

Guideline for the Imaging of Patients Presenting with Breast Symptoms incorporating the guideline for the use of MRI in breast cancer

Version History

Version	Date	Summary of Change/Process
0.1	09.01.11	First draft developed by Angela Luck (AL)
0.1	24.02.11	Reformatted by Lara Barnish for review by AL
0.2	25.05.11	Reviewed by AL and circulated to Doreen Cox
0.2	25.05.11	Circulated to the NSSG and Sally Bradley
0.3	13.06.11	Discussed and reviewed by Breast NSSG and updated by AL
1.0	11.07.11	Reviewed and endorsed by Guidelines Sub Group

Date Approved by Network Governance	July 2011
--------------------------------------------	------------------

Date for Review	July 2014
------------------------	------------------

1 Scope of the Guideline

This guidance has been produced to support the following:

- The imaging of women referred to the symptomatic breast clinic
- The use of MRI in evaluation of the breast

The imaging for follow-up following the diagnosis of breast cancer can be found in the Network follow-up guidelines:

<http://www.birminghamcancer.nhs.uk/staff/clinical-guidelines/breast-cancer>

2 Guideline Background

These guidelines closely follow the document: 'Best practice diagnostic guidelines for patients presenting with breast symptoms' published by the Department of Health (November 2010) and incorporate the Pan Birmingham Cancer Network Guidelines for the use of MRI in Breast Cancer (version 3 December 2008).

Endorsed by the Clinical Governance Committee

Guideline Statements

3 All patients

- 3.1 The triple assessment of patients with breast symptoms comprises clinical assessment, imaging assessment and needle biopsy. The tests used in an individual case depend upon the presenting symptoms, the clinical findings and the patient's age. These guidelines address the indications for imaging and which imaging modality or combination of modalities may be most appropriate.
- 3.2 Breast imaging facilities should include x-ray mammography and high frequency ultrasound. These tests should be available during the initial assessment clinic.
- 3.3 MRI may be appropriate in addition to mammography and/or ultrasound, or even the imaging modality of choice in certain patients.
- 3.4 Digital mammography is preferred to analogue mammography particularly for women with dense breasts and the technical quality of mammography should be equivalent to that in the NHS Breast Screening Programme.
- 3.5 Ultrasound probes suitable for breast imaging are 12 MHz or more, and ultrasound should only be performed by a member of the multidisciplinary team who is trained in and regularly undertakes ultrasound evaluation of symptomatic breast patients, or by a trainee under supervision.
- 3.6 Clinical assessment prior to imaging is advised to determine the patient's symptoms and relevant history, including the date of any previous mammography. The physical examination should establish the nature and site of any abnormalities within the breasts, and be correlated with the area of concern found by the patient or referring doctor. The results of the examination should be recorded clearly in terms of site and extent of any lesion or textural change found, and assessment of the level of suspicion for malignancy should be made; use of the P1-5 scale is recommended (see below). This will guide the choice of which imaging modality or modalities are most appropriate and facilitate accurate targeted ultrasound.

P1 = normal

P2 = benign

P3 = uncertain

P4 = suspicious

P5 = malignant

Endorsed by the Clinical Governance Committee

- 3.7 The imaging report should include the level of suspicion for malignancy; the Royal College of Radiologists Breast Group Classification U1-5, M1-5 and MRI 1-5 is recommended:

1 = normal
2 = benign
3 = indeterminate / probably benign
4 = suspicious of malignancy
5 = highly suspicious of malignancy

4 Biopsy for patients where cancer is suspected

- 4.1 Clinical assessment and imaging assessment should be completed before needle biopsy (fine needle aspiration cytology or core biopsy) is performed. Core biopsy is preferable to FNAC.
- 4.2 Biopsies should be performed under image-guidance to achieve greatest accuracy and reduce the need for repeat procedures. Clinically-guided biopsies are indicated when the imaging is normal but there remains a localised clinical abnormality. Clinically-guided biopsies may be appropriate for cases of palpable, locally advanced breast cancer; also suspected Paget's disease and lesions within or attached to the skin should undergo clinically-guided punch biopsy.
- 4.3 Patients with known recurrent cyst disease and a clinically obvious cyst may have cyst aspiration following clinical assessment, but ultrasound +/- mammography should still be carried out in these patients to assess for any atypical features of the symptomatic cyst and surrounding tissues prior to aspiration.
- 4.4 Some patients attending the symptomatic breast clinic will not require full triple assessment, but most will require clinical assessment and imaging as appropriate. Please see the algorithms from best practice diagnostic guidelines for patients presenting with breast symptoms' published by the Department of Health (November 2010) (see appendix 1).

5 Imaging in the Symptomatic Clinic

- 5.1 Ultrasound is the imaging modality of choice for women aged <40 and during pregnancy and lactation.
- 5.2 Mammography is used in the evaluation of women aged 40 and over, with the addition of ultrasound targeted to clinical or mammographic abnormalities.

Endorsed by the Clinical Governance Committee

Mammography should be carried out in patients aged 35-39 with clinically suspicious findings (P4, P5) and considered in those with P3 findings where ultrasound is normal. Patients of any age with proven malignancy should undergo mammography.

- 5.3 Mammography should include CC and MLO views of each breast; extended and/or paddle views may also be required as directed by the radiologist or consultant radiographer. If mammography has been performed within a year of the current presentation and is available for review, further mammography is not required unless there are new and suspicious findings on either clinical assessment or ultrasound.

6 Breast lump, lumpiness, localised change in texture

- 6.1 ≥40 year olds: Mammography and ultrasound is indicated.
- 6.2 <40 year olds: Ultrasound is indicated in patients with clinically benign or uncertain lesions (P2, P3). If ultrasound confirms normal or benign findings, eg cyst or circumscribed solid lesion, mammography is unlikely to provide additional diagnostic information. Targeted ultrasound should also be performed in patients with the above symptoms when the clinical examination is normal (P1).
- 6.3 Ultrasound should be targeted to the site of concern; whole breast ultrasound is not indicated. If suspicious findings are identified in the breast, assessment of the axilla with ultrasound should be undertaken.
- 6.4 Mammography should be considered in patients 35 - 39 with indeterminate clinical findings (P3) and normal ultrasound findings (U1). Mammography may be helpful in further evaluation of U3 lesions. Mammography should be performed in women <40 who meet P4/5 or U4/5 criteria.

7 Nipple symptoms

- 7.1 Imaging may be necessary following clinical assessment. Generally only single duct spontaneous discharges of genuine blood-stained, clear or serous colour need further evaluation. Recent unilateral nipple inversion is unlikely to be significant in the absence of any underlying palpable or mammographic abnormality, particularly if the inversion is correctable. Mammography and punch biopsy is indicated where Paget's disease is suspected.
- 7.2 ≥40 year olds: Mammography is indicated.

Endorsed by the Clinical Governance Committee

- 7.3 Ultrasound is indicated if there is a palpable or a mammographic abnormality, or if cytology raises the possibility of a papilloma.

8 Breast pain, infection

- 8.1 Breast pain alone is not an indication for imaging.
- 8.2 If infection or abscess is clinically suspected, ultrasound should be performed and any fluid or pus aspirated and cultured.
- 8.3 If there are focal clinical signs, image according to the guidelines for a breast lump.

9 Axillary lump (no clinical breast abnormality)

Image as for breast lump (mammography if patient ≥ 40 or if P4/5, ultrasound targeted to the symptomatic site and to any breast lesions identified on mammography if undertaken). Needle biopsy is indicated if enlarged axillary nodes or mass lesion (U2-5) identified, under imaging guidance. Further tests (e.g. CXR, CT) may be required if the clinical assessment or histology suggests lymphoma, TB, sarcoid etc.

10 Women with breast implants

- 10.1 Women with clinical findings should be imaged according to the above guidelines, including mammography and ultrasound as appropriate.
- 10.2 Ultrasound may identify possible implant disruption or leakage. An MRI may identify disruption with more certainty and is the imaging modality of choice where intra or extracapsular rupture is suspected. A suspicious lesion within the breast tissue may also be further evaluated with MRI, but this should follow initial imaging with ultrasound and mammography and after consultation with a radiologist (different MRI protocols are used in the assessment of implant integrity and in the assessment of breast lesions).

11 Breast lumps in men

- 11.1 Mammography and/or ultrasound should be performed in men with unexplained or suspicious unilateral breast enlargement.

Endorsed by the Clinical Governance Committee

- 11.2 Imaging is not required in bilateral male breast enlargement, unless there is clinical uncertainty in differentiating between true gynaecomastia and fatty breast enlargement.
- 11.3 Testicular ultrasound is indicated if there are suspicious findings on testicular clinical examination or raised α FP or β HCG.
- 11.4 Core biopsy should be performed in patients with any of the following findings: P3-5, U3-5, M3-5. Fine needle aspiration is not recommended.

12 Ultrasound guided biopsy

- 12.1 Following clinical assessment, if a mass or possible lesion is identified on ultrasound it is preferable to biopsy the lesion under ultrasound guidance. Core biopsy is preferable to FNAC. All patients with U3-5 findings should undergo biopsy.
- 12.2 The following solid breast lesions may be diagnosed when clinical and imaging findings are in agreement, without needing histological confirmation:
 - a) Presumed fibroadenoma: The following criteria must be satisfied: patient under 25 years of age, P2 clinical findings, U2 ultrasound findings of a solid mass eg ellipsoid shape (wider than tall), well-defined smooth outline, less than 4 gentle lobulations. Biopsy may be considered if there has been a demonstrable size increase.
 - b) Presumed fat necrosis: P2, U2 (imaging typical of fat necrosis) +/- M1/M2.
 - c) Presumed lipoma or hamartoma: P2, U2 +/- M1/M2.
- 12.3 Biopsy should be performed if there is any doubt about the nature of the lesion or discrepancy between the clinical assessment and imaging features. It is reasonable, for instance, to biopsy presumed fat necrosis if there is no history of trauma.

13 Multiple breast lesions

- 13.1 Multiple U2 lesions, having the same morphological features on ultrasound, are likely to be fibroadenomas and needle biopsy of one lesion is sufficient in a \geq 25 year old.
- 13.2 Any lesion with atypical or suspicious features (U3-5) should be biopsied. If multifocal malignancy is suspected, sampling of more than one lesion may be necessary to establish disease extent and advise appropriate surgical treatment.

Endorsed by the Clinical Governance Committee

Endorsed by the Clinical Governance Committee

s:\cancer network\guidelines\guidelines and pathways by speciality\breast\current approved versions (word and pdf)\guideline for the imaging of patients with breast sympoms version 1.0.docS:\Cancer Network\Guidelines\Guidelines And Pathways By Speciality\Breast\Current Approved Versions (Word And PDF)\Guideline For The Imaging Of Patients With Breast Symptoms

14 MRI scanning of the breast

- 14.1 MRI may be used as a screening tool for young asymptomatic patients referred to the breast clinic because they are at high risk for breast cancer (either those at genetic risk or following previous mediastinal radiotherapy¹). Surveillance MRI examinations should be independently double read by MRI readers who each report a minimum of 100 breast MRI examinations per year and at least one of the two readers should be a breast radiologist who satisfies the NHSBSP standards as a breast screening film reader.
- 14.2 MRI may also be used to support the diagnosis of breast cancer following assessment with mammography and ultrasound, including when:
- a) The examination or initial imaging suggests there may be multi-focal disease.
 - b) There is discordance regarding tumour size between the clinical examination and initial imaging, or the size of the tumour cannot be reliably assessed clinically or on imaging (this typically includes infiltrating tumours, most notably lobular carcinomas, and when the tumour is occult on initial imaging modalities).
 - c) The patient has lobular cancer, and wide local excision is being considered.
 - d) In the presence of biopsy / FNA proven lymph node metastasis suggesting a primary breast cancer where clinical examination and conventional imaging has failed to detect the primary lesion.
 - e) The patient has silicone implants.
 - f) There remains a high suspicion for malignancy and US and needle biopsy have not made a diagnosis.
- 14.3 MRI may identify a breast lesion/s not originally identified on mammography or ultrasound. A second-look ultrasound with the additional information from the MRI often identifies the lesion, enabling US-guided biopsy to be performed. MRI-guided biopsy of lesions not diagnosed with mammography or ultrasound is appropriate where this is available.
- 14.4 MRI may also be used to support the follow-up of patients with breast cancer in the following situations:
- a) In the exclusion of recurrent disease in scar tissue where conventional imaging and biopsy has failed to exclude suspected recurrence within scar tissue.

¹ See section 6 of the Network Guideline for Referral to Secondary Care Breast Services at <http://www.birminghamcancer.nhs.uk/staff/clinical-guidelines/breast-cancer>

Endorsed by the Clinical Governance Committee

- b) In young patients (i.e. under 40) where mammography is difficult to interpret.
- c) In those with neoplasms whose original tumour was occult on mammography.
- d) In the follow-up of patients on neo-adjuvant chemotherapy when conventional imaging has failed to demonstrate a response, or when the tumour is poorly delineated with conventional imaging.
- e) In the demonstration of the extent of chest wall recurrence.

15 Patient information and counselling

- 15.1 All patients, and with their consent, their partners will be given access to appropriate written information during their investigation and treatment, and will be given the opportunity to discuss their management with a clinical nurse specialist who is a member of the relevant MDT. The patient should have a method of access to the breast team at all times.
- 15.2 Access to psychological support for those diagnosed with breast cancer will be available if required. All patients should undergo an Holistic Needs Assessment and onward referral as required.

16 Clinical trials

- 8.1 Wherever possible, patients who are eligible should be offered the opportunity to participate in National Institute for Health Research portfolio clinical trials and other well designed studies.
- 16.2 Where a study is only open at one Trust in the Network, patients should be referred for trial entry. A list of studies available at each Trust is available from Pan Birmingham Cancer Research Network.
Email: PBCRN@westmidlands.nhs.uk.
- 16.3 Patients who have been recruited into a clinical trial will be followed up as defined in the protocol.

Monitoring of the guideline

Implementation of the guidance will be considered as a topic for audit by the NSSG in 2013.

Endorsed by the Clinical Governance Committee

Authors

Angela Luck Consultant Radiologist
University Hospitals Birmingham NHS Foundation Trust
Doreen Cox Consultant Radiologist
Sandwell and West Birmingham Hospitals NHS Trust
Lara Barnish Deputy Director of Nursing
Pan Birmingham Cancer Network

References

Department of Health (2010). Best Practice Diagnostic Guidelines for Patients Presenting with Breast Symptoms.

Approval Signatures

Pan Birmingham Cancer Network Governance Committee Chair

Name: Doug Wulff



Signature:

Date: July 2011

Pan Birmingham Cancer Network Manager

Name: Karen Metcalf




Signature:

Date: July 2011

Network Site Specific Group Clinical Chair

Name: Alan Jewkes



Signature:

Date: July 2011

Endorsed by the Clinical Governance Committee

s:\cancer network\guidelines\guidelines and pathways by speciality\breast\current approved versions (word and pdf)\guideline for the imaging of patients with breast symptoms version 1.0.docS:\Cancer Network\Guidelines\Guidelines And Pathways By Speciality\Breast\Current Approved Versions (Word And PDF)\Guideline For The Imaging Of Patients With Breast Symptoms

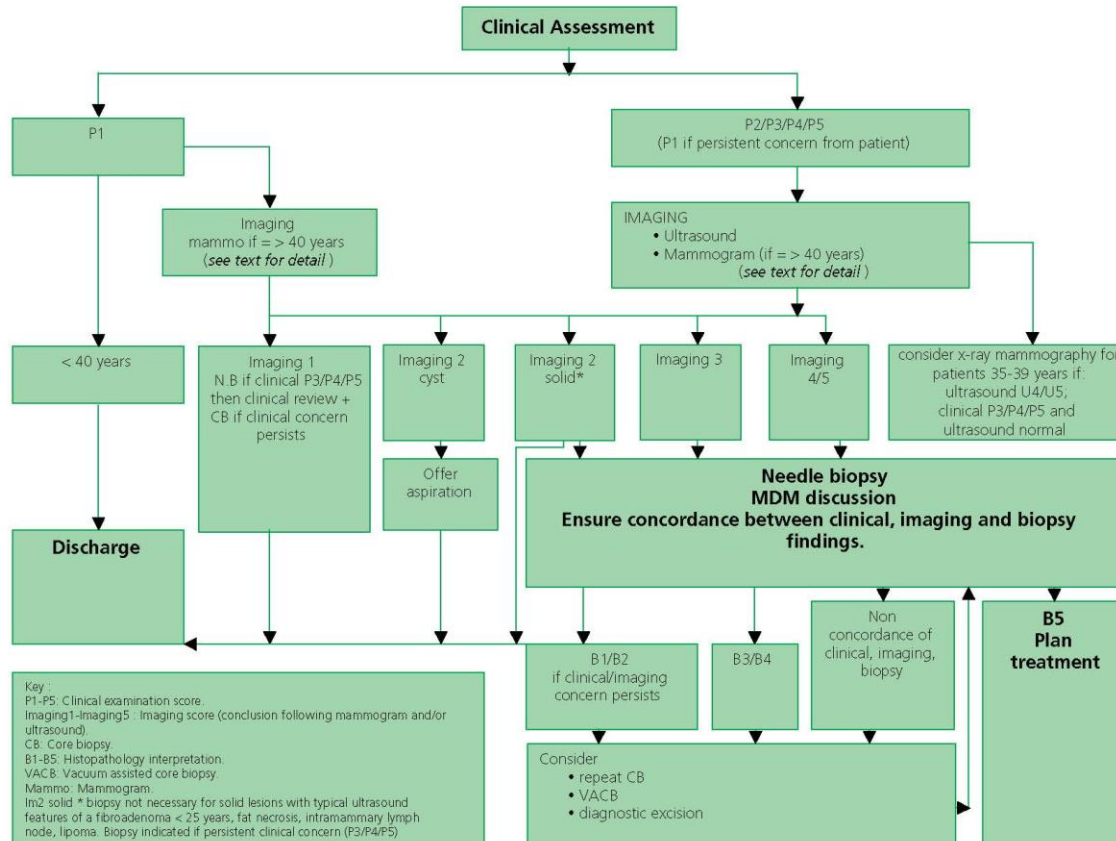
Endorsed by the Clinical Governance Committee

s:\cancer network\guidelines\guidelines and pathways by speciality\breast\current approved versions (word and pdf)\guideline for the imaging of patients with breast sympoms version 1.0.docS:\Cancer Network\Guidelines\Guidelines And Pathways By Speciality\Breast\Current Approved Versions (Word And PDF)\Guideline For The Imaging Of Patients With Breast Symptoms

Version 1.0.Doc
Page 11 of 11

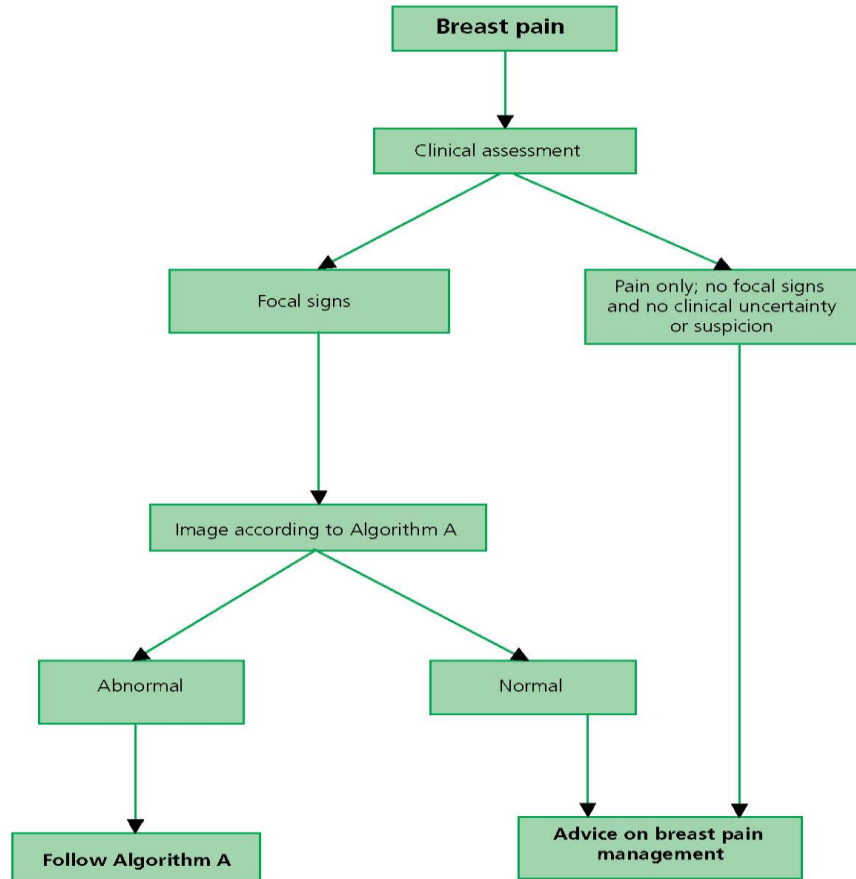
Appendix 1

5. Algorithm A. Assessment: Lump/Lumpiness



Endorsed by the Clinical Governance Committee

5. Algorithm B. Assessment: Breast pain



Endorsed by the Clinical Governance Committee