
Best practice diagnostic guidelines for patients presenting with breast symptoms



Editors

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Foreword

Breast cancer is the most commonly diagnosed cancer in the UK. We lag behind the rest of Europe in survival rates. We know that the biggest contributor to our poorer outcomes is late presentation and treatment. Yet guidance on the investigation of women presenting with breast symptoms that spans the medical disciplines involved in their care has been limited.

These guidelines define, and bring together in one place, the key clinical and process markers of quality for the multidisciplinary diagnostic team to promote both quality and efficiency. They will be vital in ensuring that all breast cancer patients receive high quality, joined up care. They are as vital a guide for the GP practice as they are for the hospital specialists.

However, guidelines alone are not enough – we need to turn policies into practice and this is why the support of health professional colleges and societies in promoting these guidelines to their members is particularly welcome.

The engagement and collaboration of stakeholders from both primary and secondary care, alongside the patient perspective, in the development of these guidelines has been essential to produce a truly coordinated diagnostic pathway. I would like to thank the editors of these guidelines and all who have contributed to their preparation and to Breakthrough Breast Cancer for supporting their preparation and dissemination.

These best practice guidelines will make a real difference to the many thousands of patients referred for suspected breast cancer each year. I hope they will also serve as a useful model for the development of similar guidelines for other cancer types to benefit many more patients in future.



*Professor Sir Mike Richards CBE
National Clinical Director for Cancer*

Introduction

Every week nearly 900 people are diagnosed with breast cancer in the UK. The incidence has more than doubled over the last twenty-five years, and it is now our most common cancer. It is therefore not surprising that hospital breast services have come under increasing pressure from their diagnostic workload in breast disease, both symptomatic and screen-detected, and this is set to increase further with two week waits for all, and the expansion of the NHS Breast Screening Programme. At the same time the commitments of breast surgeons have expanded, to include oncoplastic work, and those of breast radiologists and consultant radiographers to deal with more diagnostic and interventional procedures. Breast diagnostic pathways have changed over the past decade, in particular with increased use of guided biopsy, greater reliance on tissue core histology as opposed to cytology, and technological advances such as digital mammography. The guidelines for diagnosing screen-detected breast cancer have been updated to take account of these advances, and there is now a similar need to provide up-to-date guidelines on the diagnosis of symptomatic disease. In doing so, we are mindful of the benefits that we can achieve by making full use of all members of our multidisciplinary team, developing their skills, and extending and supporting their roles.

Statement of purpose

These guidelines cover the process of diagnosis of patients referred by their general practitioners to hospital breast units for the assessment of breast symptoms, and include all such referrals regardless of whether cancer is suspected. They deal specifically with the process of triple assessment, up to the point of diagnosis. They do not extend into the management of diagnosed benign or malignant disease. Whilst primarily aimed at patients with new symptoms, they also apply to patients with a past history of breast cancer presenting with a new concern. They are written for the benefit of all health care professionals across primary and secondary care involved in the management of breast disease in hospitals and the community; for patients; and to inform those who manage provision, commissioning and funding of services.

These guidelines are designed to be used alongside existing detailed information and guidance:

- Association of Breast Surgery at BASO. *Surgical guidelines for the management of breast cancer*. 2009
- Map of Medicine: *Symptomatic breast disease*. http://healthguides.mapofmedicine.com/choices/map/breast_disease1.html
- National Cancer Action Team. National Cancer Peer Review Programme. *Manual for Cancer Services 2008: Breast Measures*.

- National Cancer Action Team. *The characteristics of an effective multidisciplinary team (MDT)*. 2010
- National Institute for Health and Clinical Excellence. *Referral guidelines for suspected cancer*. 2005
- National Institute for Health and Clinical Excellence. *Early and locally advanced breast cancer: Diagnosis and treatment*, NICE clinical guideline 80. 2009
- National Institute for Health and Clinical Excellence. *Advanced breast cancer: Diagnosis and treatment*, NICE clinical guideline 81. 2009
- National Institute for Health and Clinical Excellence. *Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care (partial update of CG14)*. 2006
- National Institute for Health and Clinical Excellence, *Guidance on cancer services: Improving outcomes in breast cancer – manual update*. 2002
- National Institute for Health and Clinical Excellence, *Guidance on cancer services: Improving supportive and palliative care for adults with cancer: the manual*. 2004
- NHS Breast Screening Programme. *Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening*. NHSBSP Publication No 50. 2001
- NHS Breast Screening Programme & Royal College of Pathologists. *Guidelines for pathology reporting in breast disease*. NHSBSP Publication No 58(v2). 2005
- NHS Choices. www.nhs.uk
- NHS Improvement. *Ensuring better treatment: Going further on cancer waits. An improvement guide for supporting sustainable delivery*. 2009
- Royal College of Pathologists. *Tissue pathways for breast pathology*. 2009
- Skills for Health – M1: *Assess individuals with suspected breast disease*. <https://tools.skillsforhealth.org.uk/competence/show?code=M1>

Methods

- The guidelines are based on the expert opinion of a multidisciplinary working group representing all the professional disciplines involved in the management of patients presenting with breast symptoms from initial presentation in primary care to diagnosis at the breast clinic multidisciplinary meeting. The recommendations for best practice are the result of discussion between the disciplines represented on the working group and are a consensus opinion.
- A patient representative was a member of the working group and was involved in discussion at each stage of the development of the guidelines.
- Draft versions of the guidelines were circulated to the membership of each of the professional groups involved in the diagnostic process and comments received were brought to the working party for discussion and, when appropriate, for incorporation into the guideline.
- Evidence from peer reviewed published articles was sought and, where available, has been used to inform the guidelines. The articles used are cited in the references section. Reference is made to relevant existing guidelines.
- Further research and audit is encouraged in areas of practice for which there is a lack of published evidence in order to inform future versions of these guidelines.

1: Referral

1.1	Referral from primary care to breast clinic
Q11	Patients with the following symptoms or signs should be referred for assessment. All patients referred to the breast clinic should receive an appointment within two weeks of the date of receipt of the referral. Symptoms suggestive of urgent attention are denoted as U, and symptoms considered non-urgent but still requiring an appointment within two weeks are denoted as NU. (Please note that family history referrals and cosmetic referrals are excluded from the two week wait pathway.)
1.2	Lump, lumpiness, change in texture
	- Discrete lump in any woman 30 years and older that persists after next period or presents after menopause (U) At any age: - Discrete hard lump with fixation +/- skin tethering/dimpling/altered contour (U) - A lump that enlarges (U) - A persistent focal area of lumpiness or focal change in breast texture (U) - Progressive change in breast size with signs of oedema (U) - Skin distortion (U) - Previous history of breast cancer with a new lump or suspicious symptoms (U) Under 30 years: - A lump that does not meet above criteria (NU) Male patients: - Over 50 years with unilateral firm subareolar mass +/- nipple discharge or associated skin changes (U)
1.3	Nipple symptoms
	- Spontaneous unilateral blood stained nipple discharge (U) - Unilateral nipple eczema or nipple change that does not respond to topical treatment (U)

	- Recent nipple retraction or distortion (U) Women who can be managed at least initially by GP: - Women under 50 years who have nipple discharge that is from multiple ducts or is intermittent and is neither blood stained nor troublesome (NU) Male patients: - Over 50 years with unilateral firm subareolar mass +/- nipple discharge or associated skin changes (U)
1.4	Breast Pain
	Patient with minor/moderate degree of breast pain with no discrete palpable abnormality, when initial treatment fails and/or with unexplained persistent symptoms (NU)
1.5	Axillary lump (in absence of clinical breast abnormality)
	Persistent unexplained axillary swelling (U)
1.6	Communication
	Role of the GP - The general practitioner plays a fundamental role in supporting the management of symptomatic breast patients. They are supported in their decision to refer (and to re-refer where necessary) by the existence of national guidelines. General practitioners are well placed to support the patient through the referral process, by providing choice and information, and also through any subsequent treatment phases by providing ongoing holistic support. They are often seen as the first port of call by the patient. Presentation of the patient with new breast symptoms - In the initial consultation the GP should assess the patient with a view to referral to a symptomatic breast clinic. The GP may find that the patient has normal or benign changes that do not require referral and, at this point, they should give reassurance supported with the appropriate literature. - All patients should be aware of present breast screening processes and informed not to await their next screening appointment if they develop symptoms.

Referral to clinic

- Once the patient is referred to the breast clinic, clear communication between professionals is vital at this point to ensure that all relevant information regarding the patient is relayed to the clinic prior to the patient's clinic attendance.
- The patient should receive written and/or verbal information regarding the symptomatic breast clinic. This information should include waiting times for an appointment and the likely process that will occur during the clinic (see Appendix A). This information may be sent out with the appointment letter and should ideally also include information on length of visit.
- The patient should also be provided with guidance for obtaining further information.
- Patients should be reminded of the importance of keeping their appointment.

2: Assessment

2.1	Assessment
Q12	The diagnostic assessment of patients with breast symptoms is based on the Multidisciplinary Triple Diagnostic Method: A. Clinical assessment B. Imaging assessment C. Needle biopsy ● The tests used in an individual case will be determined by the presenting symptom(s), the clinical findings and the age of the patient. ● The assessment clinic should be organised so that all appropriate tests can be carried out during the same clinic attendance. ● Use of the Triple Diagnostic Method will enable a diagnosis to be established in the majority of patients and diagnostic surgical excision should be rarely required. ● The delayed diagnosis of cancers after Triple Assessment in women who present with symptoms and are subsequently diagnosed with cancer is approximately 0.2%. ● Patients in whom the Triple Assessment is negative should be advised to seek advice from their GP if they remain concerned or if there is a change in symptoms or signs. ● The breast imaging facilities should include x-ray mammography and high frequency ultrasound with probes suitable for breast imaging (12 MHz or more). Digital mammography is preferred to film screen mammography particularly for women below 50 years and for those with dense breast tissue. ● The technical quality of mammography should be equivalent to that in the NHS Breast Screening Programme (NHSBSP). ● Breast imaging facilities should be integrated with, or be within reasonable distance of, the breast clinic for patient convenience and efficient service delivery.

- Breast MRI does not form part of the initial imaging assessment of patients in the symptomatic breast clinic. It may, however, be useful in the further investigation of some breast lesions and in the evaluation of patients with confirmed breast cancer. MRI should be carried out according to local policy agreed by the multidisciplinary team.
- There should be clear administrative links between breast imaging and the breast clinic in order to ensure:
 - efficient service delivery
 - best use of resources
 - clear and rapid communication for clinic scheduling, exchange of information and results of tests
- The clinical assessment and appropriate imaging and needle biopsy should be carried out during the same clinic appointment.

Communication

Assessment

- All staff should possess appropriate communication skills for both communicating with patients and ensuring consistent communication with all health professionals involved in the patient's care.
- Healthcare professionals should assess women during the diagnostic process (i.e. ascertain the patient's understanding of the situation and expectations) to intervene accordingly as patients' own appraisals of their illnesses will affect their understanding of their situation and the diagnostic process, and their psychological well-being.
- The patient should be given clear information, that meets their individual needs, at each stage of the diagnostic process and made aware of the availability of, and contact details for, their breast care nurse.
- For patients who undergo needle biopsy, both written and verbal information should be provided, for those who wish, regarding the likely diagnosis and outcome of the biopsy.
- All patients who undergo needle biopsy should be provided with a definite appointment or other agreed arrangement for communication of the biopsy result, within five working days.
- A discussion between the patient and a clinician who has been involved with the assessment of the patient should occur prior to leaving clinic. This is to inform the patient of the likely outcome of the biopsy result in light of the clinical examination and imaging findings. If these are felt likely to be malignant a breast care nurse should be present at that consultation where possible.

Q13

- Patients should be advised of when they may receive their diagnosis – i.e. know at what point they will receive their diagnosis, so they can arrange to be accompanied by family/friend if they wish.
- Patients who perceive themselves to have a high risk of breast cancer may continue to feel distressed following a benign diagnosis so it is important to accurately address these (mis)perceptions at the initial consultation.
- The results of Triple Assessment should be discussed at a multidisciplinary meeting for all women who undergo needle biopsy. The results of each element of the Triple Assessment should be considered in order to ensure a correct diagnosis and appropriate further management. If there is discordance between the results, further assessment, if necessary including repeat biopsy, should be considered (see section 3).

Outcome of assessment

- Results should be given by an appropriately trained senior clinician who has experience and training in breaking bad news. The patient should be given their results in the presence of a breast care nurse and any relative/carer/friend of the patient that they wish to have at the consultation.
- Communicating the diagnosis takes time and it should be ensured that sufficient time and support is provided for this and that it takes place in an appropriate setting.
- Written information and supportive literature may be appropriate for the patient and their carers or family at this point. The format and language of written information should always be appropriate and easily understood and information and support should always be tailored to meet the needs of the individual.
- GPs should be informed of a diagnosis of cancer within 24 hours including details of test results and the care plan.
- GPs should be informed if the patient does not have a diagnosis of cancer within 10 working days.

Patients with benign/normal results:

- Patients should be given appropriate reassurance and an explanation of their symptoms. Literature to support this verbal conversation may be useful.

Patients who have an equivocal result or require repeats:

- Patients should have a face to face consultation to clearly discuss the need for further tests and possible outcomes, and a simple care plan put together.
- Clear explanation should be given of why further tests may be needed.

Patients who have a breast cancer diagnosis:

- Around the time of diagnosis approximately half of all cancer patients experience levels of distress that may adversely affect their quality of life, whilst around one third report significant levels of anxiety and/or depression. Clear routes of referral to specialist support services should be in place for any patient identified as needing further support beyond that provided by specialist nurses, e.g. clinical psychology referral.

Role of the Breast Care Nurse

- The Breast Care Nurse (BCN) (Cancer Nurse Specialist) can play a vital role in improving the experience for patients with breast disease throughout all stages of the patient journey starting from the referral from the GP. As well as providing information, they are able to carry out a range of technical and emotional functions, with a coordination role in providing continuity of care throughout the patient pathway whether this involves a benign or a cancer diagnosis. The BCN works as part of the integrated multidisciplinary team with engagement in appropriate 'what if' conversations. The BCN may be required to support and advise patient families and carers. They will have the relevant skills to carry out this role and have undertaken an advanced communication skills course.

A. Clinical assessment

- All patients who attend the symptomatic breast clinic should have a clinical consultation and physical breast examination carried out by a suitably trained member of the multidisciplinary team. This may be a nurse practitioner, radiographer, radiologist, breast clinician or surgeon.
- The consultation is aimed at establishing the nature, site and duration of the patient's symptoms and gathering other relevant history, e.g. past history of breast disease or investigation, date of last mammogram, participation in breast screening, family history, history of HRT. It can be helpful to ask the patient to complete a questionnaire at the time of attendance at the clinic (see Appendix B for an example of questions in a patient questionnaire).
- The physical examination should establish the nature and site of any abnormalities found either on visual inspection or palpation of the breast. In particular, the physical examination should establish whether there is a discrete lump present or an area of textural change. The findings of the clinical examination should be correlated with the area of concern found by the patient or referring doctor.

Q14a
Q14b

Q15

- The physical examination should include an assessment of the axillary and supraclavicular nodes. The results of physical examination should be recorded clearly using a diagram to indicate the site and extent of any lesions found. The level of suspicion for malignancy should be recorded using the 1-5 scale:

P1 = normal

P2 = benign

P3 = uncertain

P4 = suspicious

P5 = malignant

B. Imaging assessment

- Appropriate imaging should be carried out by suitably trained members of the multidisciplinary team e.g. radiologist, radiographer, breast clinician, nurse, surgeon.
- Ultrasound is the imaging method of choice for the majority of women aged < 40 years and during pregnancy and lactation.
- X-ray mammography is used in the investigation of women aged = > 40 years with the addition of ultrasound when indicated.
- X-ray mammography is not indicated for the majority of patients aged < 40 years.
- X-ray mammography should be carried out in patients aged 35-39 years with clinically suspicious or malignant findings (P4, P5) and should be considered in patients with clinically indeterminate lesions (P3) if ultrasound is normal.
- X-ray mammography should be carried out in all patients with proven malignancy even if aged < 40 years.
- Mammography should include MLO and CC views of each breast. Digital mammography is preferred to film screen mammography, particularly for women aged < 50 years and for those with dense breast tissue.
- If a suspicious abnormality is demonstrated on mammography, it may be helpful to further characterise the mammographic features using magnification or spot compression views. These should be carried out during the clinic as directed by the radiologist or the consultant radiographer in breast imaging.

Q16a
Q16b

- The level of suspicion for malignancy should be recorded using the RCR Breast Group Classification U1-U5 and M1-M5:

1 = normal

2 = benign

3 = indeterminate/probably benign

4 = suspicious of malignancy

5 = highly suspicious of malignancy

C. Needle biopsy (Needle core biopsy and fine needle aspiration)

- The clinical and imaging work up should be completed before needle biopsy (fine needle aspiration cytology (FNAC) or core biopsy) is performed.
- Breast needle biopsies should be performed under imaging guidance in order to achieve greatest accuracy and reduce the need for repeat procedures.
- Free hand core biopsy may be appropriate for cases of palpable, locally advanced breast cancer and cases in which the imaging is normal but there remains a suspicious localised clinical abnormality.
- Needle core biopsy is preferred rather than FNAC for most solid lesions and for lesions suspicious for cancer because of the higher sensitivity and specificity achieved in most centres and because of the importance of oncological information including tumour type, grade and receptor status obtained with histology. In units where appropriate expertise exists, FNAC is an acceptable alternative to needle core biopsy in the initial evaluation of symptomatic breast lesions and in patients presenting with a lump in the axilla alone with no known clinical abnormality of the breast. Centres using cytology should demonstrate appropriate sensitivity and specificity.
- Biopsy of lesions within or attached to skin can often be carried out using a 3mm or 4mm punch biopsy needle under local anaesthetic. This is particularly suitable for suspected Paget's disease of the nipple and local recurrences in the skin.
- Needle aspiration of clinically obvious cysts in patients with known recurrent cystic disease may be performed following initial clinical assessment. Appropriate imaging with mammography and ultrasound should still be carried out in such cases.
- Needle core biopsy and FNAC samples should be handled and reported (B1-5, C1-5) according to the Royal College of Pathologists tissue pathways guidance and NHSBSP/Royal College of Pathologists guidelines for non-operative diagnostic procedures and reporting.

Q17
Q18c
Q18a
Q18b

2.2	One-stop assessment
Q19	● At one-stop assessment all the required elements of triple assessment are performed during a single visit. This provides: – a basis for definitive diagnosis in the majority of patients – reassurance with no need for further attendance in most patients with non-malignant conditions – information for multidisciplinary meeting (MDM) treatment planning prior to review of those diagnosed to have cancer ● Some patients do not require all the elements of triple assessment, as outlined below and defined in the Algorithms. This includes those with: – resolved symptoms and no clinical abnormality – clearly identified benign conditions with no other suspicious features found on clinical and imaging assessment such as: ■ areas of benign breast change and diffuse nodularity without a dominant mass ■ simple cysts whether aspirated or not ■ breast pain ■ non-bloody nipple discharge ■ gynaecomastia ● One-stop breast assessments are generally more favourable for people without cancer as they go home without further waiting, knowing they do not have cancer. ● Generally, a same-day core biopsy reporting service is not practical. Expected turnaround time for pathology reporting of diagnostic needle core biopsy samples should be specified locally. ● Time is required during one-stop assessment for patients to raise questions and concerns (regardless of diagnostic outcome), and for these to be addressed promptly.

2.3	Breast lump, lumpiness, change in texture (Algorithm A)
Q110	Assessment - Both clinical and imaging assessment should be carried out for patients: - with a persistent lump - who remain concerned regarding the presence of a lump or localised change in the breast tissue - Many patients attending for breast assessment with a possible lump will be found to be normal or to have clearly benign change e.g. cysts, and can be reassured and discharged following appropriate imaging. <i>Clinical assessment</i> - History: the site, duration, associated pain, relationship to menstrual cycle and any recent change in the size of the lump should be established. Any previous history of breast lumps, relevant investigations or operations should be noted. - Clinical examination: both breasts should be examined. The site, size and consistency of any lump or area of abnormal texture of the breast should be noted and correlated clearly with the site of symptoms noted by the patient and/or her doctor. The presence of any associated signs of malignancy such as skin tethering or nipple inversion should be sought. The axillary and the supraclavicular lymph nodes should be examined. <i>Imaging</i> - All patients with a lump or localised change in texture should undergo appropriate imaging: - Mammography and ultrasound for patients = > 40 years. - Ultrasound for patients < 40 years with clinically benign or uncertain lesions (P2, P3). If ultrasound confirms normal, benign or probably benign findings, e.g. cyst or circumscribed solid lesion, mammography is unlikely to provide additional diagnostic information. - Mammography should be performed in women below the age of 40 years for lesions which are suspicious on clinical or ultrasound criteria P4/5 or U4/5. - Mammography should be considered in patients aged 35-39 years with clinically indeterminate lesions (P3) in whom ultrasound is normal. - Mammography may provide additional diagnostic information in the evaluation of some indeterminate U3 lesions.

Q111

- Most solid breast lesions will require a needle biopsy to complete the triple diagnostic work up and to establish a diagnosis. Patients with ultrasound features categorised as U3-U5 should undergo needle biopsy.
- The following solid breast lesions may be safely diagnosed using clinical and imaging information and do not require needle biopsy.

Presumed fibroadenoma

- For patients < 25 years a biopsy need not be performed if the following criteria are satisfied: ultrasound reveals a solid lesion which has benign ultrasound features (e.g. ellipsoid shape (wider than tall)), a well defined outline with smooth edges or fewer than four gentle lobulations.

Presumed fat necrosis

- Clinical benign (P2)
- Imaging typical of fat necrosis U2 (+/- M1/M2)

Presumed lipoma or hamartoma

- Clinically benign (P2)
- Imaging typical of a lipoma or hamartoma U2 (+/- M1/M2)

If there is any doubt about the nature of the lesion or discrepancy between the clinical and imaging features, needle biopsy should be performed.

Multiple lesions

- The lesions should be carefully assessed to establish whether they have the same morphological features and are likely to be due to the same histology.
- Multiple benign lesions U2 – these are likely to be due to fibroadenomas and needle biopsy of one lesion (usually the presenting symptomatic lesion) is sufficient for diagnosis in a patient of 25 years or more.
- Multifocal malignancy – it may be necessary to sample more than one of the lesions in order to establish disease extent and advise on appropriate surgical treatment.

QI12 QI13 QI14	<i>Assessment of the axilla</i> • Ultrasound of the axilla should be carried out in all patients when malignancy is expected. If lymph nodes showing abnormal morphology on ultrasound are found, needle sampling should be carried out under ultrasound guidance. Lymph node sampling may be performed using FNAC or needle core biopsy (published studies have shown no significant differences in sensitivity or specificity). Outcome of assessment • Following triple assessment, a definitive diagnosis of either benign/physiological changes or malignancy will be made in most patients. Where a definitive diagnosis is not established, repeat clinical assessment and needle biopsy should be considered.
2.4	<i>Nipple symptoms</i>
	Assessment <i>Clinical assessment</i> • History: establish the duration, frequency, volume and colour of nipple discharge and particularly whether it occurs spontaneously or only on squeezing; whether bilateral; and whether there are any other associated breast symptoms particularly a lump or inflammation. Generally only single duct spontaneous discharges of genuine blood-stained, clear or serous colour need further evaluation; profuse bilateral milky discharges in non-pregnant patient may justify measuring serum prolactin. Note any history of nipple retraction or inversion, its duration and whether it is intermittent or permanent. Identify whether changes in nipple and areolar skin have been noticed such as bleeding or discharge from the skin, ulceration, and eczema. • Clinical examination: in addition to normal breast examination, particular attention should be paid to trying to reproduce the discharge to determine whether it fits into the categories above. • 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. <i>Imaging</i> • Bilateral mammography in those ≥ 40. Ultrasound if any palpable abnormality.

	Other investigations ● Nipple cytology is rarely of any value and must be treated with great caution after recent lactation. Dipstick testing for blood may eliminate those with dark brown discharges due to duct ectasia. ● Punch biopsy is indicated where Paget's disease is suspected and for any unexplained nipple eczema or ulceration. Outcome of assessment ● For persistent higher risk single duct discharge with no other identifiable abnormality, diagnostic retro-areolar open biopsy may be necessary. Occasionally duct disconnection may be indicated for benign but troublesome high volume discharge ● If Paget's disease is suspected but imaging and biopsy are benign, reassess and consider need for further biopsy ● Otherwise, refer back to GP with a summary of assessment and advice ● Verbal and written advice should be provided on the management of symptoms
2.5	Breast pain (Algorithm B)
	Assessment <i>Clinical assessment</i> ● History: establish the nature, duration and periodicity of pain; any other causative or related factors including injury, hormonal medication, lump or nipple discharge, features of infection and any recent treatment for this with antibiotics; current or recent breast feeding; and any features of referred breast pain from musculoskeletal conditions. ● Clinical examination: identify any focal clinical signs in the breast, lymph nodes and chest wall; look for signs of infection (pink or red discoloration of the skin with localised swelling and tenderness, and discharge from the nipple or skin); seek evidence of musculoskeletal disorders of the cervical and dorsal spine and shoulder. Identify any features of costochondritis (Tietze's Syndrome). ● Breast pain is a common symptom and if of short duration with no other clinical concern may be managed initially in a primary care setting.

	Imaging - When there are associated, or incidental, focal clinical signs in the breast (localised tenderness, nodularity, swelling or a lump) follow the lump imaging protocol (2.3). If infection or abscess is suspected an initial ultrasound scan should be performed and any fluid or pus aspirated and cultured. - Breast pain alone is not an indication for imaging. Outcome of assessment - Full clinical assessment and imaging as appropriate - Verbal and written advice provided on the management of symptoms - Referral back to GP with summary of assessment and advice - Offer of review for severe or unremitting symptoms
2.6	Axillary lump (in absence of clinical breast abnormality) Assessment <i>Clinical assessment</i> - In patients presenting with a lump in the axilla alone with no known clinical abnormality of the breast, information about the duration of symptoms, localised tenderness and other intercurrent illness or condition associated with more generalised lymphadenopathy should be obtained. Clinical examination should determine whether the lump is likely to be related to ectopic breast tissue, enlarged axillary nodes or skin related. A general physical examination should be performed if a systemic cause is suspected. Mammography may demonstrate an abnormality on the oblique view and ultrasound and core biopsy should be carried out where appropriate. Outcome of assessment - If core biopsy demonstrates metastatic carcinoma and mammography is normal, MRI of the breast is indicated as well as more general screening for primaries elsewhere. Other investigations may be needed for abnormal core biopsy results such as for lymphoma, TB and sarcoidosis, along with appropriate clinical reassessment. - Where no significant underlying abnormality is identified, refer back to GP with summary of assessment and advice.

2.7	Women with breast implants
	Assessment <i>Clinical assessment</i> - History: in women with breast implants symptoms may be incidental or related to the implant, including changes in texture, size or shape; following reconstructive surgery for previous breast cancer there may be concern about recurrence. Record the original reason for the implant (augmentation or reconstruction); the site, i.e. submuscular or subglandular; the nature of any associated reconstructive procedure e.g. latissimus dorsi flap; the date of surgery and type of implant used. If there are symptoms of pain or lump record details as under above protocols. - Clinical examination: note any breast lump, swelling or distortion, and examine nodes. Assess the state of the implant: size, position, shape, and capsular contracture: - Baker Grade I – the breast is normally soft, and looks natural - Baker Grade II – the breast is a little firm, but appears natural - Baker Grade III – the breast is firm, and is beginning to appear distorted in shape - Baker Grade IV – the breast is hard, and has become quite distorted in shape <i>Imaging</i> - For investigation of findings in the breast tissue: the protocols described above apply, to include ultrasound and mammography as indicated. Performing needle biopsy of any breast lesion under ultrasound guidance is advisable to reduce risk of damage to the implant. Mammography can be performed by compressing the breast in front of the implant, though it is not possible to achieve full imaging of the breast tissue. - For investigation of integrity of implant: ultrasound scanning may identify possible disruption or leakage. MRI may be considered following MDM discussion in some circumstances to clarify suspicious new or recurrent breast lesions, to determine with more certainty if there is implant disruption, and to identify if there is intra- or extra-capsular rupture.

	Outcome of assessment • Full clinical assessment and imaging as appropriate • Advice provided on the management of symptoms • Referral back to GP with summary of assessment and advice • Assessment of need for revisionary surgery • Offer of review for severe or unremitting symptoms
2.8	Breast lumps in men
Q14	Male breast cancer is rare (around 300 cases are diagnosed per year in the UK; around 46,000 cases are diagnosed in women each year), whereas gynaecomastia (benign enlargement of male breast tissue) is a very common finding in normal men, with peaks of around 60% at puberty and over 50 years. Numerous drugs and a variety of medical conditions including testicular tumours may be associated with gynaecomastia. Cancer is diagnosed in only about 1% of cases of male breast enlargement. Male breast cancer can be a distressing and difficult experience for both men and their families and appropriate support from the breast care nurse may be needed. Referral for further assessment is indicated in those with: • clinical suspicion of malignancy • no obvious physiological or drug cause • unilateral lump • persistent pain and swelling • increased risk such as family history; Klinefelter's syndrome; androgen deficiency or oestrogen excess Assessment <i>Clinical assessment</i> • History: in addition to the standard assessment of a breast lump, record any relevant history of prescribed, illicit or recreational drug use including alcohol consumption and (anabolic) steroids. • Clinical examination: record findings in the breasts (P1-5) and nodal areas, examine the testicles for evidence of tumour, and note any evidence of chronic liver disease. Differentiate between true gynaecomastia with enlargement of glandular tissue and fatty male breast enlargement ('pseudogynaecomastia') related to obesity. Identify features of feminisation and consider need for referral for an endocrine assessment.

QI5 QI6	<i>Imaging</i> • Mammography and/or ultrasound scanning should be performed in men with unexplained or suspicious unilateral breast enlargement and the results recorded as M1-M5 and U1-U5 as appropriate. • Imaging may also be used if there is clinical uncertainty in differentiating between true gynaecomastia and fatty breast enlargement. • Testicular ultrasound scanning should be performed if there is any suspicious finding on testicular clinical examination, or raised αFP or βHCG.
QI15	<i>Blood tests</i> • Hormone profile (testosterone, oestradiol, prolactin, Luteinising Hormone, αFP, βHCG), thyroid and liver function tests should be obtained in men with true gynaecomastia. • Blood tests are not indicated in those with fatty breast enlargement, physiological pubertal or senile changes, identified drug cause, or clinically obvious cancer. <i>Biopsy</i> • Needle core biopsy should be performed following imaging in those patients with uncertain or suspicious clinical or radiological findings (any one of P3-5, U3-5, M3-5). Fine needle aspiration is not to be recommended. Outcome of assessment • Full clinical assessment, blood tests and imaging as appropriate • Advice provided on the management of symptoms including medical therapy • Assessment of need for referral for endocrine assessment • Referral back to GP with summary of assessment and advice • Assessment of need for surgery and in consideration of local PCT rules • Offer of review for severe or unremitting symptoms • Provision of appropriate patient support

3: Multidisciplinary meeting

3.1	The Multidisciplinary Meeting (MDM)
QI17	● The purpose of the MDM is to ensure that patients who have undergone full triple assessment including needle biopsy receive the correct diagnosis and advice regarding management. ● All patients who undergo needle biopsy during assessment should be discussed. ● Patients in whom there is a discrepancy between the clinical findings and imaging should be discussed in order to decide whether further investigation should be undertaken. ● The results of each of the elements of the Triple Assessment should be discussed to ensure that there is concordance of the results when deciding on the final diagnosis and management. ● The outcome for most cases discussed at the MDM will either be a definitive diagnosis of cancer or benign disease. Treatment is planned for those patients with cancer according to National Guidelines. The majority of patients with benign disease can be discharged from the clinic. ● Further review and/or diagnostic intervention may be required following initial assessment for the following: – discordance between elements of the Triple Assessment e.g. persistent suspicious clinical findings and normal imaging – equivocal biopsy results e.g. B3, B4 core biopsy – severe breast pain where assessment of treatment is required – breast inflammation, infection, cellulitis, abscess – nipple discharge if causing significant symptoms, for potential surgical intervention – trauma – Mondor's disease ● The MDM is an ideal forum in which to identify patients who can be offered the opportunity to take part in clinical trials.

3.2	Organisation of the MDM
QI18 QI19 QI20	• All key members of the MDM should be present in person or via video link to ensure full multidisciplinary discussion before the final result is communicated to the patient. • The diagnostic MDM must include pathologist, radiologist or consultant radiographer in breast imaging, surgeon or breast clinician and breast care nurse. • The lead clinician is responsible for accurate recording of the results of the MDM discussion and for ensuring that this is audited. • A lead clinician should be appointed for the MDM to ensure that there is good interprofessional communication, that the key personnel required are in attendance and that this attendance is recorded.

4. Quality indicators

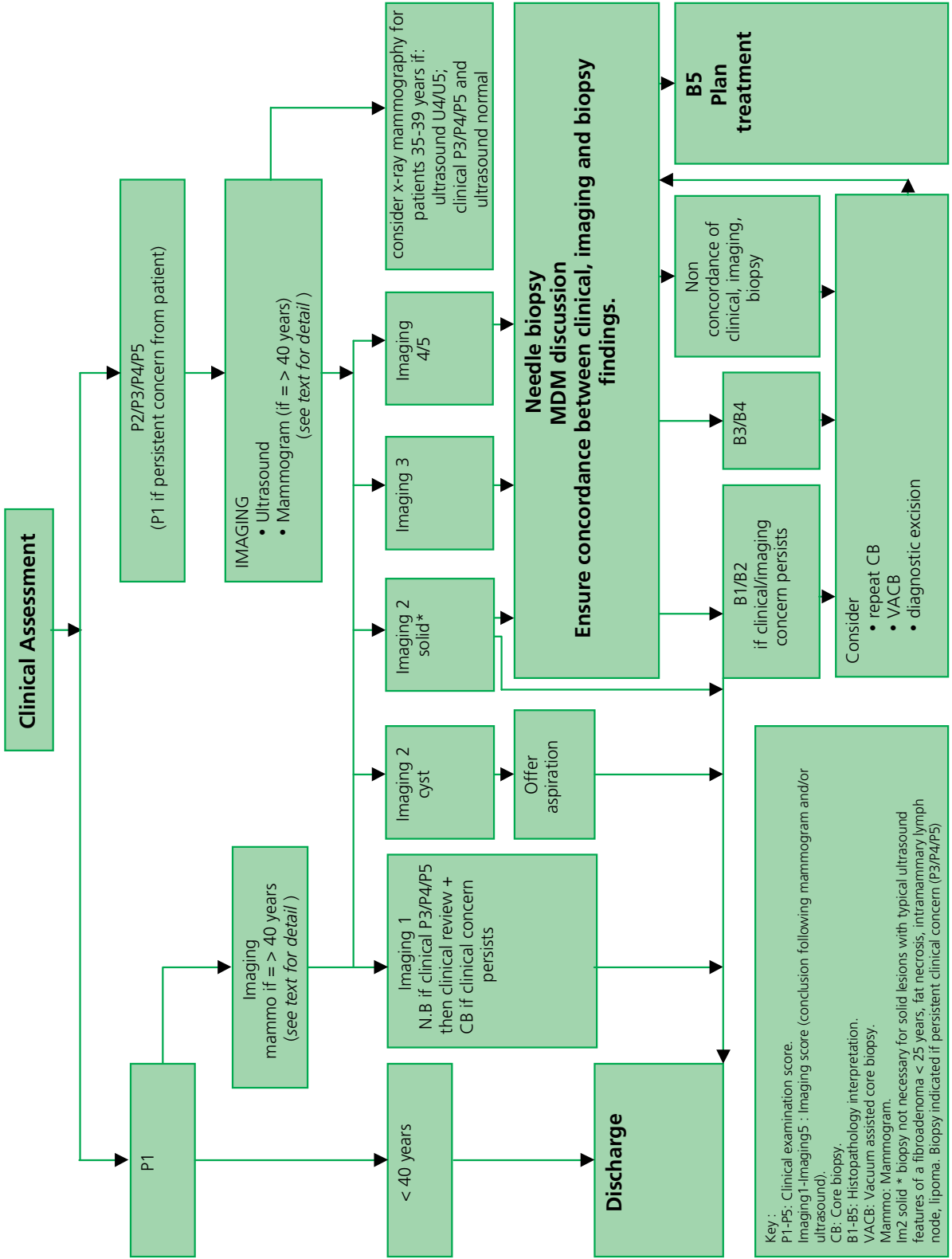
A summary of the quality indicators is provided below. Further detail on the measurement of the quality indicators is described in Appendix C.

National requirement	
QI1	Referral/Access All patients with breast symptoms referred to a specialist are seen within two weeks of referral. (national requirement = 93%)
Developmental markers of quality	
QI2	Delayed Diagnosis Cancers Less than 1% of new symptomatic cancers per annum are diagnosed between 3 and 12 months after triple assessment. (marker of quality = 99%)
QI3	Cancer Diagnosis All patients with symptomatic invasive cancer receive the diagnosis within 5 working days of initial assessment. (marker of quality = TBA)
QI4	Physical Examination All patients should have a physical examination and the level of suspicion for malignancy should be recorded using the P1-5 scale. (marker of quality = 95%)
QI5	Ultrasound X-ray mammography is not indicated for the majority of patients aged less than 40 and ultrasound imaging is the method of choice. (marker of quality = TBA)
QI6	Imaging For patients having ultrasound and/or X-ray imaging, the level of suspicion for malignancy should be recorded using the U1-5 and R/M1-5 scales. (marker of quality = 95%)
QI7	Fine Needle Aspiration Cytology [FNAC] Needle core biopsy is preferred rather than FNAC for lesions suspicious of cancer. (marker of quality = 95%)

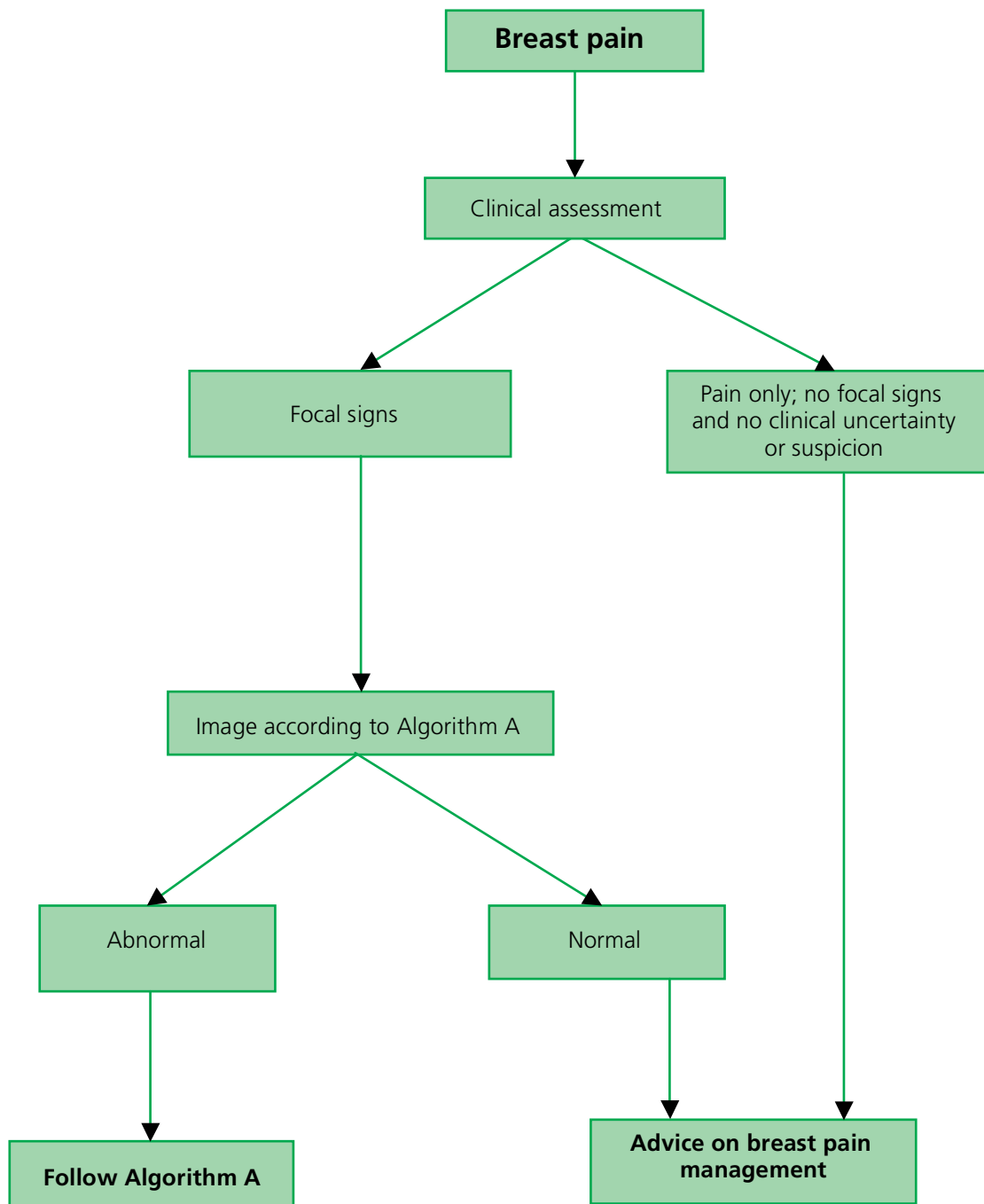
QI8	Needle Biopsy For patients having needle core biopsy and/or fine needle aspiration cytology (FNAC), the level of suspicion for malignancy should be recorded using the B1-5 and C1-5 scales. (marker of quality = 95%)
QI9	Triple Assessment All patients 'requiring' Triple Assessment (clinical, imaging, and needle biopsy) have this performed at their first visit. (marker of quality = 95%)
QI10	Imaging Under 40 Years All patients aged <40 years with ultrasound features categorized as U4-U5 should undergo X-ray mammography. (marker of quality = 95%)
QI11	Imaging and Needle Biopsy Most patients with ultrasound features categorised as U3-U5 should undergo needle biopsy. (marker of quality = TBA)
QI12	Ultrasound Assessment of the Axilla Ultrasound of the axilla should be carried out on all patients when malignancy is expected. (marker of quality = 95%)
QI13	Needle Sampling of the Axilla If lymph nodes showing abnormal ultrasound are found, needle sampling should be carried out. (marker of quality = TBA)
QI14	Outcome of Assessment Where a definitive diagnosis is not established at Triple Assessment, repeat clinical assessment and needle biopsy should be considered. (marker of quality = TBA)
QI15	Breast Cancer in Men Needle core biopsy should be performed following imaging in male patients with uncertain or suspicious clinical or radiological findings. Fine needle aspiration is not recommended. (marker of quality = 95%)
QI16	Pre-operative Diagnosis Rate Proportion of cancers having a non-operative pathological diagnosis. (non-invasive cancers marker of quality = 85%; goal = 90%) (invasive cancers marker of quality = 90%; goal = 95%)

Measures monitored via cancer peer review	
QI17	MDM Discussion The results of triple assessment should be discussed at an MDM for all patients undergoing a needle biopsy.
QI18	Outcome of Assessment – MDM Attendance All key members of the MDT should be present at or link via video conferencing at MDM discussion
QI19	Outcome of Assessment – MDT Lead Clinician Each MDT should appoint a lead clinician.
QI20	Outcome of Assessment – MDM Results Recording The lead clinician is responsible for ensuring accurate recording of MDM discussions and decisions for individual patients.
	TBA = marker of quality to be agreed based on control charts showing current practice

5. Algorithm A. Assessment: Lump/Lumpiness



5. Algorithm B. Assessment: Breast pain



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7. Appendices

Appendix A: Example of information for patient leaflet

Why have I been referred to a breast clinic?

GPs diagnose and treat many illnesses themselves. However, occasionally they may need to arrange for you to see a hospital doctor who specialises in a particular problem for more specialist care.

You may have been referred to a breast clinic for a number of reasons, such as:

- your GP feels your symptoms need further investigation;
- treatment your GP has already prescribed has not been effective;
- investigations your GP has already arranged have shown some unusual findings.
- to confirm your GP's conclusions.

Many patients referred to the breast clinic will not have cancer. It is important to establish the correct diagnosis for each patient quickly so that appropriate advice and treatment can be given.

What should I do now?

Your clinic will be in touch to arrange your appointment. It is therefore really important that they have the correct telephone number and address for you.

You may be contacted and offered an appointment at very short notice. Don't be alarmed – this is normal practice so you can see a specialist quickly.

You may need a particular time for your appointment:

- if you need to make arrangements for child care
- if you care for relatives
- or you need time off work

You can contact the appointments desk on <number> if you need to inform them of anything mentioned above.

Please do let the hospital know if you need to cancel your appointment for any reason, and agree an alternative time with them. This is very important because we could give this appointment to another person.

If you haven't heard from the hospital within a week, please contact your hospital's Appointment Booking Service, or let your GP know.

It is really important that you attend your appointment as it is better for any condition that requires prompt treatment to be identified as soon as possible.

How long will I have to wait for my appointment?

Waiting for an appointment is always a worrying time. You should be seen by a specialist within two weeks of your GP referring you.

If you have any questions before your appointment, or are worried, please call the clinic on <number>, and they will do all they can help.

Do I need to tell the clinic anything before my appointment?

It is extremely important to tell the clinic if you are pregnant, if you have breast implants or if you have had a mammogram (X-ray of the breasts) during the last 12 months. Additionally, if you are taking tablets to thin the blood (anticoagulants) you should let someone at the clinic know.

Please also let the clinic know before your visit if there are arrangements we can make for you, for example, providing wheelchair access, interpreters or signers.

Do I need to make any special preparations before attending the clinic?

You will be asked to remove all your clothes above your waist for the examination, so you may want to wear a top and trousers or a skirt instead of a dress.

As you may be having a mammogram (see below), it is important that you do not wear talcum powder. Additionally, please make sure there is no deodorant, antiperspirant or perfume on your breasts.

As you may need to have a fine needle aspiration test or a biopsy (see below), you may want to wash your breasts before you come to the clinic.

<You will be provided with a hospital gown or a dressing gown, although you may want to, or be asked to bring your own dressing gown with you.<delete as necessary>>

<There will be lockers for you to store your personal items in while you are at the clinic.<delete as necessary>>

Can I bring someone with me to the clinic?

Please bring a partner, relative or friend with you to your appointment if you feel you will need their support or company whilst you are at the clinic. They can stay with you for most of the visit, including some of the tests and your consultation with the doctor, if this is what you want. You may find this helpful as you might be given a lot of information to digest and they may help you to remember everything.

How do I get to the clinic?

By road: <add details>

What are the parking arrangements?

By rail: <add details>

By bus: <add details>=

Will I be able to reclaim my travel expenses from attending the clinic?

If you receive Income Support or Family Credit (or have an exemption certificate) you can claim your fares to and from the hospital. This however, will not include taxi fares.

The booklet *HC11: Help with health costs* gives guidance about NHS charges and help with costs in England. To get help with costs you will need to fill in form *HC1*. Booklets and forms are available from the Department of Health Publications Orderline on 0300 123 1002. Jobcentre Plus offices, NHS Hospitals and your GP or pharmacist may also have them available.

Some people are also entitled to hospital transport on medical grounds. This can be organised through your GP.

When should I arrive at the clinic?

The date and time of your appointment <will be sent to you by the breast clinic><is included in the accompanying letter><will have already been given to you by your GP> <delete as necessary>

On arrival at the clinic, please report to reception to let them know you have arrived. If you have been referred by your doctor, you may be required to bring your letter of referral with you.

How long will I be at the clinic?

The breast clinic has to see a lot of women and sometimes there may be delays. The clinic will do their best to keep you informed if this is the case.

You will have several different tests while at the clinic. Generally all the tests will take place on the same day, this is not because it's medically essential but because it is more convenient for you.

We can't always say how long your visit will take but it helps if you free up most of the day to ensure you have time for all the tests.

In a few cases the clinic may need to ask you to come back for some further tests. Your doctor or breast care nurse will tell you if this is necessary.

Who will I see at the clinic?

The breast clinic staff where you are being referred to are highly trained in breast care and will be able to diagnose your problem as quickly as possible.

Clinic receptionist

You will be welcomed by the office staff or clinic receptionist, who will provide you with assistance as required.

Radiographers

Our team of radiographers are specially trained and work solely in the field of breast imaging, explained in more detail on page X.

Doctors

The clinic has both male and female doctors who are dedicated to breast work. They will carry out any biopsies you may need (please see page X for more details).

Breast Care Nurses

Breast care nurses are qualified nurses with specialist training in breast care and can give you information and answer any questions you have if you need them to.

What tests will I need?

Whilst at the clinic, you are likely to have what is called a **‘triple assessment’**. This involves a physical examination, breast imaging and a biopsy. However, depending on your symptoms, you may not need all the tests.

It is important that you fully understand what tests you are having, why they are being carried out and when you will receive the test results. Your doctor and/or nurse will be able to explain this to you and will answer any further questions you may have.

Breast examination:

A doctor or specialist nurse will see you first at the clinic. They will take a history of your symptoms and you may be asked to fill in a short questionnaire about any family history of breast problems and any medication you are taking.

The doctor or nurse will carry out a physical examination of both your breasts while you are sitting up and when you are lying down. The glands in your armpits will also be examined.

Breast imaging:

Mammogram

A mammogram is the name for an x-ray of the breast. During the mammogram, your breast will be compressed between two x-ray plates for a few seconds in order to visualise the breast tissue.

This pressure may be uncomfortable or a little painful however, the test is over quickly with the entire process only lasting about 10 minutes.

All x-rays involve radiation but with mammograms the dose is very low – about the same as you would receive on a flight from London to Australia and back. The benefits of early detection of breast cancer through mammograms outweigh any risks. Although breast x-rays are also a very accurate form of breast imaging, they are less accurate in younger women with dense breast tissue.

Ultrasound

Ultrasound is particularly helpful in younger patients with dense breasts and in patients presenting with a lump. If you are under 40 this may be the only breast imaging required. This is performed by a doctor (radiologist) or a radiographer.

The test will be carried out while you are lying down. Gel is spread over the breast and a small hand-held sensor is pressed against the skin's surface and moved around so that the breast can be viewed from different angles.

The scan is painless, lasts only 5-10 minutes and has no known risks.

Please note you may need to have both of the above breast imaging tests.

Biopsies:

Core Biopsy

A few patients (less than 1 in 100) may need a core biopsy to further examine an area of concern. The procedure uses a large needle which is quickly fired into the lump using a biopsy 'gun' (which normally makes a loud clicking noise), removing a piece of tissue from the breast. The breast tissue can then be looked at under a microscope to see if there are any abnormalities.

After the biopsy, the area will be pressed for a few minutes to help stop any bleeding, and a dressing will be applied. Several samples are usually taken.

The procedure will be carried out while you are lying down and will normally take 15-20 minutes. A local anaesthetic will be used to numb the area so the amount of discomfort you experience during the test should normally be minimal.

In some cases, you may need an ultrasound to ensure the abnormal area can be seen by the radiologist doing the biopsy.

Fine Needle Aspiration

Some women may have a procedure called fine needle aspiration instead of a biopsy. This involves removing a sample of cells from inside the breast using a very thin needle. The procedure may be repeated once or twice more. The cells will then be looked at under a microscope and checked for any abnormalities.

In some cases, especially if the affected area is not easy to feel, the fine needle aspiration is done using ultrasound or mammogram to pinpoint the affected area.

The procedure is usually carried out while you are lying down and takes about 10-15 minutes.

As all women are different, the level of discomfort you will experience during the test will vary, however, most women say this test is as uncomfortable as having a blood sample taken from their arm. You may receive a local anaesthetic to numb the area prior to the aspiration.

Other biopsies

If your core biopsy or fine needle aspiration doesn't give enough information, you may need a vacuum assisted needle biopsy. This test involved tissue being sucked through a needle after a local anaesthetic. It normally takes 45-60 minutes and reduces the need to have surgery to find out what is going on in the breast.

In some cases, you may receive other types of biopsy. Your doctor will recommend the most suitable type of biopsy for you.

Side effects following biopsy

You may experience some bruising around the area after any biopsy however, this should fade as any other bruise would. You may also feel a small, hard 'lump' in the area of the biopsy. This is a small collection of blood which has formed into a solid bruise and is nothing to worry about. You may be more comfortable wearing a supportive bra in bed for the first couple of nights afterwards, as this can help to reduce bruising. If you are concerned about the amount of bruising you have you can contact your breast care nurse for advice.

If you experience some tenderness or discomfort after the test, you can take mild painkillers. However, please do not take anything containing aspirin as this may cause you to bruise even more.

Care has to be taken to ensure no infection occurs. The dressing applied after the test can usually be removed after 3-4 days.

The risks associated with having a biopsy are low however, on very rare occasions the lining of the lung can be punctured.

When will I get my results?

In most cases, you will get the results of your mammogram or ultrasound on the day of your visit. It also normally takes about an hour to receive the results of a fine needle aspiration, during which time you are welcome to wait for the results or another appointment can be made.

In a few cases the clinic may need to ask you to come back for some results or further tests. Your doctor or breast care nurse will tell you when to expect your results.

The results of some biopsies, including core biopsy, will generally take about 5-7 working days to be processed. If you have a biopsy, you will probably be given another appointment in a week or so to discuss the results.

Waiting for results can be a worrying or stressful time. The breast clinic will make every effort to try and process things quickly so you will have your results as soon as possible.

Once you have all your results, your doctor will be able to tell you what this means for you, give you information, and plan any treatment that may be necessary.

What should I do if I want more information?

You can contact your breast care nurse if you have any concerns or questions. They can be contacted by telephone on <number> between <hours>.

Men who have breast problems will be referred to the same clinic and undergo the same examination as women, however, if you have any more questions, please do contact <number>.

Additionally, there are a number of other organisations who produce information that may be helpful to you. These include:

Breakthrough Breast Cancer

- www.breakthrough.org.uk
- 08080 100 200

Breast Cancer Care

- www.breastcancercare.org.uk
- 0808 800 6000

Macmillan Cancer Support

- www.cancerbackup.org.uk
- 0808 800 1234

Cancerhelp

- www.cancerhelp.org.uk
- 0808 800 4040

You can also Visit the Royal College of Radiologist website to take a virtual tour of an oncology and radiology department in your hospital to find out more

- <http://www.goingfora.com/radiology/mammography.html>

Appendix B: Example of pre-clinic patient questionnaire questions

An example of questions that could be included in a pre-clinic patient questionnaire:

- Age/occupation/number of children/allergies
- Have you had any serious illnesses in the past?
- Are you taking any drugs regularly?
- Have you had any breast problems in the past?
- Have you noticed any lumps or other changes in your breasts recently?
- Is there a history of (breast/ovarian/colon/rectum) cancer in your family?
- At what age did you start your periods?
- Have your periods stopped? If so, how long ago?
- Are you currently using the contraceptive pill? If so, how long have you used the contraceptive pill?
- Are you currently pregnant?
- How old were you when you had your first child?
- Did you breast feed?
- Have you ever taken Hormone Replacement Therapy?
- Have you had a hysterectomy?

Appendix C. Quality Indicators and their Measurement

Table 1

No.	Quality Indicator (QI)	Data Source	Comment	Section
QI1	Referral/Access All patients with breast symptoms referred to a specialist are seen within two weeks of referral (national requirement = 93%)	Cancer Waiting Times data	QI1 – Monitored at national level in the Cancer Waiting Times as the 2 week wait 'Time from GP referral' to 'date first seen'. The QI would be monitored by referral type (urgent [U], non urgent [NU]), gender, age and socio-economic status (SES) to look at effect of new 2 week for all policy to see where feedback can be provided to GPs on inappropriate referrals.	1.1
QI2	Diagnosis Delayed Cancers Less than 1% of new symptomatic cancers per annum are diagnosed between 3 and 12 months after triple assessment (Marker of Quality = 99%)	CWT, HES/CDS, CR data, NCDS data items in Table 2	QI2 – Monitor time from assessment clinic attendance i.e. 'date first seen' to diagnosis of cancer and compare physical examination results [P1-P5], x-ray imaging results [R1/M1- R5/M5], ultrasound results [U1-U5], needle biopsy results – fine needle aspiration cytology [C 1-C5] and needle core biopsy [B1-B5] results for each cancer case. Cancer cases would be identified via CWT, HES/CDS and cancer registration data to ensure full ascertainment.	2.1
QI3	Cancer Diagnosis All patients with symptomatic invasive cancer receive the diagnosis within 5 working days of initial assessment (marker of quality = TBA)	Cancer Waiting Times data	QI3 – Monitored via Cancer Waiting Times – Time from the date of the assessment clinic i.e. 'date first seen' to the results clinic where the patient received their result i.e. 'decision to treat date' The marker of quality would be the median value derived from control charts plotting the times between the date of the assessment clinic and the decision to treat date.	2.1

No.	Quality Indicator (QI)	Data Source	Comment	Section
QI4	Physical Examination All patients should have a physical examination and the level of suspicion for malignancy should be recorded using the P1-P5 scale. (marker of quality = 95%)	NCDS data items in Table 2	QI4a – Monitor proportion of all patients referred to the assessment clinic who have the results of their physical examination recorded as P1-P5. QI4b – Would also look at physical examination sensitivity i.e. proportion of patients who were and were not diagnosed with cancer who had P4-P5 recorded.	2.1A 2.8
QI5	Ultrasound X-ray mammography is not indicated for the majority of patients aged less than 40 and ultrasound imaging is the method of choice. (marker of quality = TBA)	NCDS data items in Table 2	QI5 – Monitor proportion of patients aged less than 40 who were diagnosed with cancer who have x-ray mammography and not ultrasound imaging (i.e. with R/M1-R5/M5 recorded and no U1-U5 recorded). The marker of quality would be the median value derived from control charts plotting the numbers of patients in each breast unit who had x-ray imaging and not ultrasound imaging.	2.1B 2.8
QI6	Imaging For patients having ultrasound and/or X-ray imaging, the level of suspicion for malignancy should be recorded using the U1-U5 and R/M1-R/M5 scales (marker of quality = 95%)	NCDS data items in Table 2	QI6a – Monitor proportion of patients referred to the clinic who were diagnosed with cancer who have the results of their ultrasound and x-ray imaging examinations recorded. QI6b – Would also look at ultrasound sensitivity i.e. proportion of patients who were and were not diagnosed with cancer who had U4-U5 and/or R/M4-R/M5 recorded.	2.1B 2.8
QI7	Fine Needle Aspiration Cytology [FNAC] Needle core biopsy is preferred rather than FNAC for lesions suspicious of cancer (marker of quality = 95%)	NCDS data items in Table 2	QI7 – Monitor proportion of patients with P4-P5, U4-U5, R/M4-R/M5 recorded who have C1-C5 recorded without B1-B5 recorded.	2.1C

No.	Quality Indicator (QI)	Data Source	Comment	Section
Q18	Needle Biopsy For patients having needle core biopsy and/or fine needle aspiration cytology (FNAC), the level of suspicion for malignancy should be recorded using the C1-C5 and B1-B5 scales (marker of quality = 95%)	NCDS data items in Table 2	Q18a – Monitor proportion of patients referred to the clinic who were diagnosed with cancer who have the results of their fine needle aspiration cytology examination(s) recorded as C1-C5 Q18b – Monitor proportion of patients referred to the clinic who were diagnosed with cancer who have the results of their needle core biopsy examination(s) recorded as B1-B5 Q18c – Monitor needle biopsy sensitivity i.e. proportion of patients who were and were not diagnosed with cancer who had C4-C5 and/or B4-B5 recorded. The analyses would be extended to the measures used in the NHSBSP to examine the quality of needle biopsies if all results are recorded.	2.1C 2.3
Q19	Triple Assessment All patients ‘requiring’ triple assessment (clinical, imaging, and needle biopsy) have this performed at their first visit (marker of quality = 95%)	See data items in Table 2 suggested for inclusion in revised NCDS	Q19 – Monitor proportion of cases ‘requiring’ triple assessment that had a result recorded for a clinical assessment (P1-P5) [Q14], an imaging assessment (R/M1-R/M5 or U1-U5) [Q15] a cytological or histological assessment (C1-C5 or B1-B5) [Q17 and Q18] on the ‘date first seen’. Initially the patients for whom a triple assessment was ‘required’ would be identified as those diagnosed with cancer. The overall proportion of cases having a triple assessment in each breast unit would be monitored and the proportions compared on the basis of cancers detected, delayed diagnoses, gender, age and SES etc in the cohort referred. Would also monitor dates of repeat procedures and the overall time to get a definitive diagnosis for cancer patients from date of first assessment visit.	2.1A 2.1B 2.1C 2.2

No.	Quality Indicator (QI)	Data Source	Comment	Section
QI10	Imaging Under 40 Years All patients aged <40 years with ultrasound features categorised as U4-U5 should undergo X-ray mammography (marker of quality = 95%)		QI0 – Monitor proportion of patients aged <40 with U4-U5 recorded who undergo x-ray mammography i.e. have R/M1-R/M5 recorded.	2.3
QI11	Imaging and Needle Biopsy Most patients with ultrasound features categorised as U3-U5 should undergo needle biopsy (marker of quality = TBA)		QI11 – Monitor proportion of patients with U3-U5 recorded who undergo needle biopsy i.e. have C1-C5 and/or B1-B5 recorded. The marker of quality would be the median value derived from control charts plotting the proportion of patients with U3-U5 recorded who have C1-C5 and/or B1-B5 recorded.	2.3
QI12	Assessment of the Axilla Ultrasound of the axilla should be carried out on all patients when malignancy is expected (marker of quality = 95%)	NCDS data items in Table 2	QI12 – Monitor proportion of patients with C5 and/or B5 recorded for breast needle biopsies who have ultrasound examination of axillary lymph nodes [U1-U5] recorded.	2.3
QI13	Assessment of the Axilla If lymph nodes showing abnormal ultrasound are found, needle sampling should be carried out (marker of quality = TBA)	NCDS data items in Table 2	QI13 – Monitor proportion of patients who were diagnosed with cancer who have ultrasound examination of axillary lymph nodes recorded [U1-U5] who also have C1-C5 and/or B1-B5 recorded for needle biopsy/biopsies of axillary lymph nodes The marker of quality would be the median value derived from control charts plotting the numbers of patients in each breast unit who had U1-U5 and C1-C5 and/or B1-B5 recorded for the axilla.	2.3

No.	Quality Indicator (QI)	Data Source	Comment	Section
QI14	Outcome of Assessment Where a definitive diagnosis is not established at triple assessment, repeat clinical assessment and needle biopsy should be considered. (marker of quality = TBA)	NCDS data items in Table 2	QI14 – Monitor proportion of cases diagnosed with cancer who have repeat imaging and needle biopsy recorded and the results of each previous imaging (U1-U5, R/M1-R/M5) and needle biopsy (C1-C5, B1-B5) assessment. The marker of quality would be the median value derived from control charts plotting the number of repeat clinical assessments and needle biopsies in each breast unit.	2.3
QI15	Breast Cancer in Men Needle core biopsy should be performed following imaging in male patients with uncertain or suspicious clinical or radiological findings. Fine needle aspiration is not recommended (marker of quality = 95%)		QI15 – Monitor proportion of male patients who were diagnosed with cancer who have P3-P5, U3-U5 and/or R/M3-R/M5 recorded who have C1-C5 and/or B1-B5 recorded.	2.8
QI16	Pre-operative Diagnosis Rate All patients have cancers have a non-operative pathological diagnosis (non-invasive cancers: marker of quality = 85% goal = 90%) (invasive cancers: marker of quality = 90% goal = 95%)	HES/CDS, CR data, NCDS data items in Table 2	Monitor proportion of patients with non-invasive and invasive cancer who have a C5 and/or B5 needle core biopsy recorded prior to a surgical operation.	NHSBSP marker of qualities
Measures monitored via cancer peer review				
QI17	MDM Discussion The results of triple assessment should be discussed at an MDM for all patients undergoing a needle biopsy	MDT lists, NCDS data items in Table 2	Monitor MDT lists to ensure that all patients with P, R/M, U, C and B results have been discussed and the outcome of the discussion recorded.	3.1

No.	Quality Indicator (QI)	Data Source	Comment	Section
QI18	Outcome of Assessment – MDM Attendance All key members of the MDM should be present at or link via video conferencing at the MDM discussion	Peer review marker of qualities	Monitor MDT records at cancer peer review visits and in self assessment returns. The issue being whether all disciplines are covered at the MDT.	3.2
QI19	Outcome of Assessment – MDT Lead Clinician Each MDT should appoint a lead clinician	Peer review marker of qualities	Monitor at cancer peer review visits and in self assessment returns.	3.2
QI20	Outcome of Assessment – MDM Results Recording The lead clinician is responsible for ensuring accurate recording of MDM discussions and decisions for individual patients (marker of quality = 98%)	MDT sheets Somerset Cancer Register	All cancer patients should be entered onto the Somerset Cancer Register or an equivalent MDT database. This could be monitored in future via cancer registries if they receive electronic feeds from the Somerset Cancer Register.	3.2

Table 2. New Data Items Required in the National Cancer Data Set (subject to ROCR and ISB approval)

No.	Data item	Codes	Definition
Section: Diagnosis and imaging			
1	Date of breast clinical/physical examination	dd/mm/yy	Outpatient appointment at assessment clinic
2	Hospital of breast clinical/physical examination	Org code	Organisation code (code of provider)
3	Result of breast clinical/physical examination	P1	Normal
		P2	Benign
		P3	Uncertain
		P4	Suspicious
		P5	Malignant
4	Date of breast imaging mammography	dd/mm/yy	Outpatient appointment at assessment clinic
5	Hospital of breast imaging mammography	Org code	Organisation code (code of provider)
6	Result of breast imaging mammography * coded as R1-R5 in NHSBSP rather than M1-M5 (R preferred)	*R/M1	Normal
		*R/M2	Benign
		*R/M3	Indeterminate/probably benign
		*R/M4	Suspicious of malignancy
		*R/M5	Highly suspicious of malignancy
7	Date of ultrasound of the breast	dd/mm/yy	Outpatient appointment at assessment clinic
8	Hospital of ultrasound of the breast	Org code	Organisation code (code of provider)

No.	Data item	Codes	Definition
9	Results of ultrasound of the breast	U1	Normal
		U2	Benign
		U3	Indeterminate/probably benign
		U4	Suspicious of malignancy
		U5	Highly suspicious of malignancy
10	Date of ultrasound of the axilla	dd/mm/yy	
11	Hospital of ultrasound of the axilla	Org code	Organisation code (code of provider)
12	Results of ultrasound of the axilla	U1	Normal
		U2	Benign
		U3	Indeterminate/probably benign
		U4	Suspicious of malignancy
		U5	Highly suspicious of malignancy
Section : Pathology			
	Date breast FNAC sample taken	dd/mm/yy	Already included in NCDS
	Hospital of breast FNAC	Org code	
	Pathologist reporting breast FNAC	GMC code	
13	Results of breast cytology fine needle aspiration cytology (FNAC)	C1	Inadequate/unsatisfactory specimen
		C2	No evidence of malignancy
		C3	Probably benign
		C4	Suspicious of malignancy
		C5	Malignant

No.	Data item	Codes	Definition
	Date breast core biopsy taken	dd/mm/yy	Already included in NCDS
	Hospital of breast core biopsy	Org code	
	Pathologist reporting breast core biopsy	GMC code	
14	Results of breast core biopsy	B1	Unsatisfactory/normal tissue
		B2	Benign
		B3	Uncertain malignant potential
		B4	Suspicious
		B5	Malignant
		B5a	<i>In situ</i>
		B5b	Invasive
		B5c	Not assessable

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Breast Cancer Working Group



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