# Contents

1. **Assessment of Breast Referrals in the Diagnostic Clinic**  
2. **Specific Conditions**  
   2.1. Discrete Breast Mass Lesions  
   2.2. Breast Cysts  
   2.3. Fibroadenomas  
   2.4. Phyllodes Tumour  
   2.5. Nipple Discharge  
   2.6. New Nipple Retractions/Nipple Skin Changes  
   2.7. Nodularity  
   2.8. Mastalgia  
   2.9. Breast Infections/Abscess  
   2.10. Lumps in the Male Breasts  
   2.11. Vacuum Assisted Biopsy/Excision  
3. **Indeterminate /B3 Lesions**  
4. **Breast Cancer Management**  
   4.1. General Principles  
   4.2. Further Assessment of Breast with MRI  
   4.3. Communications and Information  
   4.4. Record Keeping  
   4.5. Staging  
5. **Surgery of the Breast**  
   5.1. Breast Conserving Surgery (BCS)  
   5.2. Mastectomy  
   5.3. Breast Reconstruction  
   5.4. Local Anaesthetic Surgery  
6. **Management of the Axilla**  
   6.1. Pre-operative Assessment of Axilla  
   6.2. Sentinel Lymph Node Biopsy  
   6.3. DCIS  
   6.4. Neo-adjuvant Chemotherapy  
   6.5. Prior to reconstruction  
   6.6. Intraoperative assessment of the Sentinel Nodes  
   6.7. Standard Management of Axilla after SLNB  
   6.8. Recent changes in Axillary Management after SLNB  
   6.9. Axillary Lymph Node Dissection (ALND)  
7. **Non-surgical**  
   7.1. Primary Endocrine Therapy  
   7.2. Neo-adjuvant Endocrine Treatment  
   7.3. Neo-adjuvant Chemotherapy  
8. **Breast Cancer in Pregnancy**  
   8.1. Diagnostic Aspects  
   8.2. Surgery  
   8.3. Sentinel Node
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.4. Chemotherapy</td>
<td>19</td>
</tr>
<tr>
<td>8.5. Radiotherapy</td>
<td>19</td>
</tr>
<tr>
<td>8.6. Endocrine Treatment</td>
<td>19</td>
</tr>
<tr>
<td>8.7. Other considerations</td>
<td>19</td>
</tr>
<tr>
<td>8.8. Inflammatory Breast Cancer</td>
<td>20</td>
</tr>
<tr>
<td>8.9. Other Tumours in the Breast</td>
<td>20</td>
</tr>
<tr>
<td>8.10. Teenagers and Young Adults (TYA)</td>
<td>20</td>
</tr>
<tr>
<td>8.11. Management of Breast Cancer Risk</td>
<td>20</td>
</tr>
<tr>
<td>9. Protocol for Surgical Specimen</td>
<td>20</td>
</tr>
<tr>
<td>9.1. Specimen Orientation</td>
<td>20</td>
</tr>
<tr>
<td>9.2. Histopathology for Breast Specimens</td>
<td>21</td>
</tr>
<tr>
<td>9.3. Assessment of Lymph Nodes</td>
<td>22</td>
</tr>
<tr>
<td>10. Post Treatment Follow-up</td>
<td>22</td>
</tr>
</tbody>
</table>
1. **Assessment of Breast Referrals in the Diagnostic Clinic**

Patients with breast symptoms or findings referred on the 2 week wait pathway should be seen in a ‘one stop breast clinic’ and assessed by multimodality method using clinical assessment, imaging and cytology/histology as appropriate. The three modalities of the “**triple assessment protocol**” should be available during the same visit. The majority of breast referrals should have a diagnostic conclusion during the same visit and discharged with appropriate advice. A minority of patients will require further investigations or need a further visit to discuss results if a cytology or histology sample has been taken. Besides referrals from primary care the breast clinic will also receive cross referrals from secondary care and screening service.

2. **Specific Conditions**

2.1. **Discrete Breast Mass Lesions**

A detailed clinical history including family and reproductive history should be taken in clinic.

All patients with a discrete breast mass (palpable or visible on imaging) should be investigated by **Triple Assessment** – (1) Clinical examination, (2) Imaging (US or mammogram or both) & (3) Core Biopsy/FNAC

**Imaging:** For patients under 35 years of age ultrasound alone is the imaging modality of choice while mammography is used additionally for ages 35 and above.

All palpable findings should described (nature, location and size) and palpation grading (P1 to P5) recorded in the notes. Similarly, imaging findings should be described (nature, location and size) and BIRADS grading (R/M1-S and U1-S) recorded.

Discrete masses graded P3 or R3/M3 or U3 and above should be triple assessed using core biopsy rather than FNAC unless core biopsy is not feasible. For lesions graded 2 discretion may be used in deciding whether FNAC or core biopsy is needed. For e.g.: Benign calcifications graded R2, multiple tiny cysts graded U2 etc. do not need needle tests. When deciding between FNAC and core biopsy, core biopsy will give a more robust and definitive diagnosis and should be favoured. However in some locations or situations FNAC may be more feasible or safer. Needle biopsies should be performed under image guidance.

When cytology or biopsy has been reported as C1 or B1 it will require further biopsy to delineate the pathology in most instances. The exceptions are when the lesion is suspected to be a lipoma or hamartoma following imaging and discussion. Following triple assessment if there is non-concordance by more than one grade then further biopsy and or investigations should be undertaken. In the abovementioned instances if a decision not biopsy further is to be made it should ideally occur following concurrence at a multidisciplinary discussion.

When breast cancer is diagnosed by C5 cytology from an FNAC, a core biopsy should be done and histology report made available before treatment decisions are made.
2.2. Breast Cysts
A clinical diagnosis of Breast cyst should be confirmed by imaging. Large symptomatic cysts should be aspirated. Cyst fluid with non-suspicious appearance is discarded normally. Patients can then be given advice regarding cysts and discharged.

Cyst fluid may be sent for cytological analysis in the following instances (i) blood stained fluid (ii) residual mass present after aspiration (iii) presence of radiologically suspicious appearance

If a residual mass is found after cyst aspiration it should be assessed as per protocol for discrete masses lesions.

2.3. Fibroadenomas
A clinical diagnosis of fibroadenoma should be confirmed by imaging. Triple assessment protocol for discrete mass lesions should be applied. However if the appearances are benign and confirmed by imaging a biopsy can be avoided under the age of 25 unless phyllodes tumour is suspected. A core biopsy is generally preferable to FNAC.

Following diagnosis patients can be reassured and discharged. Indications for excision are: (1) Patients request (e.g. – Symptoms) (2) increase in size (3) >3cm size

2.4. Phyllodes Tumour
If a Phyllodes tumour is suspected clinically or on imaging, core biopsy is indicated. A core biopsy will enable better planning of excision.

Following diagnosis of a benign phyllodes a wide local excision with generous margin (e.g.: 1cm) is ideal to reduce risk of recurrence and follow-up requirement. If phyllodes was not suspected and the lesion was “shelled-out” re-excision for margins is recommended. Annual follow up with clinical examination and imaging is recommended for 2 years. Longer follow-up for five years is recommended if adequate margins have not achieved or if the histology is borderline. The highest risk of recurrence is in the first 2 years. (2 to 40% recurrence rates have been recorded in some series)

For malignant and borderline Phyllodes tumours the case should be discussed at the regional Sarcoma MDT and protocol followed.

2.5. Nipple Discharge
History and clinical examination should be directed to determine key factors such as duration, unilateral or bilateral nature, colour of discharge and whether single or multiduct, spontaneous or expressed discharge. Any causative or aggravating factors including medication, known pregnancy or post lactational period should be taken into account. Nature of the nipple and areola should be closely examined to determine presence of eczema or suggestion of Paget’s disease or underlying mass lesions. Assessment should include imaging as per age related usual protocol.
If any mass lesions are found, triple assessment should be carried out. Nipple discharge if elicited should be subjected to cytological analysis. Presence of epithelial cells or RBCs should alert to the possibility of an underlying pathology needing further investigation. If local skin abnormality is present a punch biopsy is warranted.

Atypical or suspicious features in the investigations should trigger consideration of macrodochectomy (Major duct excision/ Hadfields procedure) or microdochectomy as appropriate, if malignancy needs to be ruled out.

Missed cancers are always a possibility and special attention should be given in all cases of nipple discharge. For unexplained multiduct bilateral discharge especially if milky, prolactin estimation forms part of investigation. Abnormal prolactin result may warrant referral to the endocrine physicians.

2.6. New Nipple Retraction/ Nipple skin changes
Clinical examination & imaging to look for underlying pathology – then follow usual triple assessment protocol. For skin changes the usual differential diagnoses are eczema and Paget’s disease. Skin punch biopsy can aid diagnosis. Treat dependent on the diagnosis.

2.7. Nodularity
If generalised: <40 years no imaging required, (>40 mammogram +/- US recommended)
For Focal Asymmetrical Nodularity imaging is indicated. ( <35 years – USS, >35years – mammogram +/- US)
If normal/benign – reassure and discharge. If abnormal – proceed as per triple assessment guidelines.
Pay special attention in dense breasts and when considering possibility of lobular cancers.
If focal nodularity amounts to a discrete mass follow usual triple assessment protocol.

2.8. Mastalgia
A careful history is required to establish if the pain is cyclical or non-cyclical.

If no palpable abnormality, mammogram should be requested > /= 40 years
If < 40 years, mastalgia with a normal clinical examination does not require imaging.
If there is a palpable abnormality, proceed to triple assessment. If the pain is localised an ultrasound may be considered.
If cyclical: there is no established effective treatment though Evening Primrose Oil may be useful in some instances. There is no need to follow up patients with breast pain; most patients can be discharged with a management plan at their first visit with breast care nurse support.
If non-cyclical: consider musculoskeletal origin or referred pain.

2.9. Breast Infections/Abscess
In the cellulitic stage antibiotics are appropriate.
If a collection has formed – the management can be by Needle drainage (often requiring multiple visits) or Incision & Drainage. Aspirate preferably under ultrasound guidance, and send aspirate to microbiology for Culture and Sensitivity if possible. When skin is thinned or is at risk or necrotic – incision and drainage is more appropriate. Consider sending any abscess wall or fistulous tract for histology, as occasionally infection can co-exist with carcinoma. Following resolution formal assessment is recommended to rule out underlying cancer. Mammography=/- USS especially in patients >35 years. If mass persists is present follow triple assessment protocol.

2.10. Lumps in the Male Breast
For Gynaecomastia: appropriate history, examination (including abdomen and genital examination) and investigations are required to establish an underlying cause. Investigations include imaging of the Breast (ultrasound, mammogram) LFTs, serum testosterone and oestradiol, prolactin, FSH, LH, AFP, beta-HCG, TFTs and USS testes if indicated after clinical examination. Consider CXR if risk factors for lung carcinoma present. Occasionally surgery for gynaecomastia is indicated. Surgical techniques include simple excision and/or liposuction or breast reduction type procedure in appropriate cases.

For breast lumps: proceed with triple assessment protocol.

2.11. Vacuum Assisted Biopsy/Excision
Vacuum assisted needle biopsy (VAB) provides higher calcium retrieval and definitive diagnostic rates in the presence of micro calcifications.

VAB can be used for therapeutic excisions in the following situations:
- Radial scars/complex sclerosing lesions (CSL)
- Atypical ductal hyperplasia (ADH)
- Atypical columnar cell change
- Lobular neoplasia (B3)
- Papilloma with or without atypia
Papillomas or fibroadenomas less than 2.5cm in maximum diameter may be excised by VAB.

3. Indeterminate/ B3 Lesions
The following is extracted from the London Region QARC Guidance on Indeterminate lesions.

Each case must be ideally discussed in a multidisciplinary setting and individual management plan formulated.

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

* 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

** - is referred to in table (radial scar operative box) but has no definition

Table 2: Recommended management of indeterminate lesions where the Indeterminate pathology is coincidental and not predicted by imaging.
4. Breast Cancer Management

4.1. General Principles
All patients with a diagnosis of breast cancer should have their management discussed within a breast Multidisciplinary Meeting at key points in their pathway - at diagnosis, post-surgery and when deciding key management modalities. All newly diagnosed patients should be allocated and be supported by a Breast Clinical Nurse Specialist (CNS), and contact details provided. They should also have access to rehabilitation/psychological health care professional(s) as appropriate. Patients should be given written information regarding their diagnosis and treatment options and wherever possible offered opportunity to participate in clinical trials. Patients should receive written/printed information regarding their Multidisciplinary (MDT) team and facilities available.

4.2. Further Assessment of Breast with MRI
Following a diagnosis of breast cancer some patients will also require an MRI scan.

---

<table>
<thead>
<tr>
<th>Solitary papilloma</th>
<th>Non-operative</th>
<th>Follow up</th>
<th>Operative</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred – Vacuum assisted excision to remove radiologically visible lesion</td>
<td>None if imaging lesion is totally removed</td>
<td>Local excision</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

| 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.
Key indications are (NICE guidance CG80):
- if there is significant discrepancy between clinical and imaging assessment of disease extent
- if breast density precludes accurate mammographic assessment
- to assess tumour size if breast conserving surgery is being considered for invasive lobular cancer

Other indications:
- Assessment of the breast in a case of unknown primary
- Assessment of response for neo-adjuvant chemotherapy. (baseline and during chemotherapy)
- Assessment of integrity of implants

MRI may occasionally pick up cancers in other organ systems or in the contralateral breast.

4.3. Communication & Information
Diagnosis of breast cancer should be made known to the patient’s GP within the next working day.
Available imaging results to be discussed with patient at the same one stop clinic, and if biopsy has been done the likely outcome of the biopsy.
Explain the MDT process and the date of the result clinic
Breast CNS will play an active role in providing verbal and written/printed information to the patient during the key points in the pathway.

4.4. Record keeping
Meticulous record keeping is necessary during the patient pathway. MDT outcomes should be available in the notes for reference. It is recommended that all MDT teams make a migration to electronic record keeping of MDT decisions and discussions to allow easy accessibility during current and future treatment planning.

It should be noted that in all patients the TNM stage should be recorded on MDM sheet. It should also be noted if the cancer is recurrent or metastatic.

4.5. Staging
For patients with early stage operable disease and no signs or symptoms suggestive of metastatic disease, routine pre-operative staging is not recommended.

Indications for staging using CT scan (chest/abdo/pelvis) and isotope bone scan:

1. Patients with symptoms suggestive of metastases
2. Recurrent disease, both local and distant
3. Significant Nodal involvement (e.g.:/>= 4 nodes)
4. As part of an approved clinical trial protocol
5. Inflammatory breast cancer
6. Locally advanced disease
7. Large primary tumours (e.g. >5cm)

A relative indication/lower threshold is sometimes applied to assessment prior to major reconstructive surgery. However this is not a necessary indication.

Further modality imaging (PET/CT and/or MRI) should be available and considered where the standard staging imaging is equivocal.

For patients receiving neo-adjuvant chemotherapy SLNB may be offered prior to or after chemotherapy, while the evidence for the optimum pathway remains uncertain individual MDTs should have their agreed standard policy.

5. Surgery of the Breast
Cancer excision may be performed through Breast Conserving Surgery (BCS) or Mastectomy.

5.1. Breast Conserving Surgery (BCS)
The aim to achieve complete tumour excision with adequate margins and provide acceptable cosmetic outcome.

Key variable to consider is the ratio of the volume of proposed excision to the patient’s breast volume. More than 15 to 20% volume excision will result in a cosmetic deficit unless volume replacement techniques are considered (e.g.: partial breast reconstruction). In particular sites (e.g.: lower pole / medial aspects) the breast will tolerate an even smaller volume ratio. An example is ‘bird beaking’ when the breast settles down after surgery and radiotherapy in lower pole excisions.

**Standard BCS**
Constitutes straightforward removal of the cancer with adequate margins. A favoured method is to remove the cancer from the subcutaneous plane down to the muscle in a cylindrical fashion. This will avoid needing to re-operate if inadequate margins found at histology at the posterior and anterior aspects. For a better cosmetic outcome some tissue mobilisation / volume displacement technique may be employed to bring the excision margins closer (fully or at least partially) rather than leave a cavity.

**Advanced/Extended BCS**
When larger volumes are excised, volume replacement techniques using local and regional flaps (e.g.: Thoracodorsal artery perforator (TDAP) flap, Intercostal artery perforator (ICAP) flap, Serratus anterior artery perforator (SAAP) flap, Superior epigastric artery perforator (SEAP) flap, Omental flap, Mini- Ld flap etc.) can be employed to reduce cosmetic deficit. For deficits presenting later, lipofilling may be used to correct volume and cosmetic deficit.
In a larger breast an alternative would be to use breast reduction techniques (therapeutic mammoplasty) to achieve better cosmesis. A further alternative with appropriate tumour histology and patient factors would be to use **neo-adjuvant chemotherapy** or **endocrine therapy** to downsize the cancer to allow better cosmesis following breast conservation.

**Contraindications to standard BCS**

- Multi focal or Multicentric tumours*
- Extensive microcalcification
- Difficulty in undergoing radiotherapy (e.g. Shoulder abduction issues)
- Previous radiotherapy/contraindication to radiotherapy
- BRCA gene/ Family history – discuss appropriateness of mastectomy
- Early pregnancy (potential delay in post op radiotherapy)
- Skin conditions – scleroderma, lupus

(* in certain situations breast conservation is possible with volume replacement/partial breast reconstruction techniques)

**BCS – Margins**

The aim of excision is to remove the cancer and leave behind no microscopic or macroscopic disease at the excision margins. If margins are involved re-excision must be undertaken.

Regarding further margin of uninvolved tissue, NICE CG80 recommends a margin of 2mm for DCIS. A margin of 1mm is being increasingly adopted for invasive disease. There is continuing discussion of evidence but currently no national consensus on the appropriate margin thickness both for invasive and non-invasive disease. New national guidance on this is soon awaited and London Cancer will update guidelines accordingly.

**Paget’s disease /Central tumours**

Centrally located tumours or Paget’s disease, can be well treated in most instances with central wide local excision (removing nipple & areola). In some instances especially in smaller breasts, mastectomy may be more appropriate.

**5.2. Mastectomy**

Mastectomy is considered when breast conservation is not feasible (see section above). In addition to the above indications and contraindications, patient choice will play a key factor.

**5.3. Breast Reconstruction**

In all cases the possibility/option of immediate reconstruction should be discussed. Reconstruction should be offered in appropriate cases. All current modalities of reconstruction should be available to the patient whether organised locally or regionally. At the initial discussion, potential future delayed reconstruction modalities as well as likely time frames should form part of the discussion.
If reconstruction provided at another centre, service agreements should be in place to ensure an efficient patient pathway to avoid delay compared to non-reconstruction patients. If a sentinel node biopsy is planned prior to the definitive mastectomy and reconstruction, this should take place and results discussed within the timelines required for non-reconstruction patients. Effects of potential adjuvant treatments such as chemotherapy and radiotherapy on the reconstructed breast should be considered when choosing immediate reconstruction. Patients should be made aware of potential delay to adjuvant treatments in case of any complications with reconstruction. In most cases more than one appointment may be necessary before a reconstruction choice is made.

(Further reading: “Oncoplastic Breast Reconstruction: Guidelines for Best Practice” – ABS Publication) – place at end

5.4. Local Anaesthetic Surgery
In carefully selected cases local anaesthesia may allow surgery to be undertaken in situations where a general anaesthetic is contraindicated or extremely risky.

6. Management of the Axilla

The axilla must be assessed in all cases of Invasive breast cancer.

6.1. Pre-operative Assessment of Axilla
All patients with a diagnosis of breast cancer must have USS assessment of the axilla with USS guided needle biopsy if indeterminate or suspicious features are present e.g.: cortical thickness is >2.5mm, eccentric thickening of the cortex, abnormal morphology or vascular flow, absence of fatty hilum.

If the axillary lymph node core biopsy or FNAC is metastatic proceed to axillary clearance during the definitive surgery to the breast.

6.2. Sentinel Lymph Node Biopsy
Sentinel Lymph Node Biopsy (SLNB) is the standard of care in axillary staging for early breast cancer. The recommended modality is dual technique using radioisotope tracer and blue dye. When this is not feasible (e.g.: pregnant patients, local issues, dye allergy) or if the dye fails to localise proceed to axillary node sampling (typically 4 nodes).

In certain situations the sentinel node biopsy technique may fail and axillary clearance may be indicated e.g.: inflammatory breast cancer, previous breast/axillary surgery or radiotherapy.

6.3. DCIS
SLNB is not indicated in DCIS. However patients must be made aware that 20-30% of patients with a preoperative diagnosis of DCIS may eventually be found to have invasive
cancer warranting further surgery for SLN assessment and even further surgery if SLNB is positive. Some patients may therefore choose to have SLNB at the initial operation. If a mastectomy is performed for DCIS, sentinel node biopsy is indicated as further post mastectomy SLNB would not be possible if invasive disease is found. Some factors such as extensive DCIS/micro-calcification, palpable disease, high grade histology or suggestion of possible invasion on core biopsy, may increase the chance of finding invasive disease after wide local excision.

6.4. Neo-adjuvant Chemotherapy
For patients receiving neo-adjuvant chemotherapy SLNB may be offered prior to or after chemotherapy. This may be discussed and decided in the MDT meeting. In cases where the axilla is positive on needle biopsy prior to neo-adjuvant chemotherapy the standard procedure is to proceed with axillary clearance upon completion of neo-adjuvant chemotherapy. However the axilla may be completely negative if there has been complete response. Sentinel node biopsy at this point could predict the axillary status but its validity is still under debate.

6.5. Prior to reconstruction
Sentinel node biopsy may be undertaken as an independent procedure prior to a planned breast reconstruction to avoid having to return to the axilla for clearance surgery soon after reconstruction surgery. Care must be taken to avoid delay in the definitive cancer surgery while waiting for the SLNB and histology results. SLNB should be considered as part of the diagnostic workup and will not count toward the 31 day and 62 day pathways.

6.6. Intraoperative assessment of the Sentinel Nodes
Intraoperative assessment of the SLN will help expedite the treatment pathway for the patient as the surgeon can proceed immediately to axillary clearance within the same operative episode/anaesthetic. A further advantage is avoiding surgery in a recently scarred axilla with its attendant difficulties and risks. Frozen section and imprint cytology have been traditionally used for this assessment. More recently molecular analysis (PCR) have been used to intraoperatively assess the sentinel node with accuracies approaching that of histology. However recent debate and changes in the concept and protocols for further management of the axilla in the presence of positive sentinel will impact on the role of intraoperative assessment in the future.

6.7. Standard Management of Axilla after SLNB
When the sentinel node is found to have micro (0.2 to 2mm) or macro metastasis (>2mm) proceed to axillary clearance or axillary radiotherapy as per NICE Guidance CG80. Isolated tumour cells (ITC) can be ignored and axillary clearance is not warranted. When axillary clearance is performed around half of patients will have no further axillary node involvement.

6.8. Recent changes in axillary management after SLNB
Following recent trials it is increasingly recognised that axillary clearance is not warranted in all cases of positive SLNB particularly when only 1 to 2 lymph nodes are involved and the
disease is low risk and early stage. This is particularly so in breast conserving surgery where Adjuvant Radiotherapy fields can be adjusted to cover the axilla. The underlying concept is that adjuvant treatment decisions could be made with SLNB results alone rather than using information from additional axillary clearance.

A national guidance statement is awaited imminently and London Cancer will update guidance accordingly. Currently when a decision is made not to operate further on the axilla in the presence of axillary metastasis, it must be recorded in the MDT discussion and need for radiotherapy etc. documented.

Due cognisance may be given to the Association of Breast Surgery Consensus statement from published March 2015 (See Below)
Association of Breast Surgery Consensus Statement

Management of the Malignant Axilla in Early Breast Cancer

The following summary statement has been agreed by the Trustees of the Association of Breast Surgery (ABS) following the ABS Multidisciplinary Consensus Meeting on the further management of the malignant axillary node, held in London on 26th January 2015. This should be read in conjunction with the ‘Summary of Proceedings’ of the meeting and the speaker presentations, both of which will be available on the ABS website. A review and full update of the ABS guidelines on the management of the axilla is under consideration and will be published shortly.

Further local treatment for the malignant sentinel lymph node in patients with early invasive breast cancer

Isolated tumour cells and micrometastases:

If the sentinel node(s) shows isolated tumour cells and/or micrometastases no further axillary treatment is required in addition to breast conserving surgery or mastectomy.

1-2 sentinel nodes with macrometastases:

Further axillary treatment is no longer mandatory in patients who are receiving breast conservation with whole breast radiotherapy, that are post menopausal and have T1, grade 1 or 2, ER positive and HER2 negative tumours.

These patients could also be entered into the POSNOC or equivalent clinical trial.

Further axillary treatment should usually be recommended for patients undergoing mastectomy, or with tumours with one or more of the following features: T3, grade 3, oestrogen receptor negative or HER2 positive.

These patients could also be entered into the POSNOC or equivalent clinical trial.

No consensus was reached on the management of patients with one or more of the following features: premenopausal status, T2 tumours, lymphovascular invasion or extranodal spread.

3 or more sentinel nodes with macrometastases:

Patients should usually be recommended to have further axillary treatment.
Axillary Treatment

Radiotherapy to the axilla is a valid alternative treatment to axillary lymph node dissection in patients with a low burden of axillary disease.

Pre-operative Axillary Staging

All patients with invasive early breast cancer should have a preoperative ultrasound examination of the axilla and subsequent ultrasound guided nodal biopsy when indicated.

Adjuvant Treatment Planning

The total number of involved axillary nodes is no longer considered to be essential information to decide on the most appropriate systemic treatment. The choice of systemic treatment should be based on the prediction of response rather than the perceived prognosis.

Consensus was not reached on the importance of the total number of involved axillary nodes as essential information for post mastectomy radiotherapy decision making.

Please refer to the summary of proceedings of the meeting.

Management of the malignant axillary node diagnosed pre-operatively by ultrasound guided FNA or core biopsy

There was considerable discussion regarding the management of the pre-operatively diagnosed positive axillary node where patients are planned to undergo breast conservation surgery with whole breast radiotherapy, and where pre-operative information indicates a likely good prognosis and low axillary nodal burden (T1 tumour, grade 1-2, ER positive and postmenopausal status).

However consensus was not reached as to whether sentinel node biopsy should be considered as the next step in such patients. Although there was support for this option, it was apparent that appropriate processes and protocols will be required before further guidelines are agreed.

The ABS Trustees aim to develop appropriate guidelines on this issue as soon as possible.

Association of Breast Surgery Trustees 16th March 2015
6.9. Axillary Lymph Node Dissection (ALND)
Axillary Node Clearance/ALND is the standard operation for the management of positive axillary nodes. The purpose is for treatment of the axilla as well as obtaining prognostic and predictive information to make adjuvant treatment recommendations.

For a heavily involved axilla, Level I/II/III clearance is performed. For likely low volume disease it is recommended that a less extensive dissection is performed to reduce the risk of lymphoedema.

7. Non-surgical

7.1. Primary Endocrine therapy
Surgery is the most effective local therapy for operable breast cancer. It should not be denied to patients without good cause. However for those patients who are unfit for surgery and are ER+ve, treatment with antioestrogens may keep the disease under control for prolonged periods of time.

7.2. Neo-adjuvant Endocrine treatment
In ER +ve patients anti oestrogen therapy can allow some down staging to enable a better surgical procedure. In some instances it will keep the disease in control while waiting for assessment or optimisation of fitness for surgery or anaesthetic.

7.3. Neo-adjuvant chemotherapy
Neo-adjuvant chemotherapy (NAC) can downsize/down stage the tumour to enable breast conservation rather than mastectomy. Chemotherapy administered prior to surgery in addition allows in vivo assessment of tumour response/sensitivity to specific chemotherapeutic agents. In locally advanced cancers and inflammatory cancers, NAC can improve operability to perform a mastectomy. Poorly differentiated cancers that are ER negative and Her2 positive often have the highest responses to NAC.

In a proportion of cases there will be complete pathological response. In these cases the patients should still undergo at least a wide local excision of the cancer site (unless the primary cancer was inflammatory or locally advanced). To aid this, a marker clip should have been placed within the tumour prior to commencement of neo-adjuvant therapy if future breast conserving surgery is contemplated. A baseline MRI scan should be performed so that accurate disease monitoring can be under taken.

Presence of extensive micro calcification or presence of DCIS component is a relative contraindication to neoadjuvant chemotherapy as the tumour extent may not significantly change to allow breast conservation.
8. Breast Cancer in Pregnancy

Management is complex and multidisciplinary and requires close coordination of surgeons, oncologists and obstetricians along with other MDT members. In general there is no evidence that termination of pregnancy will improve outcome or is necessary to facilitate breast cancer treatment. However for aggressive cancers presenting in the first trimester, termination may be discussed to facilitate chemotherapy if warranted. Stage for stage the prognosis is similar to an age matched patient although cancer often tends to be diagnosed at a later stage.

8.1. Diagnostic aspects
Ultrasound scanning is usually the first modality although digital mammography with appropriate shielding is safe. FNAC has a higher false positivity rate and therefore core biopsy is preferred. Other diagnostic and staging investigations during pregnancy should also be limited to essential tests with the lowest possible radiation exposure. Abdominal and pelvic CT scans for staging should be avoided if possible. MRI is contra-indicated in the first trimester. Contrast enhanced MRI (breast) is contraindicated throughout pregnancy.

8.2. Surgery
Surgery is generally the first line of management and is safe during all trimesters with special anaesthetic and surgical precautions. In the earlier trimesters, mastectomy is preferred to breast conservation as continuing pregnancy will necessitate delaying adjuvant radiotherapy until after delivery. In the third trimester, early delivery followed by standard breast cancer care should be considered.

8.3. Sentinel node
Radiotracer alone is preferred due to blue dye related risks.

8.4. Chemotherapy
After the first trimester of pregnancy, neo-adjuvant chemotherapy may be an appropriate choice allowing the patient to complete pregnancy and proceed with breast conserving surgery followed by radiotherapy.

8.5. Radiotherapy
Generally avoided, although it may be undertaken with appropriate shielding in the latter part of pregnancy. In some instances slight delay to radiotherapy may be acceptable to allow the baby to be delivered first.

8.6. Endocrine treatment
Tamoxifien is contraindicated in pregnancy due to foetal defects and miscarriage risks.

8.7. Other considerations
Patients planned for chemotherapy who are of child-bearing age but yet to start a family should be offered fertility preservation, prior to starting chemotherapy. While this should be...
discussed with all patients, NHS funding arrangements are only available for childless women for patients on tamoxifen pregnancy should be avoided for at least 2 months after stopping medication.

8.8. Inflammatory Breast Cancer
Inflammatory breast cancer is a distinct clinico-pathological entity. It is defined by the clinical findings of skin oedema and erythema. It is usually associated with dermal lymphatic invasion.
Pre-treatment staging investigations are indicated followed by neo-adjuvant chemotherapy. This is followed by mastectomy and axillary node clearance and radiotherapy. Herceptin +/-endocrine treatment indicated as per receptor status.

8.9. Other Tumours in the Breast
These are mainly either lymphoma or sarcoma diagnosed usually on core biopsy. For lymphoma, the patients will need to be referred to a haematological oncologist. Sarcoma can develop in breast tissue or overlying skin and rarely, may follow radiotherapy (angiosarcoma) to the chest wall. A further pathology is malignant phylloides. These cases should be discussed in the regional Sarcoma MDT and individualised management protocol formulated. Surgery/adjuvant treatment/ follow up may be undertaken within the local MDT in agreement with the designated regional MDT.

8.10. Teenagers and Young Adults (TYA)
Breast cancer patients aged 16 to 24 should have their management plan discussed and formulated at the regional TYA MDT.

8.11. Management of Breast Cancer Risk
Breast cancer risk management requires integration between primary secondary and tertiary centres. London cancer subscribes to the detailed NICE guidance (CG164 published 2013). Every MDT should have a designated member with appropriate training who will lead on family history and breast cancer risk management for the MDT.

Patients requesting risk reducing surgery must be discussed in the regional Risk Reducing Mastectomy MDT and fulfil the MDT criteria before going forward with surgery.

9. Protocol for Surgical Specimen

9.1. Specimen Orientation
Surgeons should ensure that all specimens are correctly orientated and scheme or orientation marked on the pathology request form along with brief clinical details including side of operation. Details such as neo-adjuvant chemotherapy should be included. Since breast excision specimens do not have definable anatomical landmarks, a diagram of the position of the excision in relation to the breast will ensure correct orientation by the pathologist. For mastectomy specimens a diagram of the location of tumour foci/extent of micro-calcification will aid the pathologist.
Within an MDT it is recommended that all surgeons follow the same orientation scheme for increased safety. An example of a system of specimen orientation is as follows:

**Short Superior** (x1 clip), **Medium Medial** (x2 clips) and **Long Lateral** (x3 clips)

Although only two markers are strictly necessary, a third suture/clip will be a safety net in case of accidental dislodgement during transport/handling of one of the sutures. Clips for specimen x-ray are ideally applied on to the sutures and not on the specimen directly. Applying clips directly to the specimen may result in damage to the tissue margins during clip removal.

Total mastectomy specimens should be clearly labelled with a short stitch superiorly and a long stitch laterally. It must be clearly stated if there is an axillary dissection in continuity with the breast tissue. For sentinel node-guided samples, it should be clearly stated which lymph nodes are sentinel (hot) nodes and which are non-sentinel axillary nodes.

Specimen X-ray should be performed for breast conservation specimens for impalpable breast lesions or calcification. If the specimen is received by pathology without a specimen X-ray, the specimen will need to be X-rayed before pathological examination.

Mastectomy and wide local excisions specimen should be weighed in theatre and weight recorded in operation notes.

### 9.2. Histopathology for Breast Specimens

For invasive carcinomas the following information should be included in the report:

1. Invasive tumour type
2. Maximum diameter
3. Grade – modified Bloom and Richardson (tubule formation, nuclear polymorphism, frequency of mitoses, each scored 1 - 3)
4. Presence of in-situ component
5. Total size (invasive and in-situ) if extensive in-situ component (EIC) present – Largest dimension of invasive+ furthest extension of in-situ (may not be in the same plane)
6. Presence of vascular invasion
7. ER, HER-2 status are required for all invasive tumours. (NICE guidelines no longer mandates PR testing but local MDTs may decide on merits of testing)
8. Sizes of all margins and indication of closest margin
9. Lymph node status (true metastasis (>2mm), size of micro-metastasis [0.2 to 2mm], isolated tumour cells)

For DCIS

Estimate of disease extent, margins, growth pattern and necrosis. Case classified according to the highest nuclear grade observed. Where relevant, indicate presence of Paget’s disease.
For LCIS
In all cases specify if present or not. Assessment of excision margins is not necessary as LCIS is multicentric in a high proportion of cases, and further surgery to clear margins is not recommended. Pleomorphic LCIS needs to be treated like DCIS.

9.3. Assessment of Lymph Nodes
Sentinel Nodes biopsy and sampling lymph nodes should be sliced at 1-2mm intervals and all slices embedded. Each node should be embedded in a separate cassette. A single H&E will be taken from each block. If considered necessary by the pathologist, further levels and/or immunohistochemistry may be carried out.

10. Post Treatment Follow-up
Following the initial phase of breast cancer treatment (surgery/chemotherapy/biological therapy/radiotherapy) patients will be moved to a breast cancer surveillance protocol. Standard mammographic follow-up is yearly mammograms for 5 years. Younger patients will continue yearly mammograms beyond 5 years until they reach the NHSBSP screening age. Known gene carriers will continue surveillance according to guidelines.

London cancer is rolling out a stratified follow-up scheme where most patients will continue with mammographic surveillance screening but will be discharged from clinical follow-up. Follow up will be patient lead, with easy access back to the service when need arises. High risk patients, recurrent cancers, patients on trials, reconstruction/oncoplastic pathways and other exclusion criteria will apply.