Introduction

These guidelines are intended to direct the investigation of patients within the symptomatic breast service. They have been developed in conjunction with guidelines already in existence within London Cancer and updated to reflect recent changes in practice.

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1.1. Imaging 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.
Equipment required for breast assessment would include:

- Full field digital mammography capable of:
  - Magnification views
  - Supplementary views
  - Small field stereotactic guided biopsies
  - Ability to obtain specimen x-rays whilst performing a core biopsy
- Approved tomosynthesis may be used where available
- Ultrasound
- Access to consumables for core biopsies, vacuum biopsies, localisation and marker placement.

2.1 Imaging of discrete breast lesions

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.

Imaging findings should be described (nature, location and size) and BIRADS grading (R/M1-5 and U1-5) recorded.

Discrete masses graded 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 or U2 solid lesions consistent with fibroadenomas under the age of 25 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.

For lesions graded as R4/M4 or U4 and above, ultrasound evaluation of the ipsilateral axilla should also be performed.

MDM discussion for concordance of imaging findings and histology/cytology should be carried out. C1 or B1 results should be reviewed and may require further sampling / investigation unless the lesion is thought to represent a lipoma or a hamartoma.

2.2 Imaging of Breast Cysts

Imaging (ultrasound) should be used to confirm the diagnosis of a breast cyst when it is suspected clinically. Large symptomatic cysts should be aspirated. Cyst fluid with non-suspicious appearance may be discarded. Patients may then be given advice regarding cysts and discharged.
Cyst fluid should 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 and undergo a core biopsy where possible.

2.3. Fibroadenomas

Imaging (ultrasound) should be used to confirm the diagnosis when a fibroadenoma is suspected. If the appearances are benign and confirmed by imaging, a biopsy can be avoided under the age of 25 unless phylloides tumour is suspected, or excision is planned. A core biopsy, when indicated, is preferable to FNAC.

2.4. Phylloides Tumour

If a Phylloides tumour is suspected on imaging, a core biopsy is indicated to confirm the diagnosis and enable better planning of excision.

2.5. Nipple Discharge

Indications that nipple discharge requires imaging include

- Single duct
- Bloody / blood stained discharged
- Unilateral
- Spontaneous

Imaging should include an ultrasound of the affected side. A mammogram should be considered if the patient is over 35 years old.

Where imaging demonstrates a focal lesion or intraductal-filling defect, histological sampling (preferably by core biopsy) should be carried out.

2.6. New Nipple Retraction/ Nipple skin changes

Imaging in these circumstances should be via the normal age related protocol. Ultrasound of the affected side if under 35 years old and over 35 years old, a mammogram should also be advised.

2.7. Nodularity

If generalised: <40 years no imaging is required, (>40 mammogram +/- US recommended) For Focal Asymmetrical Nodularity imaging is indicated. ( <35 years – USS, >35years – mammogram +/- US)
If focal nodularity amounts to a discrete mass, the usual triple assessment protocol, including consideration of histological sampling, should be followed.

2.8. Mastalgia

If there is no palpable abnormality, an opportunistiic mammogram should be performed > /= 40 years

If < 40 years, mastalgia with a normal clinical examination does not require any imaging.

2.9. Breast Infections/Abscess

In cases of clinically suspected breast abscess, an ultrasound of the breast should be performed. Where a collection has formed, percutaneous aspiration and irrigation should be performed. Aspiration should be under ultrasound guidance, and the aspirate sent to microbiology for Culture and Sensitivity if possible. Ultrasound guided aspiration should not be performed when the skin is thinned or is at risk or necrosis – incision and drainage, in these circumstances may be more appropriate.

Following resolution of an abscess, 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. Microcalcifications detected on mammography

Microcalcifications detected on mammography should be graded. Benign R2/M2 calcifications require no follow up.

Calcifications graded R3/M3 or above should undergo further evaluation. Magnification views should be performed. Those calcifications that remain R3/M3 or above on magnification views should undergo histological sampling. (14g or vacuum biopsy)

2.11 HRT

Baseline’ mammography is not routinely required prior to commencing HRT. Women receiving HRT over the age of 50 years are offered screening every three years as part of the NHSBSP as a matter of routine. In this age group, there is no evidence to support more frequent screening. For women under the age of 50 years, the effectiveness of screening may be reduced. Mammographic screening may be considered for women with >5 years of use.
2.12. Lumps in the Male Breast

Gynaecomastia

Imaging investigations for gynaecomastia may include:

- Ultrasound of the breast
- Mammogram
- USS Testes (If clinically indicated)
- CXR (if risk factors for lung cancer)

Male breast lumps

Proceed with triple assessment protocol. Ultrasound +/- mammogram and histological sampling if focal findings demonstrated.

3.1. Vacuum Assisted Biopsy/Excision

Vacuum assisted needle biopsy (VAB) provides higher calcium retrieval and definitive diagnostic rates in the presence of microcalcifications.

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 without atypia

Papillomas or fibroadenomas less than 2.5cm in maximum diameter may be excised by VAB.

3.2 Investigation of B3 lesions

Lesions categorised as B3, of uncertain malignant potential, may be associated with adjacent co-existing malignancy or a long term increased risk of malignancy. All B3 lesions should undergo histological examination whether they represent the radiological abnormality of an incidental finding. All B3 lesions should be discussed in an MDM forum and a management plan agreed.
The following table has been updated to reflect the 2016 guidelines

<table>
<thead>
<tr>
<th>Lesion diagnosed on 14g or vacuum-assisted biopsy (VAB)</th>
<th>Risk of upgrade</th>
<th>Recommended investigation</th>
<th>Suggested approach for follow-up if no malignancy on VAE – awaiting further evidence review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atypical intraductal epithelial proliferation (AIDEP)</td>
<td>18-87% with 14g; pooled value 21% after VAB</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores). If larger area of microcalcification, consider sampling more than one area. Consider histological diagnosis in light of all biopsies.</td>
<td></td>
</tr>
<tr>
<td>Classical (not pleomorphic) lobular neoplasia</td>
<td>Pooled value 27%</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores), even if lesion thought to be incidental.</td>
<td>Surveillance Mammography. [The optimal frequency and length of surveillance mammography for these lesions is unclear and awaits further guidance. At present many units are undertaking annual mammography for 5 years.]</td>
</tr>
<tr>
<td>Flat epithelial atypia</td>
<td>13-21% (in pure form); may co-exist with AIDEP +/- LN and risk then higher</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores). If larger area of microcalcification consider sampling more than one area.</td>
<td></td>
</tr>
<tr>
<td>Radial scar with epithelial atypia</td>
<td>36%</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).</td>
<td></td>
</tr>
<tr>
<td>Papillary lesion with epithelial atypia</td>
<td>36%</td>
<td>Surgical diagnostic excision (because of need to microscopically measure the atypical area for diagnosis)</td>
<td></td>
</tr>
<tr>
<td>Mucocoele-like lesion with epithelial atypia</td>
<td>21%</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).</td>
<td></td>
</tr>
<tr>
<td>Radial scar or papillary lesion without epithelial atypia</td>
<td>&lt;10%</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).</td>
<td>Return to NHSBSP. These lesions are not known to be associated</td>
</tr>
<tr>
<td>Cellular fibroepithelial lesion</td>
<td>37% (range 16-76%) phylloides tumours, but rarely (&lt;2%) malignant</td>
<td>Surgical excision</td>
<td>with long-term risk of development of carcinoma.</td>
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<tr>
<td>Mucocoele-like lesion without epithelial atypia</td>
<td>&lt;5%</td>
<td>Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).</td>
<td></td>
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<tr>
<td>Miscellaneous others such as some spindled cell lesions, microglandular adenosis, adenomyoepithelioma</td>
<td>Depends on lesion</td>
<td>Diagnostic surgical excision</td>
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### 4.1. Further Assessment of Breast with MRI

Some patients will also require further assessment with an MRI scan.

Breast MRI should be carried out on a dedicated breast coil. Contrast enhancement is required unless the scan is purely for implant evaluation. Where possible, scans should be performed within days 6-16 of the patient’s menstrual cycle.

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 in the setting of advanced mammographic density
- 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

Breast MRI should also be used for screening of high risk patients in conjunction with the NHSBSP

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

Prior to undertaking any interventional procedures, an evaluation of risk should be undertaken eg to establish allergies, bleeding diatheses or anticoagulation history. The necessary precautions should then be carried out.

5.1. Core biopsy of the Breast

This should be performed for the histological evaluation of breast lesions as described above. The procedure should be performed under local anaesthetic cover obtaining a minimum of two 14G cores. Where a core biopsy is not deemed safe, for instance due to the proximity of vessels, an FNAC should be considered.

5.2. Needle biopsy of the axilla

All patients that have a non-operative diagnosis of breast cancer should have an ultrasound assessment of the ipsilateral axilla performed, preferably at the time if the initial assessment. For patients with borderline or cortically enlarged nodes, e.g.: cortical thickness is >2.5mm, eccentric thickening of the cortex, abnormal morphology or vascular flow, absence of fatty hilum, an FNAC or preferably a core biopsy should be performed. This should be performed under ultrasound guidance.

5.3. Marker placement

Marker placement should be considered in:

- Patients embarking on neoadjuvant chemotherapy
- Patients who have undergone VAB to mark biopsy site
- Patients who have undergone vacuum excision of a lesion
- Patients where concordance of site is required

5.5. Wire Localisation

Wire localisations should be performed under ultrasound or stereotactic guidance for non-palpable breast lesions in patients undergoing breast-conserving surgery. Facility should be available to perform specimen xrays contemporaneous to surgery.
6.1. 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, Sentinel Lymph Node Biopsy (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.

7.1. Imaging during pregnancy

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.

For pregnant patients who require sentinel node studies, Radiotracer alone is preferred due to blue dye related risks.
8.1. Follow-up Imaging

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.