 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 known TP53 mutation.

*High Risk in this context is where the complete FH including the patient with breast cancer is:
  - two family members diagnosed with breast cancer at average age <50
  - three family members diagnosed with breast cancer at average age <60
  - four family members diagnosed with breast cancer at any age
  - and all are on same blood-line and all closely related; at least one is a first degree relative
  - (and in any with known BRCA mutation)

- 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
- 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 50 years (NEW)
  - breast cancer under age 30 years
  - Ashkenazi 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/very strong paternal history (four relatives diagnosed at younger than 60 years of age on the paternal side of the family).

SUMMARY STATEMENT:

OVERVIEW OF THE IMPLICATIONS AND IMPLEMENTATION OF NICE GUIDELINES ON FAMILIAL BREAST CANCER

9. CHEMOPREVENTION AND OTHER MODIFIABLE RISK FACTORS

There is evidence that 5 years treatment with tamoxifen (or similar) reduces the occurrence of a future primary breast cancer by approximately 40-50%. There may be updated evidence around the use of aromatase inhibitors in this setting in due course.

Premenopausal women
Offer tamoxifen* for 5 years to women at high risk of breast cancer, (likely from age 35). Patients can also consider it if they are at moderate risk.

Postmenopausal women
Offer tamoxifen* for 5 years to women without a uterus and at high risk of breast cancer. Offer either tamoxifen or raloxifene* for 5 years to women with a uterus and at high risk of breast cancer.
Women who are at moderate risk can also avail of chemoprevention.

Stopping treatment
Do NOT continue treatment with tamoxifen or raloxifene beyond 5 years.
Inform women that they must stop tamoxifen at least: 2 months before trying to conceive, and 6 weeks before any elective surgery under general anaesthesia.

(*unlicensed use, therefore obtain and document informed consent)

Do not offer chemoprevention after bilateral risk reducing mastectomy

Give written information on the potential risks and benefits of chemoprevention. Include information on side effects of drugs, extent of potential risk reduction, and the risks and benefits of alternative approaches, such as risk-reducing surgery and surveillance. Do not use chemoprevention concomitantly with HRT.

Provide general health style advice, advice not to smoke, on the probable increased risk of development of breast cancer if postmenopausal and overweight and the potential benefits of physical exercise on breast cancer risk and the risks associated with the use and duration of HRT in relation to their age. Advise that alcohol may slightly increase their risk of development of a future breast cancer.

10. RISK REDUCING SURGERY

Risk reducing surgery is appropriate only for a small proportion of women who are from high-risk families and should be managed by a multidisciplinary team, which should consist of a breast care nurse, breast surgeon, plastic surgeon and gynaecologist with a specialist interest in managing women at high risk. There should be an established referral pathway to a clinical psychologist. Risks and benefits of risk-reducing mastectomy should be discussed with all women who are high risk, including those with a known or suspected BRCA1, BRCA2 or TP53 mutation. If risk reducing surgery is considered in women with no proven predisposing genetic mutation, the family history should be verified and psychological assessment should be carefully considered .

Risk reducing surgery should be discussed in the context of other risk reducing strategies (chemoprevention), screening options, estimated life years gained, and complications and quality of life consequences of surgery. All women, including high risk women who chose not to have risk reducing surgery should be informed of the likely pathway of treatment and outcome of a screen-detected or symptomatic breast cancer. It is important the women are advised pre-operatively as to the possibility of an existing breast cancer being revealed on the histology of the resected tissue following a risk-reducing mastectomy.

The team performing the surgery should possess all the necessary comprehensive specialist surgical skills and techniques. Every patient should attend at least two consultations with the surgical team to allow fully informed consent.

Offer women who have BRCA1, BRCA2 or TP53 mutations but who decide against risk-reducing mastectomy, surveillance according to the protocols for their high level of risk.

SUMMARY STATEMENT:

OVERVIEW OF THE IMPLICATIONS AND IMPLEMENTATION OF NICE GUIDELINES ON FAMILIAL BREAST CANCER

Where the person has already had a breast cancer

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

- prognosis of their already diagnosed breast cancer/risk of a distant recurrence
- quantification of the risk of developing a new primary breast cancer in the other breast
- potential negative impact of mastectomy on body image and sexuality
- the very different appearance and texture of the breasts after reconstructive surgery and the potential that the additional risk-reducing surgery may be associated with complications which might delay adjuvant therapies
- potential benefits of significant reduction in the risk of developing a new primary cancer in the contralateral breast and the consequential potential alleviation of anxiety

Authors:	Philip Turton, Elisabeth Grimsey and Chandra Sekharan On behalf of the ABS Council
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Members of ABS Council and Committees met and discussed a set of topics on which it was felt clinical guidance was sought by ABS members. This document represents the considered, agreed opinions of experienced breast surgeons. It is not meant to supplant authoritative guidelines. Discussion and correspondence would be gratefully received by the ABS to lucydavies@absgbi.org.uk

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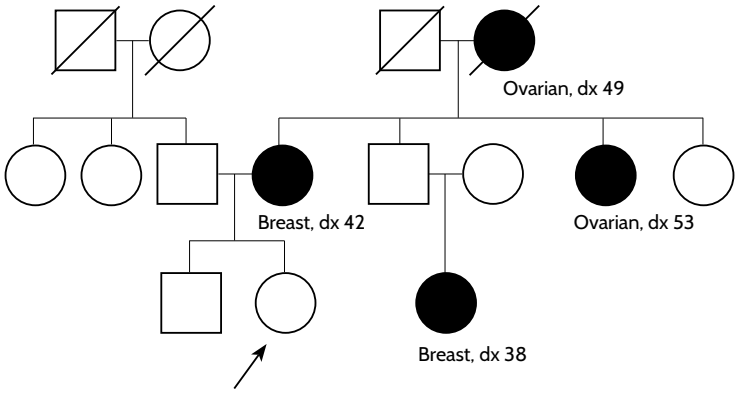
APPENDICES

APPENDIX 1. CONSTRUCTION OF A SIMPLE PEDIGREE

Information needed for a good risk assessment

- Pedigree, at least as far as grandparents and first cousins
- Maternal and paternal blood-lines
- Ages of individual at diagnosis/ death
- Diagnosis (Confirmation not essential unless considering major interventions)
- Ashkenazi Jewish ancestry

Classic BRCA1 Pedigree



This pedigree illustrates a female patient (arrowed) who has a mother who had breast cancer diagnosed at 42, and her maternal grandmother who had ovarian cancer diagnosed at 49 and is now deceased, her maternal aunt had ovarian cancer diagnosed at 53, and her maternal uncle's daughter had breast cancer diagnosed at 38

Square = male
Circle = female
Blacked out = affected individual, type of cancer, and age of diagnosis

White = unaffected individual
Line through = deceased
Arrow = patient to which the FH assessment is being applied

APPENDIX 2. NICE Algorithm: Moderate risk

These FH criteria are likely to indicate the patient is categorised as Moderate Risk and should be managed in secondary care, as long as the criteria for referral to tertiary care/Genetics are also not met. If none of these criteria are satisfied the patient is likely to be at general-population risk, and should be managed in primary care. Further advice should be sought if there is complexity: bilateral breast cancers, Ashkenazi Jewish ancestry, two or more paternal relatives with breast cancer, unusual cancers (eg sarcoma, glioma, childhood adrenal cortical carcinoma), complicated patterns of cancers at young age.

IS THERE AT LEAST ONE OF THE FOLLOWING PRESENT IN THE FAMILY HISTORY?		
A tick in **any box** below indicates that the woman is likely to be at increased risk and should be offered referral to the family history clinic		
🧍	One 1st degree female relatve diagnosed with breast cancer before age 40	❑
🧍	One 1st degree male relative diagnosed with breast cancer at any age	❑
🧍	One 1st degree relative with bilateral breast cancer where the 1st primary was diagnosed before age 50	❑
🧍 🧍	Two 1st degree relatives diagnosed with breast cancer at any age	❑
🧍 + 🧍	One 1st degree relative **and** one 2nd degree relative diagnosed with breast cancer at any age	❑
🧍 + 🧍	One 1st or 2nd degree relative diagnosed with ovarian cancer at any age **and** one 1st or 2nd degree relative diagnosed with breast cancer at any age (one of these should be a 1st degree relative)	❑
🧍 🧍 🧍	Three or more 1st or 2nd degree relatives diagnosed with breast cancer at any age	❑

APPENDIX 3. NICE Algorithm: High risk

These FH criteria indicate a patient should be referred to Genetics for more formal assessment. They are likely to be at least moderate risk but many will prove to be high risk. Some will likely be eligible for BRCA gene testing. The final risk classification can therefore be varied and will be advised by Genetics. As it is possible to have paternal transmission of an inherited predisposition the family history can still be assessed as high risk with intervening but unaffected males. Each side of the family should be considered separately.

Breast cancer only families:

- 2 close relatives diagnosed with breast cancer, average age of diagnosis < 50
- 3 close relatives diagnosed with breast cancer, average age of diagnosis < 60
- 4 close relatives diagnosed with breast cancer at any age
- 1 bilateral breast cancer (confirmed separate primary cancers), average age of diagnosis of cancers < 50
- 1 bilateral breast cancer and 1 F/SDR breast cancer, average age of diagnosis of cancers < 60
- 1 bilateral breast cancer and 2 F/SDR breast cancers diagnosed at any age
- 2 close relatives, both with bilateral breast cancers, diagnosed at any age
- Male breast cancer at any age plus 1 F/SDR with breast cancer < 50
- Male breast cancer at any age plus 2 F/SDR with breast cancer < 60

Breast/Ovarian Cancer Families:

- 1 individual with both breast and ovarian cancer, where the ovarian cancer is diagnosed at any age and the breast cancer is diagnosed < 50
- 1 ovarian cancer at any age plus 1 F/SDR breast cancer < 50
- 1 ovarian cancer at any age plus 2 F/SDR breast cancer, average age of diagnosis of breast cancer < 60

Ovarian Cancer only family

- 2 ovarian cancers, diagnosed at any age

APPENDIX 4. Manchester Score

FBC=female breast ca MBC=male breast ca	**Score**
FBC<30	**11**
FBC 30-39	**8**
FBC 40-49	**6**
FBC 50-59	**4**
FBC>59	**2**
MBC <60	**13**
MBC>59	**10**
Ovarian Ca <60	**13**
Ovarian Ca >59	**10**
Pancreatic Ca	**1**
Prostate Ca<60	**2**
Prostate Ca>59	**1**

Pathology adjustments	
Breast Cancer Adjustments (index case or closest relative):	**Score**
HER2+ve	-4*
Lobular breast cancer	-2
DCIS only (no invasive cancer)	-1
LCIS only	-4*
Grade 1	-2
Grade 3	+2
ER+ve	-1
ER-ve	+1
Grade 3 Triple negative	+4*
* Maximum - no further adjustment for breast cancer	
Ovarian Cancer Adjustments (all family members): Mucinous, Borderline, Germ cell tumours except granulosa cell - Do not count in score at all	

- Scores are added for each cancer in a direct lineage. If cancers occur on both sides of the family the lineage providing the highest score is counted.
- Scores for each cancer (including ductal carcinoma in situ (DCIS), with one score for each breast cancer in bilateral disease, are added together for the family. The score can be modified once only with a pathology adjustment, if it is known (see Evans et al. J Med Genet 2009;46:811-817)
- Affected individual testing (the score on a woman who has had breast cancer): This can be requested if the affected individual has a Manchester score >=15 as this indicates there is an approximate 10% risk that the affected individual carries a BRCA gene mutation
- Unaffected individual testing (the score on a woman who has not had breast cancer herself): This can be requested where an unaffected patient has a Manchester score >=17, plus one affected first degree relative, but where there are no affected cases available for testing (eg: the affected relative is unavailable as she lives abroad)
- Please note that any patient who has had a Triple negative cancer and is age <40yrs is still eligible for BRCA testing even if their score is =12

APPENDIX 5. Screening Summary

Unaffected women (the patient has no personal history of breast cancer)

Mammograms- taking into account the 'consider group*', annual mammographic surveillance should be offered through discussion with all women:
- at moderate risk from age 40-59
- at high risk from 30-59
- if known BRCA mutation from 30-69

MRI Surveillance annually:
- Age 30-49 with a known BRCA mutation (or >30% chance of being a BRCA carrier). Extend annually up to age 69 if mammography shows a dense breast pattern
- Age 20-49 with a known TP53 mutation (or >30% chance of being a BRCA carrier). *Consider* to age 69 with a known TP53 mutation

Affected women (the patient has had breast cancer herself and has a significant FH of breast cancer)
- All women should be offered annual mammography for a minimum of 5-years
- In addition:
  - Offer prolonged 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. High Risk in this context is where the complete FH including the patient with breast cancer, and all are on same side of family, and all closely related; at least one is a first degree relative
- High risk is where:
  - 2 family members diagnosed with breast cancer at average age <50
  - 3 family members diagnosed with breast cancer at average age <60
  - 4 family members diagnosed with breast cancer at any age
  - (and in any with known BRCA mutation)

MRI Surveillance
- 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

Extract from NICE guideline CG164 explaining how to interpret the word consider in the guideline: Recommendations are based on the trade-off between the benefits and harms of an intervention, whilst taking into account the quality of the underpinning evidence. For all recommendations, it is expected that a discussion will take place with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion should help the patient reach a fully informed decision.
'Consider'– the benefit is less certain, and an intervention will do more good than harm for most patients. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for an 'offer' recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

APPENDIX 6. Written information

NB: The following list of written information on risk is not exhaustive. It is recommended by NICE that this information should be made available.

Risk information about population level and family history levels of risk including a definition of family history.

Details of any appropriate trials or studies.

That a family member/ friend may come with them to appointments.

The benefits and risks of surveillance, including:
1. the possibility that mammography may not reveal a cancer in women with dense breasts and the increased likelihood of a screened patient to require further investigations that often result in a benign diagnosis
2. possible over diagnosis of a malignancy that was not life threatening
3. the risk associated with exposure to radiation
4. the possible psychological impact of a recall visit for further breast assessment

Lifestyle, General Advice, Advice on OCP, HRT usage, diet, alcohol intake and benefits of breastfeeding.

Provide people with standardised written information about risk, including age as a risk factor

Pathway advice
Low risk (ie average population risk group)/Moderate risk (should include information on lifestyle and screening, and Breakthrough Breast Cancer booklet on risk)/High risk (as per moderate but also need information on referral to Genetics)

Chemoprevention advice. Provide written information on the absolute risks and benefits of all options for chemoprevention to women at high or moderate risk of breast cancer. Include information on side effects of drugs, extent of potential risk reduction, and the risks and benefits of alternative approaches, such as risk-reducing surgery and surveillance.

Advice that if family history alters, their risk may alter.

Breast awareness information.

Contact details of support groups.

APPENDIX SEVEN: Breast FH Locus of Care Pathway