



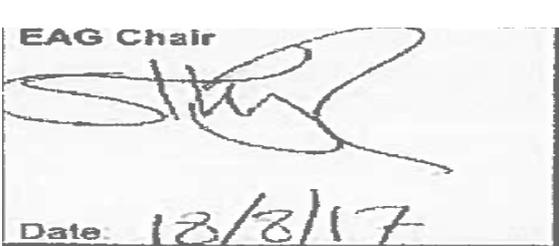
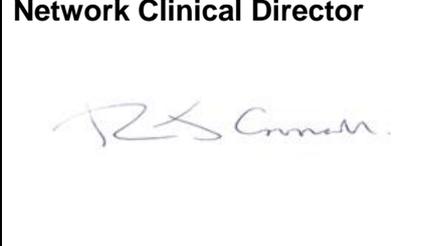
# **Clinical Guidelines for the Management of Breast Cancer**

**West Midlands Expert Advisory Group  
for Breast Cancer**

## West Midlands Clinical Networks and Clinical Senate

### Coversheet for Network Expert Advisory Group Agreed Documentation

This sheet is to accompany all documentation agreed by the West Midlands Strategic Clinical Network Expert Advisory Groups. This will assist the Clinical Network to endorse the documentation and request implementation.

<b>EAG name</b>	Breast Cancer Expert Advisory Group	
<b>Document Title</b>	Clinical guidelines for the management of breast cancer	
<b>Published date</b>	December 2016	
<b>Document Purpose</b>	Clinical guidance for the management of Breast cancer to all practitioners, clinicians and health care professionals providing a service to all patients across the West Midlands Clinical Network.	
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<b>References</b>		
<b>Consultation Process</b>	These guidelines were originally authored by Stephen Parker and subsequently modified by Abigail Tomlins for the Coventry, Warwickshire and Worcestershire Breast Group. The West Midlands EAG agreed to adopt these guidelines as the regional network guidelines. The version history reflects changes made by the Coventry, Warwickshire and Worcestershire Breast Group. As the Coventry, Warwickshire and Worcestershire Breast Group update their guidelines, the EAG will discuss whether to adopt the updated version.	
<b>Review Date</b> (must be within three years)	December 2019	
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## **Version History - Coventry, Warwickshire and Worcestershire Breast Group**

Version	Date	Brief Summary of Change
2010v1.0D	12 March 2010	Immediate breast reconstruction criteria Young adult survivors Updated follow-up guidelines.
2011v1.0D	25 March 2011	The cut off age for mammography has been increased from 35 to 40 Addition of a section about the referral process for reconstruction at UHCW.
2012 v1.0D	29 February 2012	Updated guidance on anterior resection margins Updated MRI guidelines Updated radiotherapy guidelines Updated neoadjuvant chemotherapy guidelines Guidance on cannulation after sentinel node biopsy Tamoxifen and elective surgery
2013v1.0D	5 February 2013	Management of B3 lesions Updated oncoplastic guidelines Radiotherapy treatment protocols Use of CT for metastatic screening
2014v1.0D	23 September 2014	MDT discussion of private patients Skin marking of impalpable lesions Management of positive sentinel nodes Extended adjuvant therapy Failed localisation procedures
2015v1.0D	October 2015	Follow up protocol MRI in high risk patients NICE referral guidance New TWW form

## **Version History – West Midlands Clinical Network**

Version	Date	Brief Summary of Change
2016 v1	12 <sup>th</sup> December 2018	The EAG adopted in full version 2015v1.0D of the Coventry, Warwickshire and Worcestershire Breast Group guidelines.

# Introduction

These guidelines are for the management of patients with breast cancer across the West Midlands. A guideline is not a rigid constraint on clinical practice, but a concept of good practice against which the needs of the individual patient should be considered. It therefore remains the responsibility of the individual clinician to interpret the application of these guidelines, taking into account local service constraints and the needs and wishes of the patient. It is not intended that these guidelines are applied as rigid clinical protocols.

National guidelines exist covering many aspects of breast cancer care. These regional guidelines have been developed against this background. The following guidelines have been reviewed and adapted in the production of this local document:

- Surgical guidelines for the management of breast cancer. Association of Breast Surgery at BASO. 2009
- Early and locally advanced breast cancer. Diagnosis and treatment. National Institute for Clinical Excellence. 2009
- Advanced breast cancer. Diagnosis and treatment. National Institute for Clinical Excellence. 2009
- Familial breast cancer. The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care. National Institute for Clinical Excellence. 2006
- Quality assurance guide lines for surgeons in breast cancer screening. NHSBSP Publication No.20. November 2009
- NHSBSP Guidelines for Pathology Reporting in Breast Disease, 2005
- Royal College of Pathologists Minimum Dataset for Breast cancer, 2008
- Referral for suspected cancer. National Institute for Clinical Excellence. 2005
- Oncoplastic breast surgery – a guide to good practice. Association of Breast Surgery at BASO, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the Training Interface Group in Breast Surgery. 2007
- National Comprehensive Cancer Network Breast Cancer Guideline, Version 2. 2008
- Best practice diagnostic guidelines for patients presenting with breast symptoms. Department of Health, 2010
- London Region Quality Assurance Reference Centre Guidance on management of indeterminate breast lesions. 2012
- Oncoplastic Breast Reconstruction. Guidelines for Best Practice. Association of Breast Surgery and British Association of Plastic Reconstructive and Aesthetic Surgeons. 2013

- Acellular dermal matrix assisted breast reconstruction: Joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstruction and Aesthetic Surgeons. 2013.
- Suspected Cancer: Recognition and Referral – NG12, Published June 2015

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# Organisation of breast cancer surgical services

## The multidisciplinary team (MDT)

Breast cancer care should be provided by breast specialists in each discipline and multidisciplinary teams form the basis of best practice. All new breast cancer patients should be reviewed by a multi-disciplinary team (MDT). This team is the forum for recommending treatment regimens for individual patients. These guidelines form the basis for discussion but do not preclude other treatments if deemed appropriate in individual cases. Participation in clinical trials is encouraged.

Membership of each MDT will vary. The minimum requirement is the core membership.

### Core members of the MDT

- Designated breast surgeon(s)
- Radiologist
- Histopathologist
- Oncologist
- Breast care nurse(s)
- MDT Co-ordinator

Extended member of the MDT may include:

- Plastic and reconstructive surgeon
- Data management personnel
- Research nurse(s)
- Clinical psychologist
- Palliative care team

Consultants and other core team members must have contractual time for attendance at the MDT meeting. The team should meet at least weekly and there must be representatives from each of the core membership groups. Formal arrangements should be in place to cover for absence. Video-conferencing facilities may be required to permit discussion between the Cancer Centre and Local Units. A record of attendance should be kept and the outcome of patient discussions should be recorded in the case notes. A designated member of the clerical team should have the responsibility to co-ordinate the whole process.

All new patients in whom a needle core biopsy has been taken should be discussed. Verified imaging and pathology results should be available at each MDT meeting. All patients diagnosed with breast cancer should be discussed prior to instigation of therapy – whether surgery, neo-adjuvant or primary medical therapy. Results of all required prognostic and predictive factors (including ER and HER2 status) should be available. All postoperative breast cancer patients' results should be discussed to decide appropriate adjuvant therapy. Patients should also be discussed who re-present with problems or a diagnosis of metastatic disease.

It is essential that mechanisms are in place for the timely reporting of MDT decision to primary care. The MDT decision regarding the management of a newly diagnosed breast cancer should be communicated within 24 hours of the meeting by an appropriate mechanism such as secure fax. Mechanism should also be in place for the acceptance of referrals from other MDTs and the reporting of the decision back to the referring consultant

in a consistent and timely fashion. GPs should be informed of patients with a benign diagnosis within 10 working days.

## **Private patients**

Patients undergoing investigation and treatment in the private sector should be discussed in the same fashion as NHS patients. All private patients should be under the care of a core member of the MDT, who will inform the MDT co-ordinator of the need to list the patient. The clinician is responsible for ensuring that relevant clinical information, radiology and pathology results are available at the meeting. It is not the responsibility of the MDT co-ordinator to chase reports or results. The outcome of the MDT discussion will be recorded on the MDT proforma. It is the responsibility of the clinician to record the decision in the clinical notes and to communicate the information with the breast care nurses.

## **Young survivors of cancer**

NICE Improving Outcomes Guidance for Children and Young People with cancer applies to those patients up until the age of 24 years. The West Midlands Paediatric Oncology Supra Network Group has recommended pathways for cancer care for those 16-24 years old treated by adult cancer teams. Breast cancer in women under 25 is extremely uncommon. All young women diagnosed with breast cancer under the age of 24 should be referred as required to the Regional Paediatric Teenage and Young Adult Psychological MDT and an individual treatment plan formulated.

## **Assessment and diagnosis**

### **Referral guidelines**

Patients with symptoms that could be caused by breast cancer should be referred by their GP to designated breast clinics. In addition, women aged between 47 and 73 years are currently invited for screening mammography every 3 years through the NHS Breast Screening Programme (NHSBSP). Some patients will require referral from a screening assessment clinic. Referrals may also be accepted from other cancer MDTs and individual consultants.

In most cases, the definitive diagnosis will not be known at the time of referral, and many patients who are referred will be found not to have cancer. Primary healthcare professionals should convey optimism about the effectiveness of treatment and survival because a patient being referred with a breast lump will naturally be concerned. People of all ages who suspect they have breast cancer may have particular information and support needs. The primary healthcare professional should discuss these needs with the patient and respond sensitively to them. Primary healthcare professionals should encourage all patients to be 'breast aware' in order to minimise delay in the presentation of symptoms.

A woman's first suspicion that she may have breast cancer is often when she finds a lump in her breast. The primary healthcare professional should examine the lump with the patient's consent. The features of a lump that should make the primary healthcare professional strongly suspect cancer are a discrete, hard lump with fixation, with or without skin tethering. In patients presenting in this way an urgent referral should be made, irrespective of the patient's age. The patient's history should always be taken into account. For example, it

may be appropriate, in discussion with a specialist, to agree referral within a few days in patients reporting a lump or other symptom that has been present for several months.

A patient who presents with symptoms suggestive of breast cancer should be referred to a team specialising in the management of breast cancer. Patients who attend a breast clinic should have a consultation and physical examination by a suitably trained member of the team and this can be a surgeon, breast clinician, radiologist, radiographer or advanced nurse practitioner.

Referral to a breast clinic should be considered for female patients with

### **Lumps, lumpiness and change in texture**

- Discrete lump in any woman over the age of 30 years that persists after their next period, or presents after the menopause
- At any age
  - Discrete, hard lump with fixation, with or without skin tethering
  - A lump that enlarges
  - Persistent focal area of lumpiness or change in breast texture
  - Progressive change in breast size with oedema
  - Skin distortion
  - In whom there are other reasons for concern, such as family history
  - With previous breast cancer, who present with a further lump or suspicious symptoms

### **Nipple symptoms**

- Spontaneous unilateral bloody nipple discharge
- Unilateral eczematous skin or nipple change that does not respond to topical treatment
- Nipple retraction or distortion of recent onset
- Bilateral nipple discharge sufficient to stain clothes
- Blood-stained discharge in patients of any age

### **Male patients**

- Aged 50 years and older with a unilateral, firm subareolar mass with or without nipple distortion or associated skin changes

### **Other symptoms**

- Asymmetrical nodularity that persists at review after menstruation
- Abscess
- Persistently refilling or recurrent cyst
- Intractable pain which does not respond to simple measures
- Persistent unexplained axillary swelling

## NICE guidance (NG12) has the following recommendations:

- Refer people using a [suspected cancer pathway referral](#) (for an appointment within 2 weeks) for breast cancer if they are:
  - aged 30 and over and have an [unexplained](#) breast lump with or without pain **or**
  - aged 50 and over with any of the following symptoms in one nipple only:
    - discharge
    - retraction
    - other changes of concern. **[new 2015]**
- Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for breast cancer in people:
  - with skin changes that suggest breast cancer **or**
  - aged 30 and over with an unexplained lump in the axilla. **[new 2015]**
- Consider [non-urgent](#) referral in people aged under 30 with an unexplained breast lump with or without pain. See also recommendations 1.16.2 and 1.16.3 for information about seeking specialist advice. **[new 2015]**

Patients should receive an advice sheet on what to expect at their first appointment. This should be sent out with the appointment letter. They should be provided with further supporting literature at the time of the consultation if any procedures are undertaken.

The appropriateness of referrals against the agreed referral criteria should be audited, with feedback to GPs and PCTs. The number of patient referrals and the proportion of referrals that are subsequently found to have cancer should also be monitored. This is important in order to detect the need for any change in the referral policy. Trusts should aim to see all patients within the nationally agreed waiting times. If this is not possible, additional clinic and imaging capacity should be sought. In patients presenting with symptoms and / or signs suggestive of breast cancer, investigation prior to referral is not recommended.

Patients identified with non-breast malignant pathology should be immediately referred to the appropriate MDT within or outside the Network. This referral should formally be requested by Consultant to Consultant letter however, communications between the relevant MDT coordinators support this progress ensuring that corresponding information is transferred and is available in a timely manner. Supporting diagnostic material and all cancer data regarding the patient will be forwarded to the receiving MDT and Trust. Patients requesting a second opinion will be supported to achieve this.

There should be access to a family history clinic linked to the Regional Clinical Genetics Service. Referrals to the regional genetics service should be on the following form:  
<http://www.bwhct.nhs.uk/genetics-wmfacs-home.htm>

## Diagnosis

Patients should only be seen by medical and clinical practitioners with a special interest in breast disease. Wherever possible, a non-operative breast cancer diagnosis should be achieved by triple assessment. This should include clinical and radiological assessment followed by core biopsy and / or fine needle aspiration (FNA). Core biopsy is preferable due to the additional information it can provide. However, it is recognised that there may be circumstances where only an FNA is possible. Where possible, clinical assessment and imaging should be completed before needle core biopsy. If a radiological abnormality is

seen, biopsies should be performed under image guidance. If multiple benign lesions are seen and they all have the same morphological features, needle biopsy of one lesion is usually sufficient. In multifocal malignancy, it may be necessary to sample more than one lesion to identify the extent of the disease and advice on appropriate surgical management.

Breast cancer is uncommon under the age of 30 years. In women under the age of 25 years, core biopsy should only be performed where there is clinical or radiological suspicion that a lesion is not benign.

It is best practice to carry out all aspects of the triple assessment at the same visit and the results should be available and reported to the patient within five working days. Verified imaging and pathology reports should be available at the MDT. The false negative rate of triple assessment in women who present with symptoms and are subsequently shown to have breast cancer is approximately 0.2%. Patients in whom the triple assessment is negative should be advised to seek further advice if they remain concerned or new symptoms or signs develop.

A non-operative diagnosis should be possible in the majority of invasive breast cancers with a minimum standard of achieving this in at least 90% of cases with a target of more than 95%. The majority of non-invasive cancers will be screen-detected and impalpable. The minimum standard for non-operative diagnosis for screen-detected cancer is at least 85% with a target of more than 90%.

Diagnostic excision biopsies should rarely be required. However, some breast lesions may still require diagnostic excision if the core biopsy or FNA is not benign (e.g. B3/4 or C3/4 lesions). The presence of atypia in a core biopsy is recognised as a marker of increased risk of cancer being present and consideration should be given to excision of all B3 lesions with atypia. The recommended management of B3 lesions, with or without atypia, is shown in Appendices 1 and 2. When a radial scar, sclerosing lesion or papilloma is present in a specimen without atypia, and the lesion is small enough, vacuum-assisted biopsy may be offered to the patient as the excisional technique. However, if the presence of atypia is then reported in the specimen, further excision is indicated and the patient should be advised to proceed to surgical excision of the cavity. Following vacuum excision, the cavity should always be marked using a mammographically-visible clip to facilitate future localisation prior to surgical excision.

Hypercellular fibroepithelial lesions, which are possible phyllodes tumours, should preferably be excised intact in order to facilitate histopathological reporting. This will usually require surgical excision. Columnar cell change is part of the continuum of precursor lesions and is usually classified as benign. Where atypia is also present, it is usually described as Flat Epithelial Atypia. These lesions should be sampled by multiple specimens being taken under vacuum assistance. This should be regarded as a diagnostic rather than a therapeutic surgical procedure.

Ideally, an operation for diagnostic purposes should be within two weeks of the decision to operate. All diagnostic biopsy specimens should be weighed. More than 90% of diagnostic biopsies for impalpable lesions that subsequently prove to be benign should weigh less than 20g. Any benign diagnostic resection specimen weighing more than 40g should be discussed at the postoperative MDT and any mitigating reasons recorded. Frozen sections with immediate pathological reporting should not be performed except in very rare circumstances.

The cause of axillary lymphadenopathy in the absence of breast pathology often presents a diagnostic challenge. FNA or core biopsy of an axillary node may provide useful information.

However, when there is diagnostic uncertainty or there is suspicion of lympho-proliferative disease, then formal excision biopsy of the node should be considered

## Imaging

Breast imaging should only be performed as part of a triple assessment. This is best achieved in a designated breast clinic in which both radiologists and surgeons work together. Direct access from GPs and other physicians for breast imaging is not recommended. Triple assessment clinics should be organised to ensure that, where possible, all necessary diagnostic procedures are completed at the initial visit. When not possible, imaging and biopsy should ideally be performed and reported within five working days. Imaging should precede a needle aspiration or tissue sample procedures, except in special circumstances. Imaging should be performed only where there is a clear clinical indication to do so. Inappropriate requests should be monitored and subject to audit. Digital mammography should be considered for all cases, especially if patients have breast implants, in the dense breast and in younger women.

Women who do not always need imaging include:

- Bilateral breast pain only.
- Bilateral pain and symmetrical nodularity.
- Symmetrical nodularity alone

In women under 40 years of age, ultrasound is the initial imaging modality of choice. Mammography is only indicated in strongly suspicious cases and in all cases found to be malignant on biopsy, to exclude other incidental lesions. In women over 40 years of age, both mammography and ultrasound should be performed.

In advanced breast cancer in the elderly, it is only necessary to undertake investigations which will directly affect management. This may in many cases be limited to a clinical core biopsy to confirm the diagnosis and to test for ER status. If the size of a lesion needs to be monitored because of primary endocrine therapy, an individual decision should be made on each patient as to whether clinical examination, mammographic or ultrasound measurement is most appropriate. In large or advanced breast cancer, investigation should be undertaken to determine the extent of disease, which may include breast MR and metastatic screening.

It may be appropriate to insert a marker in the breast to mark the site of the tumour, if the intent of neo-adjuvant therapy is breast conservation. This is best introduced after two cycles of chemotherapy, and is only necessary if the tumour is responding to treatment. It is particularly useful if there is a possibility that there will be no detectable tumour to localise at the time of surgery.

In men with breast lumps, the vast majority of these cases are due to gynaecomastia. Symmetrical bilateral gynaecomastia does not require imaging. P3 lesions and asymmetrical gynaecomastia in men over the age of 50 years may require breast imaging. Focal lumps in the male breast are usually amenable to clinical core biopsy.

## Axillary ultrasound

Pre-treatment ultrasound evaluation of the axilla should be performed for all patients being investigated for early invasive breast cancer. If morphologically abnormal lymph nodes are identified, especially with a cortex of more than 3 mm, then ultrasound-guided needle sampling (core biopsy or FNA) should be performed.

## **Metastatic screening**

Formal staging investigations should only be considered if they are likely to affect the primary treatment of the disease. Not all patients shown to have axillary nodal metastases on pre-operative axillary ultrasound and FNA need to be screened. Screening of asymptomatic patients for metastatic disease should be avoided as far as possible. Metastatic screening should not be allowed to delay the first therapeutic intervention. CT of the thorax, abdomen and pelvis should be considered in cases where there may be involvement of the supraclavicular nodes, where it is known or likely that more than four axillary lymph nodes are involved or in patients at high risk of metastatic disease based on the size and grade of the primary tumour.

If there is clinical suspicion of metastatic disease, the type of imaging will depend on the presentation. In patients with bone pain, plain radiographs, isotope bone scan and MRI are indicated. MRI is particularly useful when there is diagnostic uncertainty on plain radiographs or bone scan and / or clinical suspicion of cord compression. In patients with neurological symptoms, contrast-enhanced head CT is the imaging modality of choice. MRI with contrast should be considered if there are cerebellar signs or signs of meningeal involvement. In patients with respiratory or abdominal symptoms, plain chest x-ray, liver ultrasound or thoraco-abdominal CT may be appropriate dependent on the degree of clinical suspicion. In patients where there is concern about axillary recurrence, axillary ultrasound and MRI of the axilla should be considered. PET scan is not generally required in the assessment of breast cancer patients.

## **Magnetic resonance imaging**

The routine use of MRI of the breast is not recommended in the pre-operative assessment of patients with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS). MRI of the breast should be considered in patients with invasive breast cancer in the following circumstances:

- If there is a discrepancy regarding the extent of disease between clinical examination, mammography and ultrasound assessment and accurate assessment of tumour size will assist in treatment planning.
- If breast density precludes accurate mammographic assessment
- To assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer. NICE supports the routine use of breast MRI for pre-treatment assessment of all women with a diagnosis of lobular carcinoma. MRI more accurately assesses the size and extent of lobular carcinoma and may detect cancer in the opposite breast. MRI can change the treatment plan in about one-third of cases of invasive lobular cancer.
- To exclude multifocal disease in all patients being considered for neo-adjuvant chemotherapy
- To monitor response to treatment in patients undergoing neo-adjuvant chemotherapy
- In patients with axillary node metastasis suggestive of breast cancer but no obvious primary lesion seen on mammogram or ultrasound.

- In some patients with inadequate margins after breast conserving surgery. In cases where there is suspicion of extensive residual disease and there is debate as to whether further excision or mastectomy is required, MRI should be considered to assess the extent of residual disease.
- In patients with asymmetric density who are difficult to biopsy and in whom the lesion is mostly benign. MRI should not be used to preclude biopsy when such a lesion is seen. It is inevitable that some patients will need MRI-guided biopsy. This number is small and less than 2% of patients scanned. If facilities for MRI-guided biopsy are not available locally, consideration should be given to referral to other centres.

Where possible, the investigation should be carried out in the mid-portion of menstrual cycle. Fully trained radiographers should perform breast MRI. Double reporting should be considered in at least of 50% of cases. Results should be discussed in an MDT before further treatment is decided.

## Family history screening and surveillance protocols

Women with a significant family history of breast cancer should be referred to the clinical genetics service in line with NICE guidance.

### Surveillance for women with no personal history of breast cancer

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.

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.

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

- 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.
- 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.

### Chemoprevention for women with no personal history of breast cancer

5 years of tamoxifen or raloxifene can be offered for to postmenopausal women with a uterus at high risk of breast cancer unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.

## **Treatment planning and communication**

Following confirmation of a breast cancer diagnosis and appropriate MDT discussion to plan management, the results should be discussed with the patient. The person conducting the consultation should be a member of the breast MDT and a breast care nurse should invariably be present. The consultation should take place in an appropriate environment with adequate privacy. Patients must know how to access the breast care nurse and relevant components of their treatment plan. The outcome of all discussions should be recorded and a care plan for each patient should be drawn up. A key worker should be nominated in accordance with a Key Worker Policy and the patient provided with supporting literature.

MDTs should monitor and record key dates regarding access to treatment and diagnosis and should, where possible, ensure that all current government access targets are met.

## **Providing information and psychological support**

All members of the breast cancer clinical team should have completed an accredited communication skills training programme.

All patients with breast cancer should be assigned to a named breast care nurse specialist who will support them throughout diagnosis, treatment and follow-up.

All patients with breast cancer should be offered prompt access to specialist psychological support and, where appropriate, psychiatric services.

## **Surgery**

Surgical treatment of patients with breast cancer should be carried out by surgeons with a special interest and training in breast disease. Each surgeon involved in the NHSBSP should maintain a surgical caseload of at least 10 screen-detected cancers per year. When a decision has been reached to offer surgical treatment, patients should be offered a date for surgery rather than be placed on a waiting list. The need for breast reconstruction should not lead to unnecessary delay in surgery. All cancer waiting time targets should be met.

## **Surgery for invasive breast cancer**

Surgery, with or without radiotherapy, remains the mainstay of early breast cancer treatment. Surgical treatment for breast cancer may consist of an excision of the tumour with surrounding normal breast tissue (breast conserving surgery) or mastectomy. Long-term follow up of randomised clinical trials have reported similar survival rates for women treated by mastectomy or breast conserving surgery.

Accurate pre-operative assessment of the size and extent of the tumour is essential for deciding whether breast conserving surgery is an alternative option to mastectomy. This can often be achieved with clinical examination and standard breast imaging. In difficult cases, particularly lobular cancers, MRI should be used in planning surgical treatment. The decision to offer MRI should be discussed at the MDT.

## **Breast conserving surgery**

There is no exact size limit for conservation surgery. It is a balance between tumour size (as assessed by imaging) and breast volume that determines whether a patient is suitable for breast conserving surgery. However, excision of lesions over 4cm in an average sized breast tends to give a poor cosmetic result and have a higher rate of local recurrence and is not recommended. Patients of any age should be considered for breast conserving surgery but consideration must also be given to co-morbidities associated with age, the potential need for further surgery and their suitability for subsequent radiotherapy. Radiotherapy has been shown to reduce the risk of local recurrence and improve overall survival. Ongoing studies are looking to see if a subgroup of patients may do just as well without radiotherapy.

### **Indications for breast conserving surgery**

- Patient choice
- Operable tumours up to 4cm in diameter in an average sized breast
- Operable multi-focal tumour restricted to a single breast quadrant
- Two or more small tumours in different quadrants in a large sized breast
- No contraindications to radiotherapy
- Larger tumours may be treated by breast conserving surgery when combined with oncoplastic procedures
- Following neo-adjuvant chemotherapy or hormonal therapy specifically aimed at reducing tumour size

### **Skin marking of impalpable lesions**

The use of a skin mark as means of localising an impalpable lesion may be appropriate if the lesion is close to the skin (less than 1cm). The method of localisation should be agreed by the MDT. The mark should be applied with the patient in the surgical position. An ultrasound should be performed in two orthogonal planes and the position of the centre of lesion confirmed. The position should be marked with 'X' in indelible black ink. A further scan should be performed to confirm that the mark is in the correct position. The depth of lesion below the skin should be measure using minimal compression. A gauze dressing should be applied to avoid the mark being rubbed off.

### **Failed localisations**

When a malignant biopsy is followed by non-malignant surgical specimen he case must be discussed at MDT before the patient is seen in clinic for surgical results and the following procedure followed.

- A review of the localisation images should be undertaken and compared to the original screening and assessment images to ensure that the correct area has been localised
- The specimen x ray should be reviewed to see if the lesion is present in the specimen
- The initial core should be reviewed to ensure the report is correct

- The excision / mastectomy pathology should be reviewed and further blocks taken; all tissue to be examined. This review should include searching for a core track and the presence or absence of the track should be recorded in the report.
- The case should be discussed at a subsequent MDT following steps 1-4 to decide on future management
- If the lesion is not found on further pathology examination, then the radiological review should decide if it is possible that a very small lesion could have been completely removed at core or suction biopsy. For this decision the wire should have been correctly placed and there should be pathological evidence of the correct surgical site eg bruising from core, or cavity following suction biopsy.
- If the review concludes that the lesion is not likely to have been completely removed at previous biopsy, then further imaging is required.
- Further imaging could include US or mammography or MRI scan and should be decided at MDT.
- If the lesion is found on further imaging then a further localisation procedure should be performed to remove the lesion.
- If the lesion cannot be seen but is **not** thought to have been removed at biopsy then regular imaging follow up is recommended to assess for change over a time period.
- The patient should be kept fully informed during the above process

## **Mastectomy**

### **Indication for mastectomy**

- Patient choice
- Operable tumours more than 4cm in diameter in an average sized breast
- Operable multi-focal disease in more than one quadrant of the breast
- Contraindication to radiotherapy
- Failed breast conservation surgery (e.g. local recurrence or positive margins after wide local excision where further wide local excision is not feasible)
- Where breast conservation is unlikely to result in an acceptable cosmetic outcome (e.g. larger tumour in a small breast)
- Central breast cancer. It is generally accepted that adequate margins are more difficult to achieve with central breast tumours and that central wide local excision may be associated with a relatively poor cosmetic outcome. However, in many cases an adequate excision and good cosmesis can be achieved by a central wide local excision and oncoplastic techniques
- Local recurrence

### **Margins of excision**

The major surgical factor influencing local recurrence following breast conserving surgery is completeness of excision, and clear radial margins must be obtained. Close margins at the chest wall or near the skin may be less important. Controversy exists in the published literature about what constitutes an adequate margin, but agreement across the Network suggests a margin of at least 5 mm for invasive disease and at least 10 mm for DCIS when radiotherapy will not be given, should be aimed for. A 1 mm margin is acceptable and this is the minimal margin that will be accepted in all patients undergoing breast conserving surgery. Patients with a margin of less than 1 mm should be offered re-excision.

Intra-operative specimen radiography is mandatory for impalpable lesions requiring radiological localisation. Dedicated equipment should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes. If the specimen radiograph is reported by the surgeon, the result must be confirmed by a radiologist at the subsequent MDT. The specimen should be orientated and marked prior to delivery to the pathologist. The convention for marking should be agreed with local pathologists. All specimen radiographs should be available to the pathologist.

Marking of the tumour bed with metal clips should be considered to allow accurate planning and delivery of radiotherapy. This is especially important when oncoplastic techniques are used to improve cosmetic outcome.

## **Axillary surgery**

Axillary surgery should be performed in all patients with invasive breast cancer in order to stage the axilla and eradicate metastatic disease within the nodes. Axillary lymph node status is the single most important prognostic factor in early breast cancer and has a role in deciding the use of adjuvant therapy. If an axillary staging procedure is not to be carried out, the reason for this should be discussed in the MDT and documented in the patient's notes.

Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for all patients with early invasive breast cancer and no evidence of lymph node involvement clinically, on ultrasound or who have a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the axillary staging procedure of choice. If node sampling is performed, at least 4 nodes should be obtained. Patients shown to have axillary node metastases on preoperative axillary ultrasound and FNA should proceed directly to an axillary node clearance. The anatomical level of dissection should be specified in the operation notes.

A standalone SLNB procedure should be considered in patients prior to neoadjuvant chemotherapy and also in patients undergoing breast reconstruction, in order to determine the appropriate axillary staging procedure to be performed at the time of their definitive operation.

SLNB should only be performed by a team that is validated in the use of the technique, as identified in the New Start Training Programme. It should be performed using the combined technique of isotope and blue dye. Where possible a scintiscan should be obtained prior to surgery. The use of blue dye may be omitted in those in whom the scintiscan shows a strong signal. All breast units should audit their axillary recurrence rates after SLNB.

Patients with a single positive axillary lymph node have a greater than 10% chance of further axillary metastases. The subsequent management of the axilla in patients with nodal metastases will be discussed by the MDT. In patients with macrometastases, particularly if more than two nodes are involved, an axillary node clearance will usually be recommended. In patients undergoing breast conserving surgery with a single micrometastasis, assessed

by either immunohistochemistry or histopathology, an axillary node dissection can be avoided.

Further axillary treatment is not required for patients found to have only isolated tumour cells in their sentinel lymph nodes. These patients should be regarded as lymph node-negative. In units offering intra-operative assessment of sentinel nodes, the results should be audited.

## **Surgery for Ductal carcinoma *in situ***

Since the introduction of the NHSBSP, about one-third of all screen-detected tumours are due to DCIS. Retrospective studies of cases of low grade DCIS misdiagnosed as benign, found that 20 years after local excision, approximately 33% developed invasive carcinoma. DCIS should be regarded as a precursor of invasive disease. The aim of surgery for DCIS is to achieve complete excision and to minimise local recurrence. Approximately 50% of local relapses after treatment for DCIS are invasive cancer.

Current evidence would suggest that the majority of DCIS is unicentric in origin and breast conserving surgery is the treatment of choice. This sometimes requires a wire for guidance and x-ray of the surgical specimen should be performed to ensure complete removal of all microcalcification.

As in invasive disease, adequate margins are essential to reduce the risk of local recurrence and patients should be offered re-excision if the margins are close or involved. For all patients treated with breast conserving surgery for DCIS, a minimum of 1 mm radial margin of excision is essential with pathological examination of the specimen to NHSBSP reporting standards. A 10 mm margin is preferable, particularly in patients not proceeding to radiotherapy. Re-excision should be considered if the margin is less than one mm, after discussion of the risks and benefits with the patient. Three large trials have found a reduction in ipsilateral local recurrence following radiotherapy. It is recommended that adjuvant radiotherapy be discussed with all patients following breast conserving surgery for high grade DCIS and those with DCIS showing comedo necrosis.

Patients with large areas of DCIS (>4cm in diameter), patients with multicentric disease, a palpable mass and those patients where radiotherapy is contraindicated should be offered a mastectomy. Where appropriate, breast reconstruction should be discussed.

Axillary surgery should be avoided in patients with DCIS expect in patients with widespread disease requiring a mastectomy, patients with evidence of microinvasion on core biopsy and patients with a large high grade lesion, all of which have a higher incidence of an occult invasive cancer. SLNB or an axillary sample in these patients should be recommended. Axillary node clearance is contraindicated in patients with a non-operative diagnosis of DCIS alone. All breast units should audit their recurrence rates after surgery for DCIS.

## **Surgery for Paget's disease**

Breast conserving surgery with removal of the nipple-areolar complex should be offered as an alternative to mastectomy for patients with Paget's disease of the nipple that has been assessed as localised. Oncoplastic dermo-parenchymal flaps should be considered to maximise cosmesis.

## **Surgery for lobular *in situ* neoplasia**

Lobular *in situ* neoplasia (LISN) is often an incidental finding and is usually occult. Low or intermediate grade LISN is not a locally malignant precursor lesion, but it does confer an increased future risk of invasive cancer in both breasts. The risk of developing breast cancer is about 1% per year.

The limited data available on LISN suggests that clear resection margins are not required following surgery for low or intermediate grade LISN alone. A policy of close clinical and mammographic surveillance after excision biopsy is appropriate. There is however evidence that high grade or pleomorphic LCIS behaves in as an established carcinoma *in situ* and consideration should be given to formal excision with clear margins

## **Ambulatory Breast Care Model for breast cancer surgery**

The Day / Case 23 Hour Ambulatory Breast Care model pathway has been developed to support improvement in the patient experience and standardise practice in relation to patient information, exclusion criteria, perioperative and post-operative care and discharge planning for patients undergoing non-reconstructive breast cancer surgery.

### **Exclusion Criteria**

Anticipated length of surgery should be less than one hour in duration. Where intra-operative sentinel lymph node assay is undertaken, clinical judgement is required as to the actual length of time the patient is being operated on, rather than the time they may be anaesthetised and in theatre. The procedure should be associated with minimal post-operative pain or bleeding. Patients should have ASA Grade 1 or 2 and a BMI < 40 protocol. There is no upper age limit. Patients should have no previous anaesthetic or airway problems. Co-morbidities excluding day surgery include:

- Uncontrolled hypertension
- Valvular Heart Disease
- Cardiac failure
- MI or Stroke within previous 6 months
- Severe Asthma / COPD
- Poorly controlled IDDM
- Clotting disorders
- Sickle cell disease
- Epilepsy ~ if had a fit in the last 12 months

### **Drains and Dressings Policy**

The use of drain can increase the risk of infection. It is acknowledged that there may be long term cosmetic disadvantages associated with not using drains. Low suction drains should be used when required. The use of drains is to be decided by the surgeon at time of surgery. These guidelines are not intended to be prescriptive, however they are the guidelines that were agreed following the 23 hours Ambulatory Breast Care Model initiation event.

- Breast Conserving Surgery + Sentinel Lymph Node Biopsy ~ No drain
- Breast Conserving Surgery + Axillary Node Clearance ~ One drain may be taken out prior to discharge or patient may go home with drain *in situ*.

- Mastectomy + Sentinel Lymph Node Biopsy ~ One drain, may be taken out prior to discharge or patient may go home with drain *in situ*.
- Mastectomy + Axillary Node Clearance ~ 1 or 2 drains, may be taken out prior to discharge or patient may go home with one drain *in situ*.

All wounds should be closed with absorbable sutures. An occlusive dressing suitable to remain *in situ* for 4-5 days should be used.

## Discharge

All patients should be discharged with appropriate take home medication and information regarding dressings and drains. Details of nurse referrals should be given to the patient with any specific information. The patient should be provided with an emergency contact number which will be accessible 24 hours per day 7 days a week for advice. This helpline should be manned by a person with specific knowledge regarding the management of breast surgery patients and the ABC model. Patients must also be informed of the date and time of a follow-up appointment with the breast service.

## Information to General Practitioners

General Practitioners should be made aware that each patient has been listed onto the ABC pathway prior to the surgery taking place. Where possible the date of surgery should be sent to the General Practitioners to enable them to plan for any postoperative event requiring primary care intervention. It is anticipated that this information will be provided within the letter to the General Practitioner at time of treatment planning.

## Breast reconstruction

Approximately 40% of women undergo mastectomy for treatment of their breast cancer. BASO guidelines state that all patients should have the opportunity to receive advice on breast reconstruction, where appropriate. Breast reconstruction can be performed immediately at the time of mastectomy or delayed to sometime in the future. Women should be advised of this possibility at the time of their initial surgical diagnosis and treatment. Where units offer breast reconstruction they should have access to the full range of reconstructive options. If the full range of reconstructive options is not available locally, then women must be offered referral to an appropriate tertiary unit.

Concerns that immediate reconstruction may compromise oncological safety or hide cancer recurrence are unfounded. It has not been shown to significantly delay adjuvant therapy. Radiotherapy has been reported to have a detrimental effects on the cosmetic outcome of some types of breast reconstruction, especially if an implant is present. The risks of radiotherapy on outcome of breast reconstruction should be discussed and these women may be advised to consider a delayed rather than immediate reconstruction. Patients should have access to information about the various types of reconstruction available and the associated risks and complications.

Patients with large node positive cancer, extensive co-morbidity, obesity (BMI >35) or heavy smokers may not be appropriate for reconstruction. If patients are unsuitable for an immediate reconstruction this should be discussed at the MDT, the patient should be given the reasons for this decision and the discussion should be documented in the notes. Patients should be advised that delayed reconstruction may be an option. All patients who have had

a mastectomy without a reconstruction should have the option of delayed reconstruction and this should be discussed at follow-up visits.

When a referral for breast reconstruction is made from one MDT to another, full information should be available at the time of the referral and reciprocated following treatment. The oncological and reconstructive management should be discussed at the MDT. A treatment plan should be agreed and recorded. Medical photography should form part of the clinical record. Patients should have access to a key worker with expertise in breast reconstruction and should receive information in a format and level of detail that meets their individual needs. Perioperative management, audit of outcomes and patient satisfaction should be in accordance with the ABS / BAPRAS Oncoplastic Breast Reconstruction Guidelines.

Patients who have had a wide local excision for invasive disease who need adjuvant chemotherapy, but require completion mastectomy to gain adequate margins may be offered chemotherapy prior to completion mastectomy and immediate reconstruction. This enables patients to receive systemic treatment without delay, and allows more time for planning of further surgery.

## **Referral for breast reconstruction at UHCW**

UHCW welcomes referrals from other units for joint oncological and reconstructive surgery. As all major breast surgery is planned via the MDT, it is essential that all patients are discussed in advance with the relevant pathology reports and slides, and radiology reports and images available. Patients should be referred on a consultant-to-consultant basis with copies of all relevant correspondence sent to the UHCW Breast MDT Co-ordinator. A date for surgery will not be confirmed until the case has been discussed at the UHCW Breast MDT.

If the referring consultant intends to perform the surgery at UHCW in collaboration with the plastic surgeons, this should be clearly stated. If the intention is that the breast surgeons at UHCW are to perform the oncological surgery, then the referral should be copied to the lead breast surgeon at UHCW. The patient will then be seen in the joint breast / plastic surgery clinic at UHCW.

Patients operated on by a UHCW breast surgeon will have their pathology reported at UHCW, results will be discussed in the UHCW Breast MDT and the patient will be seen at UHCW post-operatively. They will normally then be referred back to the peripheral unit for subsequent oncological treatment and surgical follow up.

If the oncological surgery is performed by a breast surgeon from another unit, the pathology specimen will be sent to laboratory in the referring hospital, will be reported locally and discussed in the local MDT. Only plastic surgery follow up will continue as needed at UHCW.

## **Therapeutic mammoplasty**

Patients with large tumours, who on the traditional criteria are regarded as only being suitable for wide local excision, but have large breasts should be considered for therapeutic mammoplasty. Units offering therapeutic mammoplasty should audit their results.

## Pathology

All breast cancer cases should be reviewed by a Breast Cancer MDT. There should be a nominated lead breast pathologist for the service. All pathologists reporting breast cancer specimens should participate in:

- The Breast MDT
- The NHSBSP EQA scheme
- Local audit

If there is a significant discrepancy between the clinical and / or radiological findings, the pathological material from diagnostic breast specimens should be reviewed at the MDT, and if possible, by a second pathologist with an interest in breast cancer. Specimens should be reported in time for appropriate clinical decision making at the breast MDT.

## Specimen types

Laboratories should be able to handle and report on the following specimen types

### Diagnostic specimens

- Fine needle aspirate
- Core biopsy (clinical, ultrasound guided or stereotactic)
- Open biopsy
- Localisation biopsy
- Nipple biopsy
- Node biopsy

### Therapeutic specimens

- Wide local excision (+/- cavity biopsies)
- Mastectomy
- Post treatment excision
- Re-excision for margin clearance
- Sentinel node biopsy
- Axillary sampling
- Axillary clearance

## Specimen examination

Each pathology service should establish a defined protocol for each type of diagnostic and therapeutic breast specimen type received by the laboratory. The protocols should be regularly reviewed and updated by the lead breast pathologist in consultation with other pathologists who participate in service delivery. They should include a protocol for specimen orientation as agreed with the local breast surgical team. Access to specimen radiography and specialist radiological opinion should be available for relevant cases. Breast tissue should only be removed and stored for the purposes of research if it is surplus to the requirements of the diagnostic process. Appropriate patient consent and ethical approval should be obtained prospectively.

## **Macroscopic examination**

National guidance for the macroscopic examination of breast specimens is given in the NHSBSP Publication Number 58, "Pathology Reporting in Breast Disease. The following comments supplement this guidance:

## **Radiological-pathological correlation**

Examination of specimen slice x-rays is of great benefit in accurate identification, localization assessment and sampling of palpable abnormalities. This is particularly important in cases of mammographically detected microcalcification. Correlation with radiological appearances provides important feedback for the NHSBSP.

## **Post neo-adjuvant chemotherapy specimens**

Thorough sampling is essential and more blocks are often required than from an equivalent specimen from a patient who has not received neo-adjuvant treatment. Identification of residual disease may be facilitated by identification of a marker inserted previously by the radiologist. Large blocks may be helpful in determining the distribution of residual tumour foci if residual disease is no longer contiguous. Specimen x-rays assist the identification of subtle alterations in tissue architecture in patients who have had a good response to treatment.

## **Ductal carcinoma in situ (DCIS)**

The Sloane Project Pathology Protocol provides detailed guidance for the handling and examination of specimens containing DCIS and is recommended for all units participating in the Sloane Project. In both wide local excision and mastectomy specimens, specimen slice x-ray permits identification of the targeted lesion and appropriate sampling. Particular attention should be given to excision at the margin nearest the nipple and this margin should be separately identified by the surgeon.

## **Sentinel lymph nodes**

Each sentinel node should be sliced along the short axis at 1-2mm intervals and processed in its entirety. Very small nodes can be bisected. At least one H&E section should be examined. Pathologists may choose to examine additional sections or perform immunohistochemistry for epithelial markers to improve the accuracy of identifying metastatic cells and to measure the largest size of a metastasis, micrometastasis or isolated tumour cells (ITC) identified on initial examination. Classification of single node involvement should be done using the TNM classification.

## **Use of ancillary techniques**

Invasive carcinomas should have their hormone receptor status assessed. Oestrogen receptor (ER) status should be determined on all cases. If scored, this should be using the Quickscore method (scores 0-8). Departments providing this service in-house must have at least conditional laboratory accreditation and participate in an appropriate external quality assurance programme to ensure that their laboratory performance is satisfactory. HER2 status should be assessed on all newly diagnosed breast cancers less than 75 years of age and in the metastatic setting where the breast cancer multidisciplinary team or oncologist have decided that Herceptin therapy would be considered for the patient.

Immunohistochemistry assessment should follow current national guidance with scores of 0 and 1+ considered negative, 3+ as positive for amplification and 2+ cases requiring FISH.

A wide range of immunohistochemical markers are available. Those which are most relevant to breast cancer include CK5, CK8, CK18, CK20, EMA, CEA, e-cadherin, Smooth muscle actin, S100 protein, high molecular weight cytokeratin (34bE12), laminin and CD45. Particular circumstances where these may be useful are shown at Appendix 3.

## Reporting of specimens

Staging of breast cancer is based on the size of the primary tumour (T), the lymph node status (N) and the presence of metastases (M), known as the TNM system. Tumour grading should be by the Nottingham modification of the Bloom and Richardson criteria. The WHO classification of breast tumours depends on the presence of specific differentiation based on histological characteristics seen in surgical biopsies and resection specimens.

## Minimum dataset for reporting

### Diagnostic specimens:

For all breast core biopsy specimens

- Diagnostic category code (B1-5)
- For B3 lesions the presence or absence of atypia should be reported

For malignant core and diagnostic breast biopsy specimens

- Presence of invasion, microinvasion and / or DCIS
- Invasive tumour type\*
- Invasive tumour grade\*
- Lymphovascular invasion\*
- Hormone receptor status
- HER2 status (all patients less than 75 years old)

\*as far as can be judged in the material present

For breast fine needle aspiration specimens

- Diagnostic category code (C1-5)

### Screening and symptomatic therapeutic resections:

The minimum dataset required for screening and therapeutic resections is shown at Appendix 4

Optional local additional items in use, as agreed with locality MDTs may include:

- Comment if neo-adjuvant treatment
- Presence of extensive in-situ carcinoma
- Distance to deep margin or all radial margins
- Presence of skin invasion

- For axillary and lymph node procedures
  - Status of apical node
  - Extracapsular spread
  - Size of largest nodal metastasis

Additional data items for screening cases may include:

- Presence of histological calcification and whether benign/ malignant
- Whether the specimen radiograph was seen
- Whether the mammographic abnormality is in the specimen
- Nature of significant benign lesions
- Presence of epithelial proliferation, type and whether atypical
- Final histological diagnosis as normal, benign or malignant

The dataset items should be reported in a proforma either within, or separate from or instead of the free text part of the pathology report. Departments and MDTs should work towards recording and storing the dataset items as individually categorised items in a relational database, so as to allow electronic retrieval and to facilitate the use of pathology data in clinical audit, service planning and monitoring, research and quality assurance. Laboratories should use an agreed diagnostic coding system (e.g. SNOMED). All malignancies must be reported to the West Midlands Cancer Registry, in accordance with the national contract for acute services.

## **Audit**

All pathologists reporting breast cancer specimens should participate in the National NHSBSP EQA scheme and local audits (including an assessment of consistency where more than one pathologist participates in service provision).

The audits should include:

- Review of compliance with procedures for specimen examination and reporting
- Completeness of minimum datasets
- Diagnostic agreement / disagreement during review of cases for MDTs
- Review of diagnostic consistency between pathologists using data from cases in EQA or blind circulations

## **Referral for review or external opinion**

In cases of diagnostic difficulty, breast cancer referrals should be directed to the network lead and / or recognized expert breast pathologist.

All breast lymphomas should be referred to a specialist haematopathologist for phenotypic analysis and confirmation of diagnosis.

## **Adjuvant therapy**

The oestrogen receptor (ER) status of all invasive breast cancers should be assessed, using immunohistochemistry with a standardised and qualitatively assured methodology and the result reported quantitatively. The progesterone receptor status of tumours in patients with invasive breast cancer should not be reported routinely but will be available where it is considered that it will influence the patient management. The human epidermal growth receptor 2 (HER2) status of all invasive breast cancers should be assessed, using a standardised and qualitatively assured methodology, in all patients under 75 years of age. It should be ensured that the results of ER (+/- PR) and HER2 assessments be available and recorded at the MDT meeting when decisions about systemic treatment are made.

## **Adjuvant therapy planning**

Adjuvant therapy should be considered at the MDT meeting for all patients and the decisions recorded in the patient's notes. Decisions should be made based on assessment of the prognostic and predictive factors and the potential benefits and side effects of the treatment. Decisions should be made following discussion of these factors with the patient.

Consideration should be given to using Adjuvant Online for patients with early invasive breast cancer to support estimations of individual prognosis and the absolute benefit of any proposed adjuvant treatment. Adjuvant chemotherapy or radiotherapy should be started as soon as clinically possible and certainly within 31 days of completion of surgery.

## **Radiotherapy**

### **Radiotherapy after breast conserving surgery**

Patients with early invasive breast cancer who have had breast conserving surgery with clear margins should have breast radiotherapy. Adjuvant radiotherapy should be discussed with patients with high-grade DCIS following adequate breast conserving surgery and the potential benefits and risks explained.

Following breast conserving surgery, postoperative radiotherapy to the intact breast should be delivered via a tangent pair. Standard dose will be 40 Gy in 15 fractions. In large volume breasts, consideration should be given to treatment with 50 Gy in 25 fractions.

An external beam boost to the site of local excision should be considered in patients with early invasive breast cancer who are at high risk of local recurrence, following breast conserving surgery with clear margins and whole breast radiotherapy. If an external beam boost to the site of local excision is being considered, the patient should be informed of the side effects associated with this intervention, including poor cosmesis, particularly in women with larger breasts.

Boost with electron beam or brachytherapy implant to tumour bed should be at the discretion of the treating clinician depending on age, pathology, margin status and menopausal status of the patient.

### **Radiotherapy after mastectomy**

Adjuvant chest wall radiotherapy should be given to patients with early invasive breast cancer who have had a mastectomy and are at a high risk of local recurrence. Patients at a high risk of local recurrence include those with tumours more than 5 cm in diameter, four or more positive axillary lymph nodes or close / involved resection margins.

Consideration should be given to entering patients who have had a mastectomy for early invasive breast cancer and who are at an intermediate risk of local recurrence into the current UK trial (SUPREMO) assessing the value of postoperative radiotherapy. Patients at an intermediate risk of local recurrence include those with less than 3 nodes involved, lymphovascular invasion, histological grade 3 tumours, ER-negative tumours, and those aged under 40. Radiotherapy should not be given following mastectomy to patients with early invasive breast cancer who are at low risk of local recurrence. Radiotherapy doses of 40 Gy in 15 fractions or 50 Gy in 25 fractions via tangent pair to chest wall or direct electron beam therapy to chest wall should be given.

## **Radiotherapy for DCIS**

Patients with low or intermediate grade disease with adequate surgical margins may avoid radiotherapy. The potential benefits and risks of radiotherapy should be discussed with all patients with high grade disease. Following mastectomy, there is no established role for postoperative radiotherapy.

## **Radiotherapy to nodal areas**

Adjuvant radiotherapy to the axilla should not be offered to patients with early breast cancer who have been shown to be histologically lymph node-negative. Adjuvant radiotherapy should not be given to the axilla after axillary lymph node dissection. If axillary lymph node dissection is declined following a positive axillary SLNB or four-node sample, adjuvant radiotherapy to the axilla should be considered.

Adjuvant radiotherapy to the axilla and supraclavicular fossa should be given to patients with early breast cancer post axillary sampling when four or more axillary lymph nodes are involved or there is macroscopic evidence of residual disease in the axilla. It should also be considered for patients with early breast cancer and one to three positive lymph nodes if they have other poor prognostic factors and good performance status.

Adjuvant radiotherapy to the supraclavicular fossa alone should be after axillary node clearance when the highest node is involved or four or more lymph nodes are involved.

Adjuvant radiotherapy to the internal mammary chain should not be given to patients with early breast cancer who have had breast surgery.

Consent forms should document the increased risk of lymphoedema post axillary surgery with subsequent radiotherapy. The doses to be used should be 40 Gy in 15 fractions or 50 Gy in 25 fractions direct field using asymmetric technique to match the tangent pair used for the chest wall or intact breast.

Radiotherapy protocols are shown in Appendix 5

## **Endocrine therapy**

Women with ER positive tumours will benefit from at least 5 years of anti-oestrogen therapy. All patients with ER positive disease should, therefore, receive endocrine therapy. Following results of the ATLAS and ATTom trials, ASCO guidelines published June 2014 recommend extended adjuvant endocrine therapy for women with early breast cancer either with tamoxifen alone or using sequential treatment with tamoxifen and aromatase inhibitors, with

the exception being those women treated with aromatase inhibitors for 5 years as there is currently a paucity of data to support the use of aromatase inhibitors beyond 5 years

Patients with hormone receptor negative disease should not receive endocrine therapy. If the patient is receiving adjuvant chemotherapy, endocrine therapy should be deferred until chemotherapy has finished. Any vaginal bleeding whilst on tamoxifen should be investigated by a gynaecologist.

## **Pre-menopausal patients**

There is good evidence that adjuvant tamoxifen works in pre-menopausal women. All pre-menopausal women should receive at least 5 years of tamoxifen 20 mg once a day. Treatment beyond 5 years can be with either tamoxifen or an aromatase inhibitor dependent on menopausal status. There is no evidence that ovarian ablation should be used in addition to tamoxifen unless tamoxifen is not tolerated, there is a desire by the patient to avoid menstruation or there are problems with compliance.

## **Postmenopausal patients**

Postmenopausal women with ER positive early invasive breast cancer who are not considered to be at low risk (NPI >3.4), should be offered an aromatase inhibitor, either anastrozole or letrozole, as their initial adjuvant therapy. Tamoxifen should be offered to women at low risk and also if an aromatase inhibitor is not tolerated or contraindicated. The choice of treatment should be made after discussion between the responsible clinician and the patient about the risks and benefits of each option. The aromatase inhibitors anastrozole, exemestane and letrozole, within their licensed indications, are recommended as options for the adjuvant treatment of early ER-positive invasive breast cancer in postmenopausal women. Therapy should be continued for at least 5 years. Treatment options beyond 5 years include, tamoxifen for 10 years or switching to an aromatase inhibitor for extended therapy. An aromatase inhibitor, either exemestane or anastrozole should be offered, instead of tamoxifen to postmenopausal women with ER positive early invasive breast cancer who are not at low risk and who have been treated with tamoxifen for 2–3 years.

Factors to consider when making the choice include whether the woman has received tamoxifen before, the licensed indications and side-effect profiles of the individual drugs and, in particular, the assessed risk of recurrence.

All aromatase inhibitors increase the risk of osteoporosis and its complications. Therefore, all patients who receive an aromatase inhibitor should be advised regarding the implications for osteoporosis. Concerns regarding bone density should not prevent the prescription of aromatase inhibitors. All women who have finished chemotherapy and who are commencing treatment with an aromatase inhibitor should have a baseline dual energy X-ray absorptiometry (DEXA) scan. Lifestyle advice should be given to help reduce the risk of osteoporosis such as regular weight bearing exercise, cessation of smoking and a high calcium diet.

## **Ovarian suppression for early invasive breast cancer**

Ovarian suppression / ablation should be offered using gosarelin 3.6 mg subcutaneously once monthly for 2 years in addition to tamoxifen in pre-menopausal women with ER positive early invasive breast cancer who have been offered chemotherapy but have chosen not to

have it. It should also be considered in premenopausal women who are unable to tolerate tamoxifen.

## **Tamoxifen for ductal carcinoma in situ**

Adjuvant tamoxifen should not routinely be offered to patients with DCIS.

## **Male breast cancer**

Male breast cancer patients who are ER positive should be offered adjuvant tamoxifen 20mg daily for 5 years.

## **Chemotherapy**

The Arden Cancer Network Breast NSSG has agreed to adopt the NCNN breast cancer chemotherapy guidelines with local addenda. Clinical trial entry will be encouraged which may necessitate variation from the standard treatment regimes.

Standard adjuvant chemotherapy regime options include:

- FEC x 6 cycles
  - Fluorouracil 600mg/m<sup>2</sup>
  - Epirubicin 75 mg/m<sup>2</sup>
  - Cyclophosphamide 600mg/m<sup>2</sup>
- AC x 4 cycles
  - Doxorubicin 60 mg/m<sup>2</sup>
  - Cyclophosphamide 600 mg/m<sup>2</sup>
- FEC – T x 6 cycles
  - Fluorouracil 500mg/m<sup>2</sup>
  - Epirubicin 100mg/m<sup>2</sup>
  - Cyclophosphamide 500mg/m<sup>2</sup> x 3 cycles,
  - Followed by Docetaxel 100mg/m<sup>2</sup> x 3 cycles

Where an anthracycline is contraindicated regime options include:

- CMF x 6 cycles
  - Cyclophosphamide 600mg/m<sup>2</sup>,
  - Methotrexate 40mg/m<sup>2</sup>
  - Fluorouracil 600mg/m<sup>2</sup>
- Docetaxel/Cyclophosphamide x 4 cycles
  - Docetaxel 75mg/m<sup>2</sup>
  - Cyclophosphamide 600mg/m<sup>2</sup>

All node positive patients considered for adjuvant chemotherapy should be offered a taxane containing regime, most commonly FEC – T.

## **Neo-adjuvant chemotherapy**

The decision to offer neo-adjuvant chemotherapy should be made at the MDT and decision regarding the extent of likely definitive surgery should be considered at that juncture. Breast conserving surgery following neo-adjuvant chemotherapy can be considered. Based on the following factors

- Size of the tumour
- Focality of the tumour
- Position of the tumour within the breast
- ER and HER2 receptor status

The data available from randomised trials shows that breast conserving surgery after neo-adjuvant chemotherapy is associated with a increased risk of local recurrence. When neo-adjuvant chemotherapy is being considered with a view to breast conserving surgery, the increased risk of local recurrence should be discussed with the patient.

The majority of inflammatory cancers will be treated with neo-adjuvant chemotherapy, definitive mastectomy followed by postoperative radiotherapy.

Pre-operative/neo-adjuvant chemotherapy regime options include:

- FEC x 6 – reassess at 3-4 cycles.
  - Fluorouracil 600mg/m<sup>2</sup>
  - Epirubicin 75 mg/m<sup>2</sup>
  - Cyclophosphamide 600mg/m<sup>2</sup>
- FEC-T (+/-Trastuzumab) x 6 cycles
  - Fluorouracil 500mg/m<sup>2</sup>
  - Epirubicin 100mg/m<sup>2</sup>
  - Cyclophosphamide 500mg/m<sup>2</sup> x 3 cycles
  - Followed by Docetaxel 100mg/m<sup>2</sup> x 3 cycles
- TC (+/-Trastuzumab) x 6 cycles
  - Docetaxel 75mg/m<sup>2</sup>
  - Carboplatin AUC 6

## Biological therapy

When applicable, trastuzumab (Herceptin) should be given at 3-week intervals for one year or until disease recurrence (whichever is the shorter period), as an adjuvant treatment to women with HER2-positive early invasive breast cancer following surgery, chemotherapy, and radiotherapy.

An assessment of cardiac function should be made before starting treatment with trastuzumab and it should not be offered to women who have any of the following:

- a left ventricular ejection fraction (LVEF) of 55% or less
- a history of documented congestive heart failure
- high-risk uncontrolled arrhythmias
- angina pectoris requiring medication
- clinically significant valvular disease
- evidence of transmural infarction on electrocardiograph (ECG)
- poorly controlled hypertension

Repeat cardiac functional assessments should be made every three months during trastuzumab treatment. If the LVEF drops by 10 % (ejection) points or more from baseline and to below 50%, then trastuzumab treatment should be suspended. Trastuzumab therapy should only be restarted after further cardiac assessment and a fully informed discussion of the risks and benefits with the woman. The standard protocol is a loading dose of 8mg/kg followed by 6mg/kg repeated three weekly to a total of 17 doses.

## **Recurrent / metastatic disease**

If not previously documented, ER and HER 2 status should be determined at time of first relapse either from the original tumour specimen or biopsy from a recurrent or metastatic lesion.

### **Hormonal therapy**

In pre-menopausal who have received prior treatment with tamoxifen, goserelin 3.6 mg subcutaneously once monthly and / or an aromatase inhibitor should be considered. If ER positive and no prior endocrine therapy has been given patients should receive tamoxifen.

In post-menopausal who have received prior treatment with tamoxifen, an aromatase inhibitor should be given. If they have had prior treatment with anastrozole or letrozole, they should be offered exemestane, or tamoxifen if not previously exposed. Fulvestrant should be considered for those patients who are intolerant of or are not able to comply with oral medication.

For those patients who are primarily inoperable, or where operative intervention is declined, primary therapy with Letrozole 2.5 mg per day should be offered.

### **Palliative cytotoxic chemotherapy**

The decision regarding chemotherapy for metastatic disease will depend on prior treatment, disease free interval, performance status and patient preference. Indications for palliative cytotoxic chemotherapy include:

- Hormone insensitivity
- Disease progression on hormone therapy
- If rapid disease control is required (e.g. visceral metastases)

Palliative chemotherapy options include:

- Single agents:
  - Epirubicin
  - Doxorubicin
  - Paclitaxel
  - Taxotere
  - Capecitabine
  - Vinorelbine

- Combination regimes:
  - FEC (600/75/600 mg/m<sup>2</sup>)
  - EC (90/600 mg/m<sup>2</sup>)
  - CMF
  - Docetaxel/Capecitabine
  - MMM
  - MM
  - Gemcitabine/Paclitaxel.

Trastuzumab can be considered for HER2 positive patients and used as single agent or in combination with chemotherapy. Trastuzumab should be discontinued if progression during adjuvant therapy or if progression whilst receiving a combination of trastuzumab with chemotherapy. Lapatinib is not currently approved by NICE but may be considered with capecitabine in trastuzumab resistant patients.

## Clinical trials

An up-to-date list of open and recruiting clinical trials is accessible via the Arden Cancer Research Network

## Fertility issues

Issues surrounding ovarian function and fertility should be discussed with patients prior to starting adjuvant therapy.

## Assessment of bone loss

Patients with early invasive breast cancer should have a baseline dual energy X-ray absorptiometry (DEXA) scan to assess bone mineral density if they:

- Are starting adjuvant aromatase inhibitor treatment
- Have treatment-induced menopause
- Are starting ovarian ablation / suppression therapy

A DEXA scan should not be offered to patients with early invasive breast cancer who are receiving tamoxifen alone, regardless of pre-treatment menopausal status.

## Complications of local treatment and menopausal symptoms

### Lymphoedema

All patients with early breast cancer should be given information about the risk of developing lymphoedema and should receive relevant written information before treatment with surgery and radiotherapy. Advice should also be given on how to prevent infection or trauma that may cause or exacerbate lymphoedema. It should be ensured that all patients with early breast cancer who develop lymphoedema have rapid access to a specialist lymphoedema service.

### Arm mobility

All breast units should have written local guidelines agreed with the physiotherapy department for postoperative physiotherapy regimens. Breast cancer patients with pre-

existing shoulder conditions should be identified preoperatively as this may inform further decisions on treatment. Instructions should be given to all breast cancer patients undergoing axillary surgery on functional exercises, which should start the day after surgery. This should include relevant written information from a member of the breast or physiotherapy team. Patients should be referred to the physiotherapy department if they report a persistent reduction in arm and shoulder mobility.

## **Menopausal symptoms**

Hormone replacement therapy (HRT) should be discontinued in women who are diagnosed with ER positive breast cancer. HRT (including oestrogen/progestogen combination) should not be routinely offered to women with menopausal symptoms and a history of breast cancer. HRT may, in exceptional cases, be offered to women with severe menopausal symptoms and with whom the associated risks have been discussed.

Information and counselling should be offered to all women about the possibility of early menopause and menopausal symptoms associated with breast cancer treatment. Tibolone or progestogens are not recommended for women with menopausal symptoms who have breast cancer. The selective serotonin re-uptake inhibitor antidepressants paroxetine and fluoxetine may be offered to women with breast cancer for relieving menopausal symptoms, particularly hot flushes, but not to those taking tamoxifen. Clonidine, venlafaxine and gabapentin should only be offered to treat hot flushes in women with breast cancer after they have been fully informed of the significant side effects. Soy (isoflavone), red clover, black cohosh, vitamin E and magnetic devices are not recommended for the treatment of menopausal symptoms in women with breast cancer.

## **Follow Up**

### **Clinical follow up**

Routine protocol driven clinical follow-up in secondary care has not been shown to alter outcome or patient satisfaction. There is not good evidence to support risk stratification.

Patients can be discharged to patient initiated follow-up following completion of treatment, providing;

- A written summary of treatment is given to the patient and GP\*
- Clear instructions on symptoms to watch for and contact details are provided
- A database or similar mechanism is in place to ensure surveillance mammography and any switch in endocrine treatment is accurately monitored
- Clinic capacity is maintained to enable rapid entry back into secondary care for patients with concerns regarding symptoms or survivorship issues.

\*The written care plan, should be completed by a named healthcare professional, a copy sent to the GP and a personal copy given to the patient. This plan should include:

- Designated named healthcare professionals
- Dates for review of any adjuvant therapy
- Details of surveillance mammography
- Signs and symptoms to look for and seek advice on
- Contact details for immediate referral to specialist care

- Contact details for support services.

For patients entered into a clinical trial follow up should be in accordance with the trial protocol.

Patients being treated with primary hormonal therapy should be followed up at 6 monthly intervals for the first year to ensure clinical response. Further follow up should be determined by patient fitness and clinical need.

If follow-up mammography is delegated to the breast imaging department, clear protocols should be in place for further assessment of any abnormality and for referral back to the surgical clinic and MDT meeting.

## **Follow up mammography**

Annual follow up mammography for patients who have undergone breast conserving surgery and at least two yearly mammography for patients who have undergone mastectomy should be offered to all patients with early breast cancer, including DCIS, for at least 5 years after diagnosis or until they reach breast screening age. Patients will then revert to the 3-yearly screening offered by the NHSBSP.

Mammography will not be offered to the ipsilateral soft tissues after mastectomy. Ultrasound or MRI will not be used for routine post-treatment surveillance in patients who have been treated for early invasive breast cancer or DCIS.

## Appendix 1

Recommended management of indeterminate lesions where the pathology corresponds to the mammographic abnormality

	Non-operative	Follow up	Operative	Follow up
Solitary papilloma Well-defined Discrete lesions	Preferred – Vacuum assisted excision to remove lesion	None if imaging lesion is totally removed and no atypia	Local excision, fully excised	None
Multiple peripheral papillomas	Diagnostic vacuum excision of index lesion	Standard increased risk surveillance policy*	Remove lesion (consider risk reducing surgery)	Standard increased risk surveillance policy*
Radial Scar <2cm	Preferred for lesions <2cm: – at least 12 VACB core biopsies to sample lesion. If atypia, then surgical excision recommended	None	MDM may elect to recommend excision for lesion >2cm	None if no atypia.If atypia Standard increased risk surveillance policy*
Atypical ductal Proliferation (ADH) (1cm or less calcification)	VACB – if no DCIS and lesion fully removed, consider further vacuum assessment of site.	Standard increased risk surveillance policy* (marker to be placed)	Preferred – to remove area of mammographic abnormality	Standard increased risk surveillance policy*
Extensive calcification >1cm with Atypical ductal proliferation on initial biopsy	Vacuum biopsy of more than one area	If no DCIS refer for diagnostic biopsy	Diagnostic biopsy of most suspicious area	If only atypia from Representative surgical sample, Standard increased risk surveillance policy*
Lobular neoplasia (ALH/LCIS – not pleomorphic LCIS or LCIS with necrosis)	Assess mammographic Abnormality and manage accordingly	Standard increased risk surveillance policy*	LCIS – remove imaging abnormality unless already diagnosed as benign by vacuum	Standard increased risk surveillance policy*

\* at present the recommended follow-up for women at increased risk is five years annual mammography, after which women are returned to routine NHSBSP screening

## Appendix 2

Recommended management of indeterminate lesions where the indeterminate pathology is coincidental and not predicted by imaging.

	<b>Non-operative</b>	<b>Follow up</b>	<b>Operative</b>	<b>Follow up</b>
Solitary papilloma	Preferred – Vacuum assisted excision to remove radiologically visible lesion	None if imaging lesion is totally removed	Local excision	None
Multiple papillomas	Diagnostic vacuum excision of index lesion	Standard increased risk surveillance policy*	Remove lesion For recurrent lesions consider prophylactic surgery	Standard increased risk surveillance policy*
Radial Scar	No action needed if no corresponding mammographic abnormality	None	No action needed	None
Atypical ductal proliferation	VACB recommended to exclude DCIS, if minimal atypia only - follow up	Standard increased risk surveillance policy*	Operative biopsy preferred if severe atypia (pre-operative VACB may be used to identify DCIS)	Standard increased risk surveillance policy*
Lobular Neoplasia (non-pleomorphic)	VACB suitable for lobular neoplasia	Standard increased risk surveillance policy*	Operative biopsy for mammographic abnormality if Needed	Standard increased risk surveillance policy*

\* at present the recommended follow-up for women at increased risk is five years annual mammography, after which women are returned to routine NHSBSP screening

## Appendix 3

### Use of ancillary pathological investigation

Diagnostic Problem	Immunohistochemical markers	Notes
Distinguishing hyperplasia of usual type from ADH/DCIS	CK5/6	
Lobular carcinoma phenotype	e-cadherin,	
Assessment of stromal invasion	Smooth muscle myosin (SMM), Smooth muscle actin (SMA), p63, Calponin	
Primary -v- metastatic carcinoma	CK7, CK20, ER, PR, TTF1, CEA, CA125, CA19.9, S100, HMB45, MelanA etc	Select panel dependant on clinical situation
Paget's disease (nipple biopsies)	Low molecular weight cytokeratin (eg CAM or CK8)	
Sentinel node evaluation	Cytokeratin (e.g. AE1/3 or CAM)	

# Appendix 4

## Royal College of Pathologists Breast Cancer Minimum Dataset

### BREAST CANCER HISTOPATHOLOGY MINIMUM DATASET REPORT

Surname	Forenames	Date of birth
Sex	Hospital number	NHS number
Date of reporting	Report number	
Side	<input type="checkbox"/> Right <input type="checkbox"/> Left	

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Specimen type	<input type="checkbox"/> Localisation biopsy	<input type="checkbox"/> Open biopsy
	<input type="checkbox"/> Wide local excision	<input type="checkbox"/> Segmental excision
	<input type="checkbox"/> Mastectomy	<input type="checkbox"/> Wide bore needle biopsy
Specimen weight	..... g	
Axillary procedure	<input type="checkbox"/> No lymph node procedure	<input type="checkbox"/> Sentinel node biopsy
	<input type="checkbox"/> Axillary node sample	<input type="checkbox"/> Axillary node clearance

---

*In situ carcinoma*  Not present

Ductal carcinoma in situ

DCIS grade	<input type="checkbox"/> High	<input type="checkbox"/> Intermediate	<input type="checkbox"/> Low	<input type="checkbox"/> Not assessable
DCIS growth pattern(s)	<input type="checkbox"/> Solid	<input type="checkbox"/> Cribriform	<input type="checkbox"/> Micropapillary	<input type="checkbox"/> Papillary
	<input type="checkbox"/> Apocrine	<input type="checkbox"/> Flat	<input type="checkbox"/> Other (please specify) .....	

Size ..... mm (DCIS only)

Lobular carcinoma in situ

Paget's disease

Microinvasion  Not present  Present

---

*Invasive carcinoma*  Not present

Size Invasive tumour: ..... mm (largest dimension of dominant invasive tumour focus)

Whole size of tumour: ..... mm (invasive plus surrounding DCIS if DCIS extends > 1 mm beyond invasive)

Type  No special type (ductal NST)

Pure special type (90% purity, specify components present below)

Mixed tumour type (50–90% special type component, specify components present below)

Other malignant tumour (please specify) .....

Specify type component(s) present for pure special type and mixed tumour types:

Tubular/cribriform  Lobular  Mucinous  Medullary like  Ductal/no special type

Other (please specify) .....

Invasive grade  1  2  3  Not assessable

Tumour extent  Localised  Multiple invasive foci

Vascular invasion  Not seen  Present  Possible

Axillary nodes present:  No  Yes Total number ..... Number positive .....

For single node positivity, specify  Metastasis (> 2 mm)

Micrometastasis (≤ 2 mm to > 0.2 mm)

Isolated tumour cells (≤ 0.2 mm)

Other nodes present  No  Yes Total number ..... Number positive .....

Site of other nodes .....

Excision margins (for DCIS or invasive carcinoma)

Not assessable  Reaches relevant margin  Does not reach relevant margin

Closest relevant margin ..... mm

Oestrogen receptor status  Positive  Negative ..... Quick (Allred) score

Not performed

# Appendix 5

## Clinical indications for radiotherapy

### 1.1 Radiotherapy to the breast after breast conserving surgery

Indications for adjuvant radiotherapy:

- Invasive breast cancer following surgery with clear margins, or positive margins where no further surgery is possible.
- High grade and selected intermediate grade DCIS following adequate breast conserving surgery

Postoperative radiotherapy to the intact breast should be delivered via a tangent pair, as described below and in department work instructions. Earliest clinically appropriate date (ECAD) for radiotherapy is 31 days after day 1 of the final course of chemotherapy

#### **Bolus**

Tangential field radiotherapy with photon beams is associated with sparing of the skin and subcutaneous tissue. Bolus around the scar is indicated if the margin is involved or tumour is within 5mm of anterior margin. If bolus is used patients must be consented for the likely cosmetic outcome

#### **Electron boost**

Electron boost to tumour bed is indicated for early invasive breast cancer with high risk of local recurrence, following breast conserving surgery

- Involved or margins 2mm – 5mm, including deep margin
- A boost is suggested for all patients under 40 years and for patients aged 40-49 years with either grade 3 tumours and/or lymphovascular invasion. A boost is also suggested for patients aged 50-59 years with one or more adverse prognostic factor, such as grade 3 tumours or lymphovascular invasion.

The position of the boost is chosen by palpation, taking note of the position of the scar and cavity when visible on CT data. CT images are used to choose the appropriate energy. Use of gold seeds or metallic clips to the tumour bed to allow accurate localisation is recommended.

### 1.2 Radiotherapy to the chest wall after mastectomy, with or without reconstruction surgery

Indications for adjuvant radiotherapy is based on tumours size at presentation:

- Invasive breast cancer with a high risk of local recurrence and including Inflammatory and locally advanced breast cancer i.e. tumours more than 5 cm in diameter, four or more positive axillary lymph nodes or involved resection margins.
- Radiotherapy may be offered at the discretion of the treating clinician to patients with invasive breast cancer with involvement of 1-3 axillary lymph nodes, lymphovascular space invasion or grade 3 disease. The SUPREMO trial should be considered in this group of patients.

Radiotherapy should NOT be given to patients who are at low risk of local recurrence, or following mastectomy for DCIS.

Postoperative radiotherapy to the chest wall should be delivered via a tangent pair or direct electron beam therapy, as described below.

### **Bolus**

Full chest wall bolus should be applied. This may be shaped at the discretion of the prescribing consultant and patients must be consented for the likely cosmetic outcome.

For reconstruction post Mastectomy no bolus is routinely indicated.

## **1.3 Radiotherapy to nodal areas**

1. Adjuvant radiotherapy to the axilla is **not** routinely indicated. It may be indicated after positive SLNB or a positive sample of axillary nodes where further dissection is declined.
2. Adjuvant radiotherapy to the supraclavicular fossa alone is indicated: after axillary node clearance, when the highest node is involved or four or more lymph nodes are involved.
3. Adjuvant radiotherapy to the axilla and supraclavicular fossa may be indicated after axillary clearance when four or more axillary lymph nodes are involved and there is macroscopic evidence of residual disease in the axilla.
4. Adjuvant radiotherapy to the internal mammary chain should not be given to patients with early breast cancer who have had breast surgery. Radiotherapy should be delivered with a 3 field technique, as described below, and in department work instructions.

## **1.4 Primary radiotherapy for locally advanced breast cancer**

- Radical radiotherapy perhaps in combination with hormonal therapy or chemotherapy is indicated where surgery is declined or impractical and tumour can be encompassed within 2 or 3 fields. On occasion a local boost may be indicated.
- Palliative fractionation to reduce bleeding or pain.

## **1.5 Palliative Radiotherapy**

Palliative radiotherapy is used for localised metastatic disease, this could be bony, brain, soft tissue disease or spinal cord compression. Treatment delivery will be dependent on the site treated.

## **1.6 Review and Follow up**

Patients undergoing radiotherapy to the breast or chest wall will routinely be reviewed by the Macmillan Support Radiographers unless clinically indicated.

It is the clinicians' responsibility to indicate the outpatient review schedule for each individual patient.

## 2. Radiotherapy techniques

<b>Table 2.1</b>	<b>Radical breast / chest wall only (2 field tangent pair)</b>
<b>Energy / modality</b>	6 or 25 MV Photons
<b>Patient position, incl immobilisation equipment and technique.</b>	Flat on Breast board. Both arms abducted, neck in neutral position and supported in an O ring Patients with large breasts /short neck may require clinical line up on set to facilitate use of angled breast board.
<b>Localisation and scar delineation</b>	CT planning scan. Levels: From: above clinical area, clavicle To: bottom of clinical area, diaphragm
<b>Planning technique</b>	CT planned – isocentric Field-in-field technique as necessary to reduce hot spots in the CTV. 'Line up' – non isocentric
<b>Target definition. Field /volume</b>	CT planned: Fields placed on virtual sim with gantry angled to create non divergent posterior/lung border, should cover tumour bed and scar. Cover from: sternal notch or lower border humerus; midline; mid axillary line; 1cm below inframammary fold. Ref: Isocentric 2 & 3 Field Breast Technique, RTW09.01.57. Clinical line-up: marked on set and portal image taken.
<b>OAR</b>	Ideally no more than 2cm lung depth, Maximum 3cm Exclude heart as far as is practical
<b>Dose / Fractionation &amp; overall treatment time</b>	40 Gy in 15# 50 Gy in 25# (for selected large patients)
<b>Boost:</b>	Direct electron field. 10 Gy in 5# if indicated. Ideally tumour bed boost volume should be derived from insertion of gold seeds or surgical clips
<b>Shielding</b>	N/A
<b>Bolus</b>	Intact Breast: Scar if tumour involved or was close to skin. Mastectomy: Chest wall
<b>Patient instructions</b>	Breast care. See department patient information leaflets.

<b>Table 2.2</b>	<b>Radical Breast/chest wall + SCF (3 field) +/- axilla.</b>
<b>Energy / modality</b>	6 or 25 MV Photons
<b>Patient position, incl immobilisation equipment and technique.</b>	Flat on Breast board, ipsilateral arm up, neck extended and supported in an O ring Patients with large breasts /short neck may require clinical line up on set to facilitate use of angled breast board.
<b>Localisation and scar delineation.</b>	CT planning scan. Levels: From: above clinical area, chin To: bottom of clinical area, diaphragm
<b>Planning technique</b>	CT planned – isocentric Field in field technique as necessary to reduce hotspots in CTV 'Line up' – non isocentric
<b>Target definition. Field /volume</b>	Fields placed on virtual sim. <ul style="list-style-type: none"> <li>• Tangent fields: angled to give non divergent superior border as clinically prescribed (Ref: Arden Cancer Centre, RTW09.01.57) and gantry angled to create non divergent posterior/lung border. Fields should cover tumour bed and scar, and cover from sternal notch or lower border humerus to 1cm below inframammary fold, and from midline to mid axillary line.</li> <li>• SCF field: <ul style="list-style-type: none"> <li>○ asymmetric field with non-divergent axis on inferior border to match tangential fields</li> <li>○ Feet through 90°, gantry angled to match divergence.</li> </ul> </li> </ul> Medial – pedicles cervical spine off cord. Lateral – humeral head or lateral extent of axilla. Inferior edge – tangential field Sup - to allow corridor of soft tissue If the infraclavicular fossa and axillary apex are to be treated, the junction is best chosen at the lower border of the clavicle and the humeral head shielded.
<b>OAR</b>	Ideally no more than 2cm lung depth, Maximum 3cm Exclude heart as far as is practical
<b>Dose/fractionation and overall treatment time</b>	40 Gy in 15# 50 Gy in 25# (for selected large patients)
<b>Boost</b>	Direct electron field. 10 – 15 Gy in 5# if indicated to Breast
<b>Shielding</b>	N/A
<b>Bolus</b>	Intact Breast: Scar if tumour involved or was close to skin. Mastectomy: Chest wall
<b>Patient instructions</b>	Breast care. See department patient information leaflets.

<b>Table 2.3</b>	<b>Electron chest wall +/- SCF</b>
<b>Energy / modality</b>	8 MeV (10 MeV degraded Electrons ) to chest wall 6MV photon field to the supraclavicular area (if clinically indicated).
<b>Patient position, incl immobilisation equipment and technique.</b>	Flat on bed. Head on foam. Ipsilateral arm abducted at 90 degrees Head turned to contralateral side
<b>Localisation</b>	Sim or machine line up
<b>Planning technique</b>	Non – planned.
<b>Target definition. Field /volume OAR</b>	Clinical mark-up Midline to mid-axillary line; sternal notch to 1cm below inframammary fold <ul style="list-style-type: none"> <li>• Med sternomastoid edge</li> <li>• Lateral border of SCF</li> <li>• Inferior edge of chest wall field</li> <li>• Sup to allow corridor of soft tissue.</li> </ul>
<b>Dose / Fractionation &amp; overall treatment time</b>	40 Gy in 15#
<b>Boost:</b>	N/A
<b>Shielding</b>	Chest wall – Lead on patient SCF – shaped Lead on tray to shield any overlap between the two fields.
<b>Bolus</b>	Chest wall
<b>Patient instructions</b>	Breast care. See department patient information leaflets.

<b>Table 2.4</b>	<b>Palliative whole breast (2 field tangent pair)</b>
<b>Energy / modality</b>	6 or 25 MV Photons
<b>Patient position, incl immobilisation equipment and technique.</b>	Flat on Breast board. Both arms abducted, neck in neutral position and supported in an O ring. Consider bolus if fungating tumour. Patients with large breasts /short neck may require clinical line up on set to facilitate use of angled breast board.
<b>Localisation and scar delineation</b>	CT planning scan. Levels: From: above clinical area, clavicle To: bottom of clinical area, diaphragm
<b>Planning technique</b>	CT planned – isocentric. 'Line up' – non isocentric
<b>Target definition. Field /volume</b>	CT planned: Fields placed on virtual sim with gantry angled to create non divergent posterior/lung border, should cover tumour bed and scar. Cover from: sternal notch or lower border humerus; midline; mid axillary line; 1cm below inframammary fold. Ref: Isocentric 2 & 3 Field Breast Technique, RTW09.01.57. Clinical line-up: marked on set and portal image taken.
<b>OAR</b>	Ideally no more than 2cm lung depth, Maximum 3cm
<b>Dose / Fractionation &amp; overall treatment time</b>	30-36 Gy in 5-6 fractions, one fraction per week
<b>Shielding</b>	N/A
<b>Patient instructions</b>	Breast care. See department patient information leaflets.

<b>Table 2.5</b>	<b>Palliative</b>
<b>Energy / modality</b>	6MV
<b>Patient position, incl immobilisation equipment and technique.</b>	Supine, head block and knee supports. Mattresses can be used to ease discomfort. Whole brain or Orbit treatments will be treated in an orbit.
<b>Localisation</b>	Sim or CT scanned with virtual Sim
<b>Planning technique</b>	Direct field or parallel pair
<b>Target definition. Field /volume OAR</b>	To cover disease with 1cm margin. For spinal disease treat affected bones and include one whole vertebrae above and one below.
<b>Dose / Fractionation &amp; overall treatment time</b>	8 Gy single # or 20 Gy in 5 #
<b>Boost:</b>	N/A
<b>Shielding</b>	
<b>Bolus</b>	As required
<b>Patient instructions</b>	Instructions for the area treated