

**Guideline for the Multidisciplinary Management of Patients Considering a Risk
Reducing Mastectomy**

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| DATE APPROVED BY NETWORK GOVERNANCE | SEPTEMBER 2012 |
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1. Scope of the Guideline

- 1.1 This guideline has been produced to support the referral of patients for a risk reducing mastectomy (RRM) in the following two groups:
- Those with a family history. These patients may have a population, moderate or high risk of developing breast cancer.
 - Those with a personal history. These patients have been diagnosed, with breast cancer. They may be newly diagnosed or had treatment previously and are concerned about their risk of developing a second primary breast cancer in the contra or ipsilateral breast.
- 1.2 There are other groups of patients (without a current/new diagnosis of breast cancer) who may be suitable for the consideration of mastectomy, but would not fall into the category of RRM. See the first 4 examples in [appendix 1](#). The management of these patients is not included in this guideline.

2. Guideline Background

- 2.1 RRM is one of a range of options available to patients who are concerned about their risk of developing a primary breast cancer.
- 2.2 Three advances have resulted in an exponential rise in the popularity of risk reducing mastectomy. Firstly, recent developments in gene testing and cancer epidemiological models have allowed physicians and surgeons to better estimate some individual's risk of developing breast cancer. Secondly, there is good evidence that RRM reduces the occurrence of breast cancer *in cases where there is a significant risk*. Thirdly, recent advances in surgical techniques of both mastectomy and reconstruction have resulted in more reliable, high quality outcomes.

Guideline Statements

3 Patient selection

- 3.1 Patient groups for whom RRM is being considered includes:
- Bilateral RRM (family history group – see 3.2 below)**
 - Those classified as high risk and making the request.
 - Those classified as moderate risk (see table 1) and making the request.
 - Contra lateral RRM (personal history group – see 3.3 below)**
 - Personal history of breast cancer (this may be recent or past history)
 - High or moderate risk group (see table 1) and making the request after diagnosis of high risk pathology.
- 3.2 Group 1: Family History Group
- 3.2.1 National guidelines published by NICE (Clinical Guideline 14, May 2004) identify three risk groups, and recommend the management of each group (see table 1).

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Table 1. Family history risk groups and their recommended management

| | 10 year risk Aged 40-49yrs | Lifetime Risk | Management |
|-----------------|-------------------------------|---------------|---|
| Population risk | <3% | <17% | Primary Care |
| Moderate Risk | 3-8% | 17-30% | Secondary Care, Tertiary Care if requesting RRM |
| High Risk | >8% | >30% | Tertiary Care (Genetics Service) |

3.2.2 There is debate about the management of the moderate risk group, and whilst NICE recommends this group is managed in secondary care, ABS (p76 ABS at BASO Yearbook 2007) recommends this group is managed in tertiary care centres. In PBCN patients that are deemed moderate risk **and** requesting RRM should be assessed by the tertiary service.

3.2.2 Risk of developing breast cancer is determined using the genetics referral guideline attached in [appendix 2](#).

3.2.3 High Risk

Patients are at a high risk of developing breast cancer by virtue of their family history, pre-existing breast changes or positive genetic screening (BRCA 1 or 2). Such patients should consider undergoing a risk reducing mastectomy. There is good evidence to support the use of risk reducing mastectomy in women at high risk of developing breast cancer (Hartmann, 1999 NEJM).

3.2.4 Moderate risk

Patients are at a moderate risk of developing breast cancer by virtue of their family history and/or pre-existing breast changes. These patients may consider undergoing a risk reducing mastectomy.

3.2.5 Population (low) Risk

There are some women who are concerned about developing breast cancer but in reality their actual risk of developing breast cancer is nominal (i.e no greater than for the general population). For women who remain concerned following information and reassurance, a referral to psychology may be useful (Physical Health Psychology if linked to other health issues; or Mental Health Psychology if there are mental health issues).

3.3 Group 2: Personal History Group

3.3.1 In addition to the family history group, increasing numbers of women who have a personal history of breast cancer in one breast are requesting risk reducing mastectomy of their contra-lateral breast. Patients in the personal history group can be subdivided into two groups according to the stage of treatment of their breast cancer.

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3.3.2 *Personal History Group: Previous Breast Cancer*

- a. These patients have already had a mastectomy for cancer in one breast and are now requesting a contralateral mastectomy; with or without reconstruction. There are two considerations for this group:
 - i. Have they got a family history or positive genetic testing (see table 1)?
 - ii. What is their prognosis / risk of metastases compared to their risk of a new contra lateral primary breast cancer?
- b. For patients in this elective RRM group, the time factor for consultation with the genetics team and psychologist is less urgent, and several sessions with the psychologist may be appropriate, either for RRM assessment/discussion or for cancer-related psychological issues.

3.3.3 *Personal History Group: Current (recently diagnosed) Breast Cancer*

- a. This is a relatively small group of patients who have been diagnosed with breast cancer and are awaiting treatment. They may request a contra-lateral risk reducing mastectomy and bilateral immediate reconstruction. If this decision is appropriate, the patient may benefit by having these procedures simultaneously; it avoids the need for a second operation and consequent recovery time. Furthermore, if abdominal tissue is used for the reconstruction, it can be used to reconstruct both breasts simultaneously and thus maintain symmetry. However if the mastectomy/reconstruction is staged, abdominal tissue can only be used once so the second reconstruction must use alternative tissue and hence there is less chance of maintaining symmetry.
- b. Due to the necessary time limit in operating on their breast cancer there is an urgency to evaluate and assess their suitability for a risk reducing mastectomy. Mechanisms should be in place (see below and [appendix 3](#)) to enable rapid assessment of risk by a genetics team and by a psychologist prior to discussion and decision at the multidisciplinary team meeting. It is just as important in these cases to calculate true risk and to clearly discuss this with the patient. If there is any concern or doubt over the patient's suitability to proceed with a RRM, it is recommended that the patient undergoes the ipsilateral therapeutic mastectomy without delay, and elective contralateral surgery can be planned at a later date. Alternatively, patients could be considered for neoadjuvant treatment while awaiting genetic or psychological advice. This approach would also allow time to consider the various reconstructive options.

3 **Treatment options for RRM**

Treatment options include mastectomy alone, or mastectomy and reconstruction (either delayed or immediate). Either of these can be contra lateral or bilateral.

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4 Contra-indications to RRM

- 4.1 Contra-indications to RRM include:
- a. significant co-existing underlying disease that might interfere with the success of surgery
 - b. presence of metastatic disease
 - c. patients over the age of 60 years as are unlikely to benefit clinically from reduced risk
- 4.2 Anxiety alone is not an indication for surgery; before any surgical decisions are made, psychological input should be considered.
- 4.3 RRM is also contra-indicated where further psychological support is recommended by the psychologist prior to treatment, i.e. due the following, rather than due to an increased risk of developing breast cancer:
- a. in the case of psychological unpreparedness
 - b. where the patient has not fully thought through their decision
 - c. where their decision is based primarily on anxiety/fear of recurrence
 - d. where the patient has a cancer phobia

5 Other considerations

- 5.1 Significant emotional distress or mental illness that impairs the ability to make relatively informed decisions can be a poor prognostic sign for satisfaction with the outcome and / or adaptation in the post-surgery phase. These patients are likely to require additional support before and after surgery.
- 5.2 Mental capacity: On the rare instances where mental capacity needs to be considered, appropriate assessments will need to be arranged with an appropriate assessor; other agencies and the Trust safeguarding team should be involved.

6 Principles of treatment / patient pathway

- 6.1 All patients should be reviewed by a geneticist / genetics counsellor, an appropriately trained breast / plastic surgeon, specialist breast care nurse, and, once this has been completed, the psychologist (see [appendix 3](#) for the pathway).
- 6.2 Patients should be fully informed of the risks and benefits. This is the responsibility of the surgeon. The risks and benefits that the patient should understand include the following:
- a. A mastectomy will not completely remove the risk of the patient developing breast cancer, distant recurrence of their original cancer or other forms of cancer. It can significantly reduce the risk of them developing new primary breast cancer. For patients who have initially had a lumpectomy a subsequent mastectomy will reduce the chance of local recurrence.
 - b. A mastectomy is major surgery that will remove the patient's normal breast and (if the patient is having reconstruction) will leave an imitation breast in its place, which will feel numb, will be a little firmer, will lack a nipple and will not have any erogenous/sexual sensation.

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- c. The operation takes a long time, and depending on the procedure, requires up to a week in hospital to recover and up to six weeks of recuperation at home.
- d. The operation carries risks of complications in up to one half of all women who undergo reconstruction. These include loss of all or part of the breast skin, infection of the wound, loss of the tissue flap, chronic pain, nerve injury, DVT, PE and even death.

6.3 The patient should have been given all the relevant medical/surgical and genetics information before they are seen by the psychologist to ensure they can make an informed decision. The psychologist should be the last in the RRM assessment pathway to see the patient and referrals for a “RRM psychology assessment” should only be made where the patient’s risk has been established and the decision is about the patient’s psychological suitability for a RRM. **At this point the patient should be made aware that the role of the psychologist is not to ‘give permission to go ahead or not with the RRM’, but to help them think through their decision.**

Patients should be given the information leaflet ‘psychology services for women considering risk reducing mastectomy’ which can be found at the following link: http://www.birminghamcancer.nhs.uk/uploads/document_file/document/4cc5b6c9358e9875680001ca/considering_risk_reducing_mastectomy.pdf.

6.4 The following information should be faxed to the geneticist and psychologist when requesting an assessment:

- referrer details
- patient details and contact numbers
- nature of breast cancer
- family history details
- treatment plan
- proposed date of surgery
- date of next MDT
- MDT members involved
- any additional reasons as to why the patient/professional is considering RRM
- any potential contra-indications

6.5 A formal report of the evaluated risk should be forwarded to the psychologist by the referring clinician (usually the surgeon). This should be done in time for the patients initial consultation with the psychologist (who will see the patient last, once they have discussed all the relevant RRM medical, surgical and genetics information).

6.6 Where mastectomy *with reconstruction* is agreed, surgery should be carried out by a surgeon/team appropriately trained in breast and reconstructive plastic surgery.

6.7 Systems should be in place within each Trust to ensure that those requesting contralateral RRM for a newly diagnosed cancer should not experience a delay in their primary surgery and should, wherever possible, be offered both procedures at the same time if this is considered medically appropriate and fulfils the RRM criteria.

6.8 See [appendix 4](#) for an outline of the role of each team member

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7 Patient Information and Counselling

- 7.1 All patients, and with their consent, their partners will be given access to appropriate written information during their investigation and treatment, and on diagnosis will be given the opportunity to discuss their management with a clinical nurse specialist who is a member of the relevant MDT. The patient should have a method of access to the breast team at all times.
- 7.2 Access to psychological support will be available if required as described above. All patients with cancer should undergo an holistic needs assessment and onward referral as required.

8 Patient Support Groups

Sometimes it helps for a patient considering a risk reducing mastectomy to have an opportunity to meet and discuss the operation with other patients who have been through the same process. However introduction to the group should only be considered once the patient has been assessed by both the general and plastic surgeons and their suitability for RRM/immediate reconstruction has been confirmed.

MONITORING OF THE GUIDELINE

Adherence to the Network guidelines may from time to time be formally monitored.

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APPENDIX 1 - Scenarios of Complex or Inappropriate RRM requests:

Below are examples of referrals to the Cancer Psychology Service for an RRM psychology assessment that have required further psychological exploration.

1. *Genetically and medically an RRM is not indicated. The patient has been referred for an RRM psychology assessment with the decision primarily linked to body re-alignment. The main reason/motivation is related to body image and a desire for physical symmetry/body alignment, feeling uncomfortable wearing a prosthesis and not being able to wear certain clothes.*
2. *Genetically and medically an RRM is not indicated. The patient has always had “lumpy” breasts and/or has a history of cysts in both breasts which may be painful; she feels that this makes it difficult to check for lumps and given her recent cancer experience she is worried she will not be able to check herself properly, or that mammograms may not be able to clearly resolve a potential cancer tumour.*

In these cases, the decision for a mastectomy would be a surgical decision and would not fall under the remit of an RRM (in terms of this guideline and pathway) nor would need a referral to psychology.

3. *Genetically and medically an RRM is not indicated. However even though she is considered at low risk, the patient is anxious about the possibility of another primary breast cancer and feels that the only way to manage this is to pre-emptively remove the remaining breast. For example, “the fear of my cancer coming back is worse than the reality”.*

Patients with a personal cancer history can be referred to the Cancer Psychology Service for psychological support if their issues are cancer-related but this would not be in the remit of a RRM psychology assessment.

4. *Genetically and medically an RRM is not indicated. The patient has no previous history of breast cancer but appears to have a cancer phobia or body image issues and is requesting a mastectomy.*

Patients who have no medical or genetic indication for an RRM and have no personal history of cancer, but have fears about cancer should be referred to the Community Mental Health Services for psychological support (via their GP).

5. *Genetically and medically an RRM is indicated. However exploration of the issues relating to RRM assessment highlights longer-term body image issues pre-dating the breast cancer experience. This would be considered a **complex** RRM and it would not be a reason to exclude them from having a RRM. However this group of patients would need to be better informed about the whole range of possible outcomes whilst also addressing their psychological issues.*

This case highlights a *complex* RRM referral where several factors need to be taken into consideration and the role of the cancer psychologist would be more specialist; an in-depth psychological assessment of the issues and the possibility of an RRM would be undertaken. It would be useful for psychology to be guided by surgeons in terms of whether they are requesting an RRM assessment or psychological support and also where the cut off would be in terms of “borderline” risk. If longer-term psychological support was needed unrelated to cancer, a referral to local psychology services would be recommended.

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Appendix 2

The Cancer Genetics Service: Information for Referrers

This is a service for patients with a family history of cancer. If your patient is symptomatic, please refer them to your local fast track service in parallel with giving them a family history form.

General information about cancers

Many individuals have concerns about a family history of cancer. However, less than 10% of all cancer is due to an inherited predisposition. It is less likely that familial cancer clusters are inherited if:

- The cancers occur later in life
- The cancers have a strong environmental influence such as smoking or U.V. light

Family history forms

All patients now need to be referred by family history form except in exceptional circumstances. This is essential to allow us to obtain all the information we require to advise the patient about their family history within department of health 18 week targets.

It may not be necessary for a patient to complete a family history form if:

1. They or a relative have already been seen by a cancer genetics service or completed a family history form before.
2. There is a known alteration in a cancer gene in the family.

If this is the case, please ask them to complete pages 1 and 6 of the form only and return them to us. We will contact them if we need further information. If the patient themselves have had a young cancer diagnosis, or diagnosis particularly associated with a cancer gene, it is still important for them to complete the form as a negligible family history can help with risk assessment.

We apologise that there is a lot of information to complete on the form. There are detailed instructions on page 2 but if a patient is likely to have a significant problem with completing it, please let us know and we will try to help.

DNA banking

In the small number of families in whom we can consider genetic testing, it is most useful to have a blood sample from an affected family member. If an affected family member is terminally ill, please let us know as soon as possible. We may be able to arrange for a blood sample to be taken in order to store some DNA while we assess the family history. This can help to preserve the option of genetic testing in the future.

Cancer Family History Referral Guidelines

Patients meeting *at least one* of the criteria below should be referred.

Breast cancer in:

- 1 close relative*, age under 40.
- 1 close relative* with bilateral disease.
- 1 male relative, any age.
- 2 close relatives*, age under 60.
- 3 close relatives*, any age.

Or Grade 3, breast cancer in self or relative under age 45, with oestrogen, progesterone and herceptin receptor negative status.

Ovarian cancer in:

- 2 close relatives*, any age.

Breast AND ovarian cancer in:

- Minimum of one of each cancer; ovarian cancer any age, breast cancer age under 60.

Colorectal cancer (or colorectal polyps) in:

- 1 close relative*, age under 45.
- 2 close relatives*, average age under 70 (includes both parents).
- 3 or more close relatives*,
- 1 close relative, with gastrointestinal, uterine, ovarian or renal cancer in other relatives at any age.

A clinical diagnosis of Familial Adenomatous Polyposis (FAP).
Or an individual with 5 or more colorectal polyps.

Other cancers:

- Multiple primary cancers in one individual.
- 3 or more relatives with cancers at the same site.
- 3 or more relatives with any cancer at an earlier than average age.
- 3 or more relatives with a combination of cancers of either breast, ovary, prostate, pancreas, melanoma or thyroid.

*Close relatives: mother/father, sister/brother, son/daughter, aunt/uncle, grandmother/grandfather
If uncertain, please refer the form for assessment.

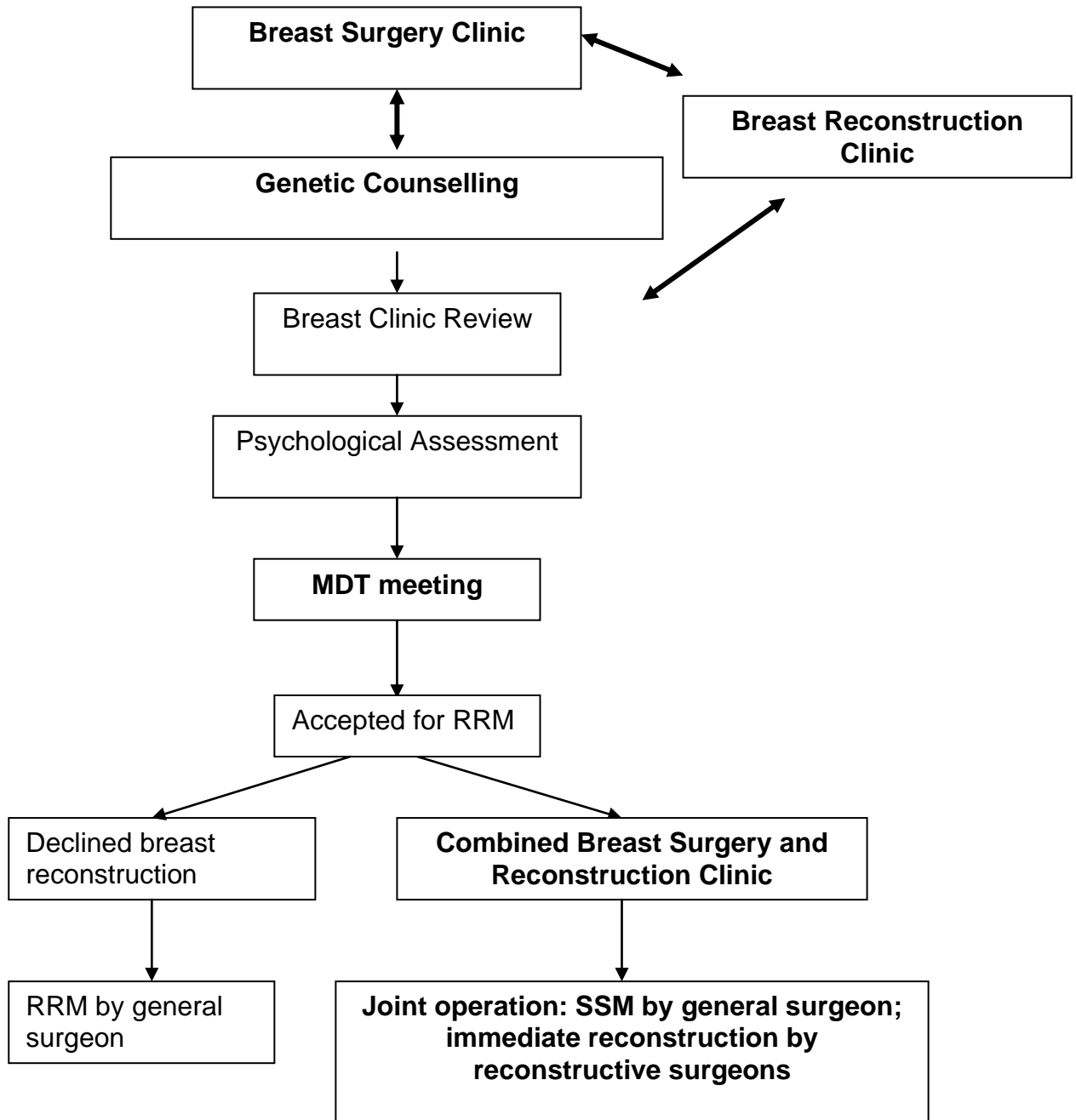
Contact details: WMFACS, Clinical Genetics Unit, Birmingham Women's Hospital, Edgbaston, Birmingham B15 2TG

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**APPENDIX 3
Risk Reducing Mastectomy Patient Pathway Flow Chart**



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APPENDIX 4

Role of each Team Member

Clinical Cancer Genetics Team

The genetics team (comprising consultant clinical geneticists and genetic counsellors) estimate the risk of developing a new primary breast cancer in women with or without breast cancer who may have a family history of breast and/or ovarian cancer. A small number of women with a high risk family history may subsequently be offered genetic testing. Based on this risk level the genetics team will discuss management options including prophylactic mastectomy (and/or salpingo-oophorectomy). In addition, the cancer genetics service also aims to provide information, diagnosis, counselling, management and support for patients and families with breast/ovarian cancer family histories.

The genetics team will also discuss the non-surgical strategies for breast cancer risk reduction including: cessation of smoking; discontinuation of hormone replacement therapy; the role of chemoprevention etc.

Psychologist

Every woman considering a risk reducing prophylactic mastectomy is referred to the psychology team. The role of the psychologist is to assess and support the patient's psychological wellbeing (for this procedure), to explore their motivation for and expectations of RRM, what it means for them psychologically and emotionally in terms of their quality of life (before and after) and their ability to make an informed and meaningful decision, including a realistic understanding of the outcome.

Psychologists work with each person to explore:

- Their expectations from surgery (e.g. in terms of what the procedure actually involves; what the result will look and feel like; physical and sensory changes; physical recovery; quality of life issues; the patient's emotional and psychological response to it).
- Their understanding of the procedures and risks involved (e.g. in terms both of risk of cancer occurring/recurring in the [other] breast or elsewhere in the body; risk of surgery and of possible complications).
- Whether the patient has come to a meaningful decision involving a realistic assessment of all of the issues, i.e. able to discuss reasons for wanting to pursue RRM, including the arguments for and against their choices. The psychologist would be worried for patients who do not appear to have considered these issues and are completely focussed only on pursuing RRM.

Psychologists will normally meet once or twice with the patient. Written feedback to the breast team/referring consultant will be fully discussed with the patient. Sometimes further meetings can be arranged if that would support the patient with specific difficulties.

Since women will have been through the previous stages (even where there is concern at an early stage that RRM may not be in their best interests) they may well feel that the

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psychologist is the final stumbling block, and that they need to convince them. It is important for the patient to know prior to attending the psychology appointment that this is not the case and it is not the responsibility of the psychologist to make this decision. It is therefore important that patients (and when we pass information to each other) know the outcome of each meeting/stage (e.g. with surgeons, genetics and psychologists etc).

Breast Surgeon

The role of the breast surgeon in risk reducing mastectomy is two fold. First they need to act as the central point of reference in organising and advising patients as to the appropriateness of mastectomy and if reconstruction is a realistic possibility. Individuals considering RRM would normally be seen by the breast surgeon at an early stage in the process and then referred to other members of the pathway if appropriate. The breast surgeon will co-ordinate and collate the advise from other health care professionals involved before the final decision is made. The surgeon would also be central in discussing and advising at the MDT. Ultimately it is the breast surgeon who is most likely to be involved in the final discussions with the patient in order that a final treatment plan can be made.

Secondly the breast surgeon would perform the skin-sparing mastectomy prior to planned plastic surgical reconstruction. The surgeon would thus have to advise the individual concerning the risks and appropriateness of such surgery and will have coordinated with the plastic surgeon who will be undertaking reconstruction. This may be immediate, delayed or not at all depending on patient preference.

Plastic Surgeon

Breasts can be reconstructed in a number of different ways. Each has specific advantages and disadvantages. The role of the plastic surgeon is to conduct a thorough medical history and examination and understand the patient's goals and expectations from reconstructive surgery. The various types of reconstruction can then be discussed together with the advantages and disadvantages of each. The plastic surgeon can then help to guide the patient to the most appropriate method of reconstruction, if any.

Breast Care Nurses

Breast care nurses play in central role as patients advocate and confidante throughout this entire episode. They should facilitate a seamless integration between the initial outpatient consultation, decision making process and provide continued support and advice to the patient throughout their evaluation and treatment period, continued into their postoperative recovery. Many CNS have level 2 psychological training and can begin the process of exploring patients anxieties and concerns regarding their situation. As the clinical genetics team and psychologists are unable to attend the MDT meetings, the breast care nurses will contact the genetics team and psychologist prior to the MDT and represent their views at the MDT.

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