Public Health England

NHS Breast Screening Programme

Clinical guidance for breast cancer screening assessment

NHSBSP publication number 49
Fourth edition November 2016

Public Health England leads the NHS Screening Programme

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH
www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk

Prepared by: C Borrelli, S Cohen, A Duncan, R Given-Wilson, J Jenkins, O Kearins, S Pinder, N Sharma, M Sibbering, J Steel, A Turnbull, M G Wallis
For queries relating to this document, please contact:
phe.screeninghelpdesk@nhs.net

Published November 2016
PHE publications gateway number: 2016426

Contents

Executive summary

This document is a refresh of the third edition of NHS Breast Screening Programme (NHSBSP) guidance for assessment in breast screening, produced in 2010.

An expert group has made changes to the guidance following consultation with national groups and organisations. See appendix 1 for a list of expert group members.

The refresh includes:

- guidance on leadership and documentation of assessment
- the use of markers (clips)
- localisation of breast lesions
- investigation of B3 lesions
- assessment and staging of the axilla
- datasets for transfer of women to symptomatic services for treatment
  (we will issue further guidance on B3 lesions at a later date)

Revision changes and rationale

Description of change from existing guidance	Page no.	Rationale
Requirement for all assessments to have a 'responsible assessor'	7	To ensure that responsibility for decision-making and recording findings can be attributed to a single qualified practitioner for both governance and monitoring purposes. Change required because increasing number of units employ double reading at assessment and responsibilities are not clearly defined.
Changing method of recall from letter to make it more generic	8	To recognise that other methods of communication other than letters are frequently used within trusts.
Option to undertake second opinion	9	To give units and screening directors conditions where they might consider having a second opinion at assessment.
Tomosynthesis	11	Use of new technology referenced.
Vacuum Assisted Core Biopsy	11	Use of new technology referenced.
Markers (Clips)	12/13	New technology documenting change in practice to improve confidence in concordance between mammography and US and reduce unnecessary procedures and second operations.
B3	13	Reflection of increasing evidence around these lesions – awaiting further guidance.
Axilla	14	No change - updated references.
Microcalcification	16	Updated in light of new technology and references.
Documenting outcome of assessment	18	New – strengthening governance and documentation in the light of recent incidents.
Documenting assessment on NBSS	21	To ensure accurate recording of assessment process. This is to support women getting correct result, improved MDM discussion and audit process.
Giving results	19	Reflecting current practice which is patient-centred for benign results.
Data transfer	22	To ensure sufficient information for the management of the patient.

Introduction

The aim of assessment is to obtain a definitive and timely diagnosis of all potential abnormalities detected during screening. This is best achieved by using ‘triple assessment’, comprising imaging (usually mammography and ultrasound), clinical examination and image guided needle biopsy for histological examination if indicated. Cytology should no longer be used alone to obtain a non-operative diagnosis of breast cancer.

The assessment process

Screening is a two-part process. Some women will be sent a normal screening result after initial reading. Others will be recalled to assessment either to confirm the presence of breast cancer (or a high risk lesion) or to be reassured that they have a normal result and can be discharged back to screening. Figure 1 shows the assessment process in further detail including the possible start and end points.[*]

The director of screening of the breast screening unit is responsible for verifying that failsafe mechanisms are in place to ensure that decisions to recall for assessment are actioned.[1] If a recalled woman fails to attend there should be processes in place for issuing a second recall appointment. If she fails to attend a second a time, there should be processes for contacting the woman and her primary care team to agree on appropriate further management.

A new role, ‘responsible assessor‘(RA) is the person taking clinical responsibility for the assessment of individual cases. The purpose of designating an RA is to accurately monitor assessment performance. This is to support governance, training and improve quality; as well as providing clear leadership during clinics. RAs should therefore ensure that data entry accurately represents their clinical activity.

The director of screening is responsible for ensuring that the assessment process is appropriately carried out by all RAs. This should be confirmed by audits of individual RA assessment performance, including:

- number of assessments performed
- quality of data entry
- adherence to unit and national protocols

Clinical performance will be supported by national audits.

[*] All figures appear at the end of the document.

These audits should be regularly repeated at not less than yearly intervals and the results disseminated to ensure learning. This should be in a supportive environment with a view to improving quality wherever possible. If difficulties are encountered that cannot be dealt with in the unit, the assistance of the screening QA service and a professional clinical advisor should be sought. These audits will be reviewed at QA visits. RAs have responsibility for complete and accurate data entry on NBSS for all assessment episodes.

Organisation of assessment clinics

There should be enough capacity to ensure assessment takes place in a timely fashion and meets national standards as set out in the programme service specification at: https://www.england.nhs.uk/commissioning/pub-hlth-res/

Prior to assessment, the RA is responsible for confirming the area of interest to be assessed, to ensure that assessment investigations are clear, appropriate and comprehensive. This may be done by holding a pre-assessment briefing.

Method and timing of recall

Most women who take part in the breast screening programme have no breast symptoms. The expectations and needs of these 'well women' recalled for assessment of a screen-detected abnormality are very different from those of women referred to symptomatic breast clinics.[2] Recall for assessment is associated with significant anxiety, particularly as most women have had no previous indication of a breast problem.[3] For this reason, invitation to recall should be made in a timely and sensitive fashion, taking into account that most women recalled for assessment will not have breast cancer.

Recall by letter is currently the recommended method. Any written communication (electronic or otherwise) should convey the basic minimum information, including a contact telephone number for women seeking more detail. Invitations to assessment should be timed to arrive when the breast service team can be contacted with the minimum of delay[4] and avoid receiving invitation letters on Fridays or at the weekend. The primary care team should be kept informed about the outcome of the assessment process.[5]

Phoning women to invite them for assessment may increase their anxiety. If it is unavoidable, the telephone call must be made only by suitably trained individuals and must comply with written local guidelines.

Number of assessment visits

The number of diagnostic assessment visits needed to achieve a definitive primary diagnosis should be as low as possible. Appointments and facilities should be arranged so that stereotactic biopsy is routinely available on the same day as assessment.

No more than two visits for needle biopsy procedures should normally be needed to achieve an initial non-operative diagnosis. This does not include further visits where women have additional workup following a cancer diagnosis to aid surgical planning (such as upgrade to invasive cancer).

Personnel for the assessment clinic

Individuals with the appropriate skills in radiography, radiology, breast care nursing and clinical examination should be present as core members of the assessment team. Other support staff will also be required.

Professionals involved in screening assessment are expected to fulfil the requirements for individual professional training and for their continuing professional development (CPD). They should carry out assessments and procedures regularly, so they can maintain their skills and competence.

Those involved in formal screen reading should also participate regularly in screening assessment.

The service should ensure all women who are recalled for assessment receive information, advice and support appropriate to their needs. A clinical nurse specialist in breast care should be available in the clinic to provide this.[6]

Responsible assessor

The RA must be an accredited breast radiologist, consultant radiographer or breast clinician. They must have the required range of qualifications, abilities, experience and current CPD to decide the outcome of assessments. An assessment can only be considered complete when the RA is satisfied that all appropriate investigations have been adequately performed, whether undertaken by themselves or others. The RA should request any additional investigation they believe necessary. Each individual case requires sign off in this way. There may be more than one RA working in a single clinic.

Second opinion

There have been a number of incidents in assessment. These often involve single-handed clinicians who have worked unsupported, or occur where new or locum colleagues would have benefitted from the support of more experienced colleagues. Screening directors should consider second opinion to mitigate some of these risks. It is recognised that for smaller units, and particularly units lacking sufficient resources, this may present severe challenges to implement. In such circumstances reciprocal arrangements between adjacent units could be considered.

Before final sign-off, and at a stage when a second opinion may still influence final outcome, a second assessor may review the case. This should ideally be during the assessment clinic so that the patient can be given a definitive outcome immediately. This is particularly important in cases when a biopsy has not been taken. Some services already routinely employ a second opinion during assessment for some cases. Others arrange review of assessments after clinics.

The RA makes the final decision regarding assessment cases, but should work collaboratively with colleagues during clinics to improve consistency, quality and outcomes.

Equipment for assessment

The equipment for breast assessment includes:

- digital mammography equipment which should be capable of:
  - magnification mammography
  - special views
  - small field digital stereotactic x-ray guided biopsy[7]
  - undertaking specimen radiography during a core biopsy procedure[8,9,10]
- approved tomosynthesis (may be used where available)
- ultrasound equipment
- consumables and devices necessary for core biopsy and vacuum biopsy, including biopsy site markers

All equipment should meet standards within national guidance.[7]

Indications for assessment following screening

Assessment is indicated in the following circumstances:

- significant mammographic abnormality
- significant breast symptoms or signs identified at screening
- review of short term recall
- significant MRI abnormality in women at high risk[11,12]

Mechanisms must be in place to identify and record significant signs and symptoms of breast problems in women attending for screening. This information must be made available at the time of screen reading.[13,14]

Significant symptoms and signs noted by the patient or the radiographer at screening should be documented and recalled (figure 2). These include:

- a lump
- distortion of the breast
- suspicious nipple or skin change including fixed nipple inversion
- a bloody discharge

Radiographers and assistant practitioners should be trained to recognise signs at the time of screening.[15] Recall for assessment of signs and symptoms may be appropriate even if the screening mammograms appear normal. Radiographers may instigate recall for assessment where local protocols dictate, but ultimate responsibility for this rests with the authorised mammography readers.

Screen detected mammographic and MRI abnormalities should be clearly documented, so as to make the feature and the location in the breast for the recall clearly identifiable to those undertaking the assessment.

Right results protocol

All screening units must have a quality management system to ensure the right result is sent to the right woman.[16]

Assessment procedures

Assessment protocols

Each assessment clinic should have at least one RA and should follow the triple assessment model:

- appropriate further imaging with mammography
- ultrasound
- clinical examination
- needle sampling when indicated

Each assessment unit should have written protocols for triple assessment based on this document, but take local circumstances into account, for example the availability of vacuum-assisted core biopsy (VACB) and tomosynthesis.[17,18,19,20] Protocols should be agreed by all members of the local breast assessment team. The protocols should clearly define the assessment methods to be used and the diagnostic and referral pathways appropriate to each possible assessment outcome. These should include responsible assessor identification, second opinion, recording of outcomes and arrangements for multidisciplinary discussion.

Further imaging

Most women are recalled as a result of a mammographic abnormality. Unless this abnormality is considered to be immediately identifiable, further imaging is carried out to assess the nature of the lesion. This assessment should include the minimum imaging required to confirm or exclude an abnormality, including further mammography (repeat routine views, magnification or special views in at least two planes/tomosynthesis) and/or ultrasound where indicated. Depending on the nature of the breast abnormality, some women will not need further imaging.

Where they do, it should be directed by the RA for the case. Ultrasound should be used in most assessment cases, even if the recalled abnormality appears to have resolved on further views and in all cases where the original abnormality involved a soft tissue density.

The correlation between mammography and ultrasound is important to ensure any abnormalities seen relate to the same lesion on both modalities. Lesion size, shape and position should be considered and in cases where correlation is challenging, difficult or uncertain, then the placing of a marker (clip) under ultrasound and subsequently repeating the mammogram may be helpful.

If a cancer is suspected, ultrasound should be extended to cover at least the affected quadrant. For dense breasts, consider the whole breast as well as the ipsilateral axilla.

Extended breast ultrasound reduces the risk of a second unexpected lesion being identified at localisation, or inadvertently missing the index lesion, in particular when MRI staging has not been performed.

There is evidence from small studies on staging[21,22,23] and screening trials that a small number of additional foci are found but at a risk of additional benign biopsies.[23,24,25,26] To date, as with preoperative MRI staging, there is no evidence for improved patient outcomes.[26,27]

Clinical examination

The clinical examination of women recalled for assessment should be carried out before biopsy for anyone who was recalled for a clinical reason, by an individual who has the necessary clinical skills.

Needle biopsy of breast

Significant breast abnormalities should be assessed by core biopsy or vacuum-assisted core biopsy (VACB).[28,29,30,31] Wide bore needle biopsy provides information on invasive status, tumour subtype, histological grade and receptor status. It also aids the definitive diagnosis of benign lesions[32] and reduces repeat operations.[33,34] If a service has access to high quality cytology with immediate reporting, then fine needle aspiration cytology (FNAC) may be used in addition to core biopsy, but not instead of it. In exceptional cases FNAC may be used alone if core biopsy is not possible.

Ultrasound is the technique of choice for guided needle sampling. A permanent record of images showing the biopsy needle in the target lesion should be made. VACB should be used for re-biopsy and in the investigation of B3 lesions.

Marker (clip) insertion is advised to confirm the correct area has been sampled for example when changes are difficult to perceive, or if there is any doubt that the lesion seen on ultrasound corresponds to the mammographic changes. Marker (clip) placing is particularly important to facilitate treatment planning/surgical localisation when there are multiple lesions or when there is any risk that the area of concern could be removed or rendered difficult to see by the biopsy.

A marker (clip), with mammographic documentation of its position, is the safest way to facilitate communication within and between teams and to ensure the correct lesion is removed at surgery or to facilitate follow-up.

All needle biopsies carried out as part of screening assessment should be reviewed at the multi-disciplinary meeting (MDM). Management of each case should be agreed and documented.[35]

Investigation of B3 lesions

Lesions categorised as B3 (of uncertain malignant potential) may be associated with co-existing adjacent malignancy (upgrade), see appendix 2 and some are also associated with a longer term increased risk of developing cancer.[36]

Appendix 2 provides guidance on the standardisation of clinical management, without resort to first line diagnostic surgical excision. B3 lesions may present as a range of radiological abnormalities and it is essential that management decisions are made at an MDM. Review of current literature on upgrade rates for each type of B3 lesion shows that all types warrant further histological examination (unless fully excised already), whether a lesion is seemingly coincidental or interpreted as the cause of radiological abnormality.

When deciding whether to undertake vacuum-assisted excision (VAE) or diagnostic surgery, the multi-disciplinary team (MDT) should specifically consider how representative the sampling is and the degree of pathology concern. This should take into account the summation of the 14g core or VACB and any further vacuum-assisted excision procedure.

Observational studies show that some of these lesions of uncertain malignant potential are also associated with a risk of developing breast cancer that is three to five times greater than that of the general population. The bulk of the evidence suggests that this group has a relative risk (RR) of greater than four. The risk is not restricted to the breast where the biopsy or excision of the benign condition occurred, and surveillance programmes must not focus on one breast only.

The elevated level of risk for these women is not significantly altered by a family history of breast cancer, but there is evidence that the woman's age at diagnosis of a premalignant lesion, the type of lesion, and the time that has elapsed since her biopsy do modify the level of risk. However, these data are partly conflicting and have not, at present, been shown to affect the risk estimates to an extent that would affect decisions about surveillance.[36]

In light of this, the NHSBSP is not in a position to provide advice on, or commission, follow up surveillance. It is noted that many units are providing annual mammography for five years through their symptomatic service.
Services should make every effort to register these women in the Sloane Project phase two atypia audit.[37]

Needle biopsy of the axilla

All patients with a non-operative diagnosis of invasive breast cancer should have ipsilateral axillary ultrasound performed, preferably at the time of initial assessment.[38,39,40,41] If this was not performed initially, it should be done as soon as possible following core biopsy diagnosis of the breast cancer. The number and morphology of any abnormal nodes should be documented.

If an abnormal node(s) is identified, the most suspicious one should be sampled by either FNA or core biopsy.[41] It cannot be assumed that an ultrasonically abnormal node is malignant. The evidence around what cortical thickness can be considered to be abnormal is not clear[39] so the criteria and procedure for sampling should be agreed locally and subject to audit. FNAC and core biopsy of axillary nodes are recognised techniques and staff involved in assessment should have the necessary skills to carry these out under ultrasound guidance. If the breasts are normal and other nodal pathology is suspected, then local protocols should be followed to obtain a tissue diagnosis.

Occasionally the sentinel node is situated in a very low position, well into the breast, and there are reported cases of these unusually-placed nodes being missed at surgery. In these circumstances care should be taken in documenting the position of the node and consideration given to pre-operative marking following MDM discussion.

Assessment of mammographic abnormalities

Masses

Ultrasound is the preferred imaging method for establishing the nature of a breast mass (figure 3). Further mammography, including focal compression views or tomosynthesis, may be needed to confirm the presence, morphology and site of the mass. All solitary and/or new masses recalled for assessment that are confirmed as solid on ultrasound and that do not have the typical features of a hamartoma, lipoma, fat necrosis or normal lymph node should undergo needle core biopsy. This should normally be performed under ultrasound guidance.

Cysts with atypical features require further evaluation, including aspiration and core biopsy of any residual internal or mural solid component. If a mass is confirmed on mammography but is not visible on ultrasound, it should be managed according to its mammographic features and not assumed to be insignificant. Unless the mammographic features are definitively benign, stereotactic core biopsy should be performed.

If a B1, B3 or B4 result is reported at initial core biopsy of a solid lesion then either a second core biopsy or VACB should be considered. A further biopsy should also be performed if B2 histology is not thought to be concordant with the imaging opinion.

Architectural distortion

Possible architectural distortion found during screening mammography requires imaging work-up in the first instance. This should comprise standard mammography views and localised compression/magnification views or tomosynthesis as well as ultrasound, to establish whether there is a persistent localised abnormality. The initial assessment should also include clinical examination to check for relevant clinical findings such as a mass or scarring from previous surgery (figure 4). If surgical scarring is ruled out, architectural distortion may indicate malignancy and needle biopsy should always be performed.[33,42,43]

Asymmetric density

Further mammography or tomosynthesis, ultrasound and clinical examination should be performed for all asymmetric densities considered significant enough to warrant recall (figure 5). Core biopsy should be performed on all significant asymmetrical densities found on imaging or clinical examination which could not be accounted for as normal glandular tissue after these tests.

Microcalcifications

It is difficult to distinguish between benign and malignant microcalcifications from their mammographic appearance alone (figure 6). Cranio-caudal and lateral magnification/spot compression views aid further characterisation and help in the assessment of the probability of malignancy. There is conflicting evidence on the value of tomosynthesis for both detection and characterisation of calcification, so this should not be routinely used until further evidence is available.[44,45] Magnification views are also useful in defining the extent of ductal carcinoma in situ (DCIS) if conservation surgery is being considered.

Ultrasound assessment of micro-calcification may identify focal areas of altered echotexture, indicating possible invasive foci within DCIS.[46,47,48] Microcalcifications with definitively benign features do not require needle biopsy. If there is thought to be any risk of malignancy, image guided core biopsy with specimen radiography should be performed.[6]

Representative microcalcification must be demonstrated in the core specimens on specimen radiography.[6,7] If it is not, the procedure should be repeated. Ideally, this repeat biopsy should be by means of VACB. Otherwise a diagnostic surgical biopsy should be performed, unless malignancy has been diagnosed within cores that contain no calcification. Pathology request forms should document the presence or absence of representative calcification and the pathologist should be able to access the specimen x-rays.

The identification of microcalcification on histology is not in itself a reliable indicator of adequate sampling. Histological microcalcification is a common incidental finding and may be present when there is no calcification visible on mammography. Surgical biopsy is unnecessary when histology shows a definitively benign cause for calcifications in core specimens and when specimen radiography confirms the presence of calcifications clearly representative of those considered suspicious on mammography.

A marker with a metal component may be useful to mark the site after needle biopsy. This is especially the case for:

- small lesions which might be removed by biopsy
- lesions which could be difficult to identify if subsequent excision biopsy is required
- when multiple areas have been biopsied to mark the relevant sites

Multiple foci and extensive microcalcification

Careful consideration needs to be given to cases with multiple foci of abnormality or extensive microcalcification. It is important to ensure that adequate sampling is undertaken to guide both the MDT and the patient in their decisions about surgery. It is important that there is enough evidence to justify recommending mastectomy, for example support by tissue diagnosis.

Multi-disciplinary team meetings

Effective MDT meetings[49,50,51,52,53] are patient centred although their format and the composition of their attendance will vary between different screening units. It is an important principle, however, that each patient having had a needle biopsy should be discussed at an MDT meeting

The outcome of assessment should be decided according to agreed MDT written protocols. A provisional opinion as to the nature of the problem and its possible management may be discussed with the woman at the time of her assessment. Any woman who has undergone needle biopsy should have her result discussed in an MDT meeting and her management options agreed in the presence of the recipient surgeon or his or her surgical representative. This should happen before the patient receives her result and before any treatment options are discussed with her.

Clear documentation is required at assessment and at the MDT meeting of the area(s) biopsied, and any unbiopsied area(s) that may need additional sampling as a result of the initial pathology and MDT discussion.

An MDT meeting to discuss the results of screening assessment should occur at least weekly. It is important that correlation between imaging, clinical findings and pathology is checked as part of the triple assessment process. If there is discordance between the imaging and pathology outcomes then further action should be taken, such as a repeat biopsy, depending on the disagreement.

In exceptional circumstances, if the screening director feels that there are local reasons why the service should not follow this model of an MDT, it is recommended that a formal document is produced that describes:

- the deviation from this MDT model
- the rationale for the deviation
- any mitigating action to minimise possible reduction in quality
- evidence of discussion and support from referring and receiving surgeons
- any relevant audits to monitor quality

This document should be taken to the local screening programme board for consideration and agreement. The screening QA service should be asked to comment and advise on possible impact. Commissioner’s support should be sought, and the programme board should be asked to provide formal sign off and a document review date.

Clear documentation is also required at assessment and at the multidisciplinary team meeting of the area(s) biopsied and any unbiopsied area(s) that may need additional sampling, resultant on the initial pathology and MDT discussion.

Exceptional circumstances

In certain circumstances, clinical factors such as patient co-morbidity may make it neither possible nor prudent to adhere to normal assessment practices. These cases should be reviewed by the MDT and the reasons documented.

MRI should be considered for the further assessment of difficult cases where conventional triple assessment is inconclusive and for cases where needle biopsy is not possible. MRI should not be used as a substitute for needle biopsy of a focal abnormality.

Outcomes of assessment

There are four possible outcomes of assessment:

1. Return to the routine screening programme.
2. Referral for treatment.
3. Referral for therapeutic vacuum-assisted excision or open surgical biopsy.
4. Short-term recall.

Documenting assessment outcome

A minimum data set is required at completion of the NHSBSP assessment process, to inform surgical referral, localisation and treatment planning of patients. It is imperative that appropriate information is recorded for onward referral for surgery (appendix 3).

Short-term recall

A short-term recall is defined as a further invitation to assessment. Short-term recall must not be considered a routine outcome of assessment.[13,54,55] The use of triple assessment makes it possible to reach a definitive conclusion in the majority of cases. For a small number of patients however, assessment may not yield a definitive decision and the MDT may consider surgical biopsy inappropriate. In such exceptional cases, short-term recall is required. A woman should only be placed on short-term recall only if:

- there is clear justification
- all the options have been discussed with the woman
- the decision has been discussed in detail at the MDT meeting, agreed and documented

This option should not be used as an alternative to definitive assessment.

All assessment processes should normally be completed within two months of the first assessment attendance and the episode closed. Short-term recall is a new screening episode and is reported in table D on the KC62 statutory return. It is not a delayed screening assessment follow-up. Women placed on short-term recall should not be recalled at a time interval of less than 12 months. They should be invited to the assessment clinic for bilateral two-view mammography and given their result immediately. They should not be given a routine mammography screening appointment. Short-term recall cases should be the subject of regular clinical audit and are included in the peer review of radiologists' performance as part of quality assurance visits.[13,56]

Results after assessment

All women with a diagnosis of breast cancer should receive their results in the presence of a clinician and a clinical nurse specialist in breast care. Enough time should be allocated to provide the necessary counselling and support.

Even for a normal result, the provisional and final results of assessment should be given to the patient by a clinical practitioner.[57,58,59] All women who have been assessed and do **not** have a diagnosis of cancer should receive written confirmation of the outcome of their assessment.[2,4]

Primary care teams must therefore be informed without delay of the assessment outcome. Some women with a benign outcome and most of those with a diagnosis of cancer requiring treatment will seek support from primary care, both for themselves and for their families.

Appendix 1: members of the expert writing group

Matthew Wallis	Consultant Radiologist, Cambridge Breast Unit, Cambridge University Hospitals NHS Foundation Trust
Claire Borrelli	Radiographic Advisor to PHE, Education and Training Manager, St Georges, London
Sue Cohen	National Lead for Quality Assurance, PHE
Alison Duncan	Consultant Radiologist, Director of Screening, Warwickshire, Solihull and Coventry Breast Screening Service
Ros Given-Wilson	Consultant Radiologist, St Georges, London
Jacquie Jenkins	National Breast Screening Programme Manager, PHE
Olive Kearins	National Breast Screening Portfolio Lead, PHE
Sarah Pinder	Professor of Breast Pathology & Head of Research Oncology, Division of Cancer Studies, King's College London
Nisha Sharma	Lead Consultant Radiologist, Leeds Teaching Hospital
Mark Sibbering	Consultant surgeon, Vice President Association of Breast Surgery, Royal Derby Hospital
Jim Steel	Consultant Radiologist, Director of Breast Screening, West Devon & East Cornwall Breast Screening Service
Anne Turnbull	Consultant Radiologist, Chair Radiology Clinical and Professional Group, South Derbyshire Breast Screening Service

Appendix 2: guidance on the management of B3 lesions

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

Appendix 3: minimum dataset for referral from assessment

This includes patients diagnosed with breast cancer, and certain non-breast cancers (such as lymphoma), and certain benign conditions (such as phyllodes tumour), that need further treatment at the end of assessment.

The transfer of information from a named clinical lead in the screening centre should include:

- full patient details – name, address, date of birth (DOB), screening number, NHS number
- the name of the referring centre
- the screening lead name and address
- the centre contact details including email and telephone numbers
- the patient's GP and contact details
- the key worker name (if allocated)
- information on how imaging and all other documentation will be forwarded, for example via IEP link, email

A proforma generated for referral to surgeon or treating centre should clearly state:

- patient details on every sheet of the referral – full name, DOB, screening and NHS number – (preferably at the top and the bottom)
- date screened
- date of first assessment
- 62-day target date for treatment
- MDT meeting discussion dates
- details of all lesions assessed and biopsy result(s) at each location – including method of guidance, type of biopsy/gauge needle, if marker (clip) placed, & type of localisation advised
- ultrasound of axilla
- list of any additional investigations – why performed and result eg breast MRI, second look US
- clinical findings
- comments on patient's general health and any other important patient factors (for example, a frozen shoulder, which would be problematic for radiotherapy positioning, recent MI and anticoagulated)
- high risk screening patient Y/N; if Yes, reason – eg BRCA, Mantle DXT
- details of any previous breast surgery or treatment and side/site of this (for example previous WLE and DXT to breast)

- any trials the patient has been offered or may be suitable, for example LORIS

An example proforma for the clinical components may look like this:

- assessed lesions:
    1. Left upper outer ,15mm calcifications, stereo 14g core, B3 with AIDEP, 9g stereo VAB – B5a, intermediate grade DCIS, marker (clip) placed, calcs excised.
    2. Left lower inner – 20 mm spiculate mass, US core B5b invasive carcinoma of no special type, provisional grade 2, no marker (clip).
    3. Left axilla – indeterminate node, US FNA – no malignant cells, lymphocytes present. Accepted.
- additional investigations: none
- patient's general health: well
- Previous breast history: right WLE, DXT to breast 10 yrs ago with 5 yr tamoxifen
- MDT summary: Advise left mastectomy and SNB, as multiple foci. Refer for surgical treatment. Note previous contralateral breast cancer 10 years ago (If one lesion – specify if clinical, US skin marker, US wire or x-ray guided localisation advised)

Figure 1 Assessment process

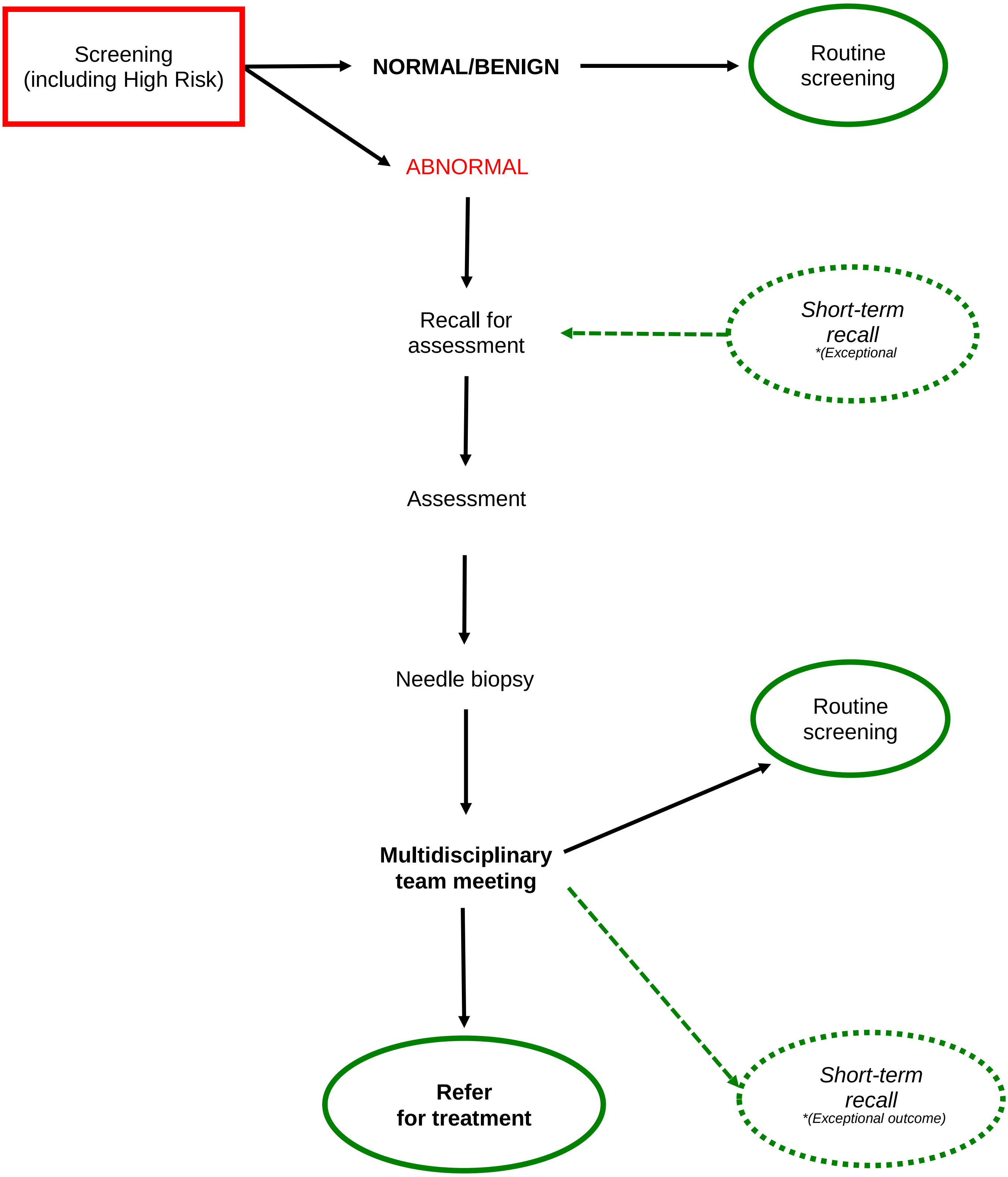


Figure 2 Assessment of clinical signs/symptoms

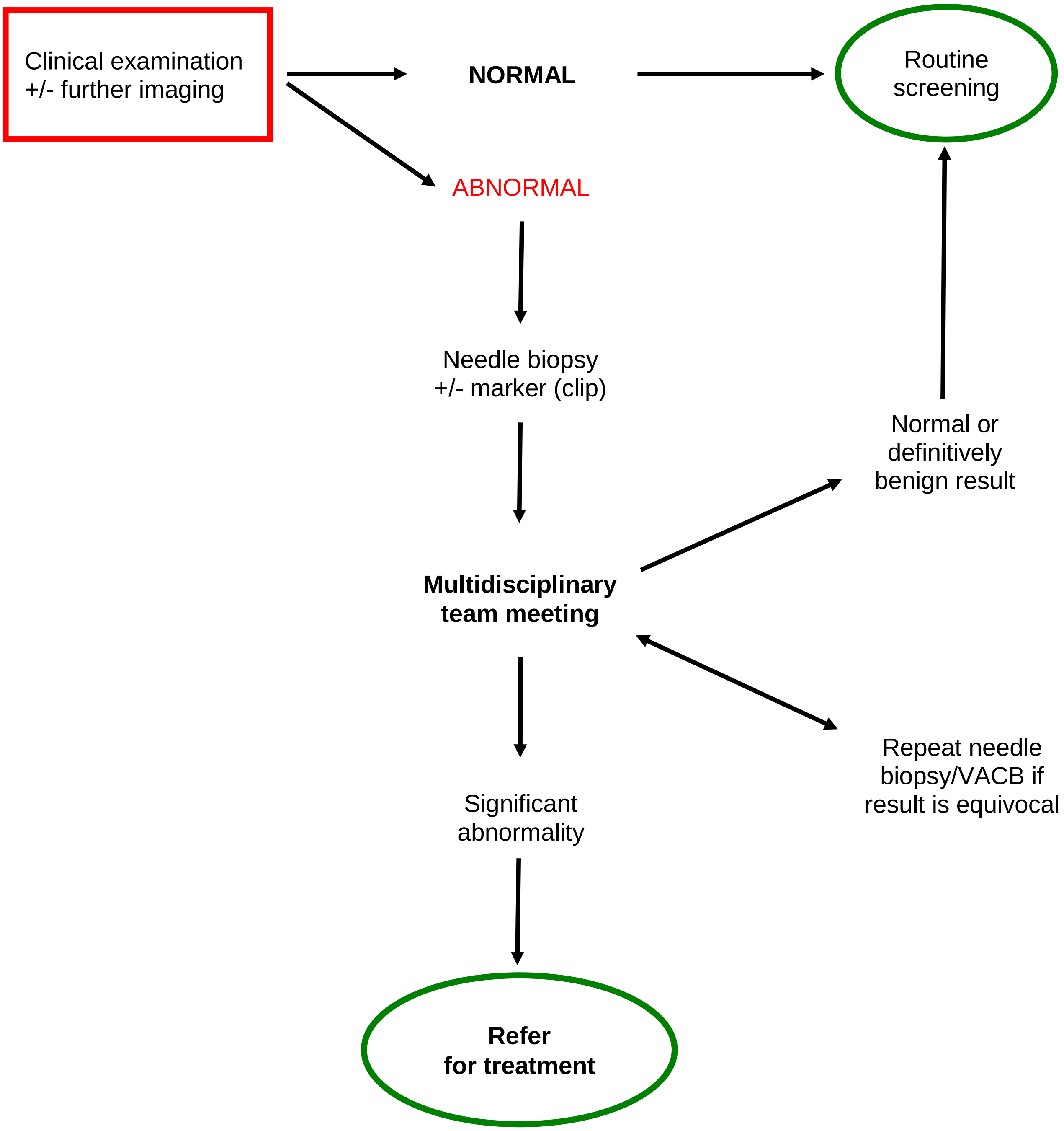


Figure 3 Assessment of breast masses

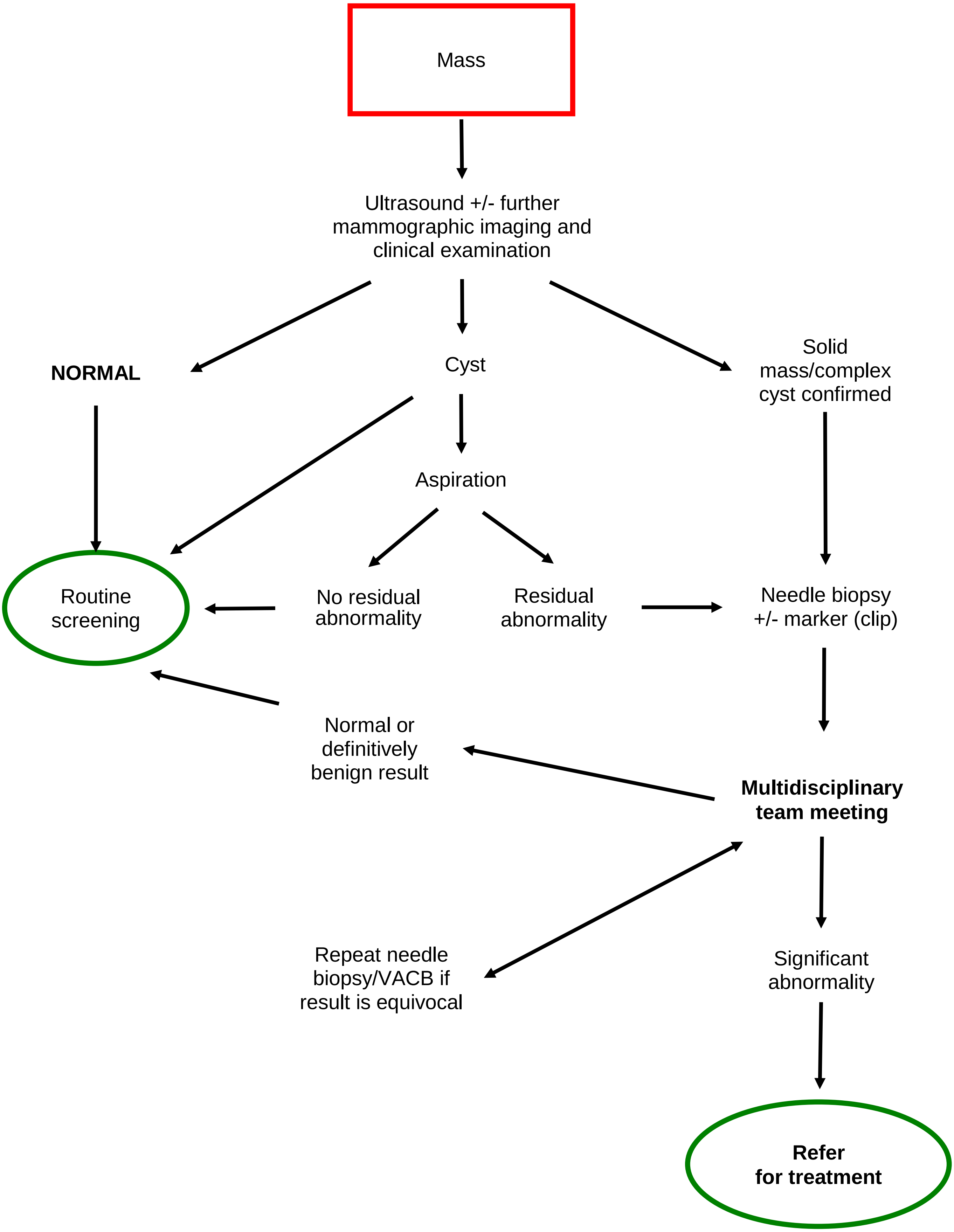


Figure 4 Architectural distortion

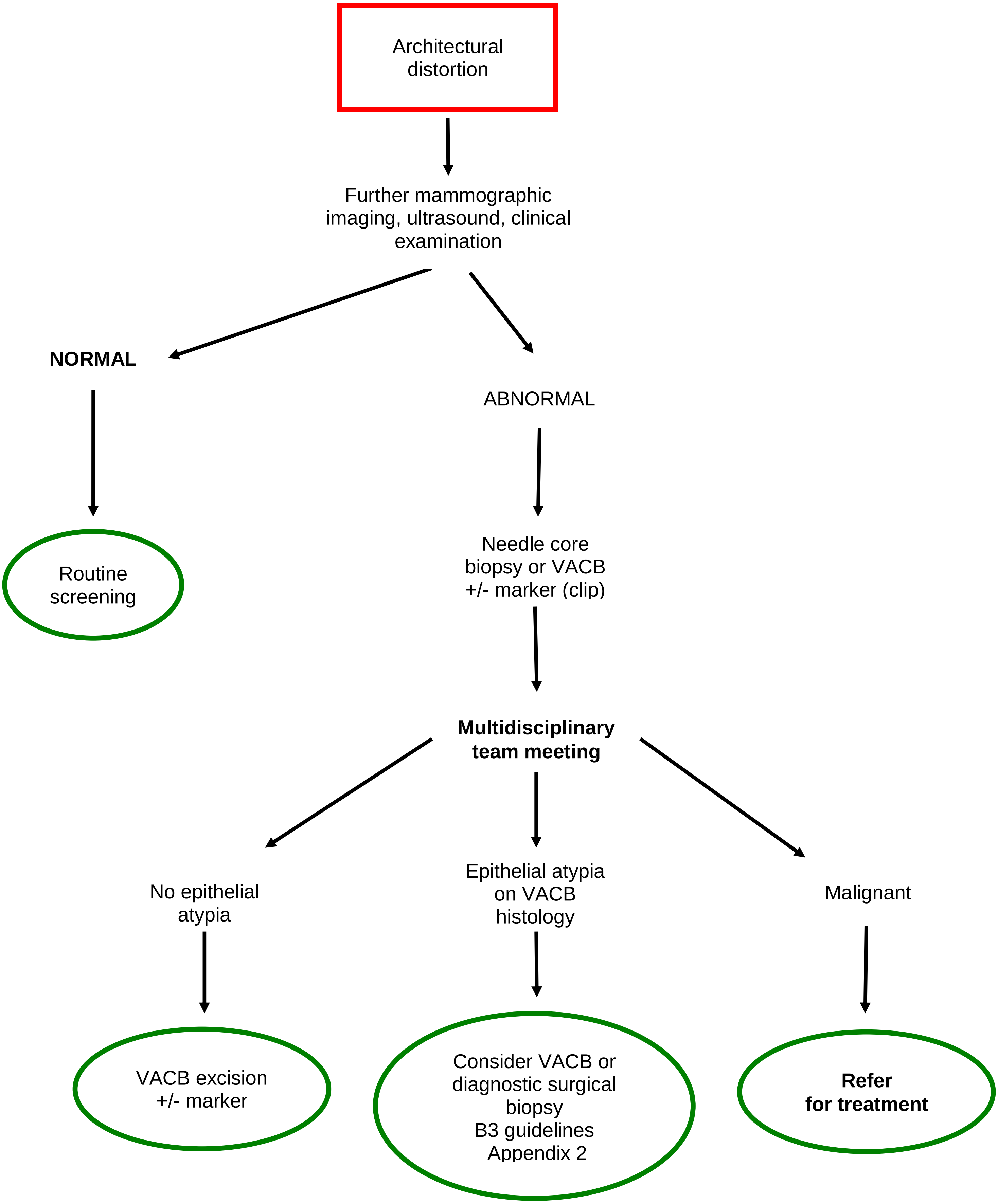


Figure 5 Asymmetric density

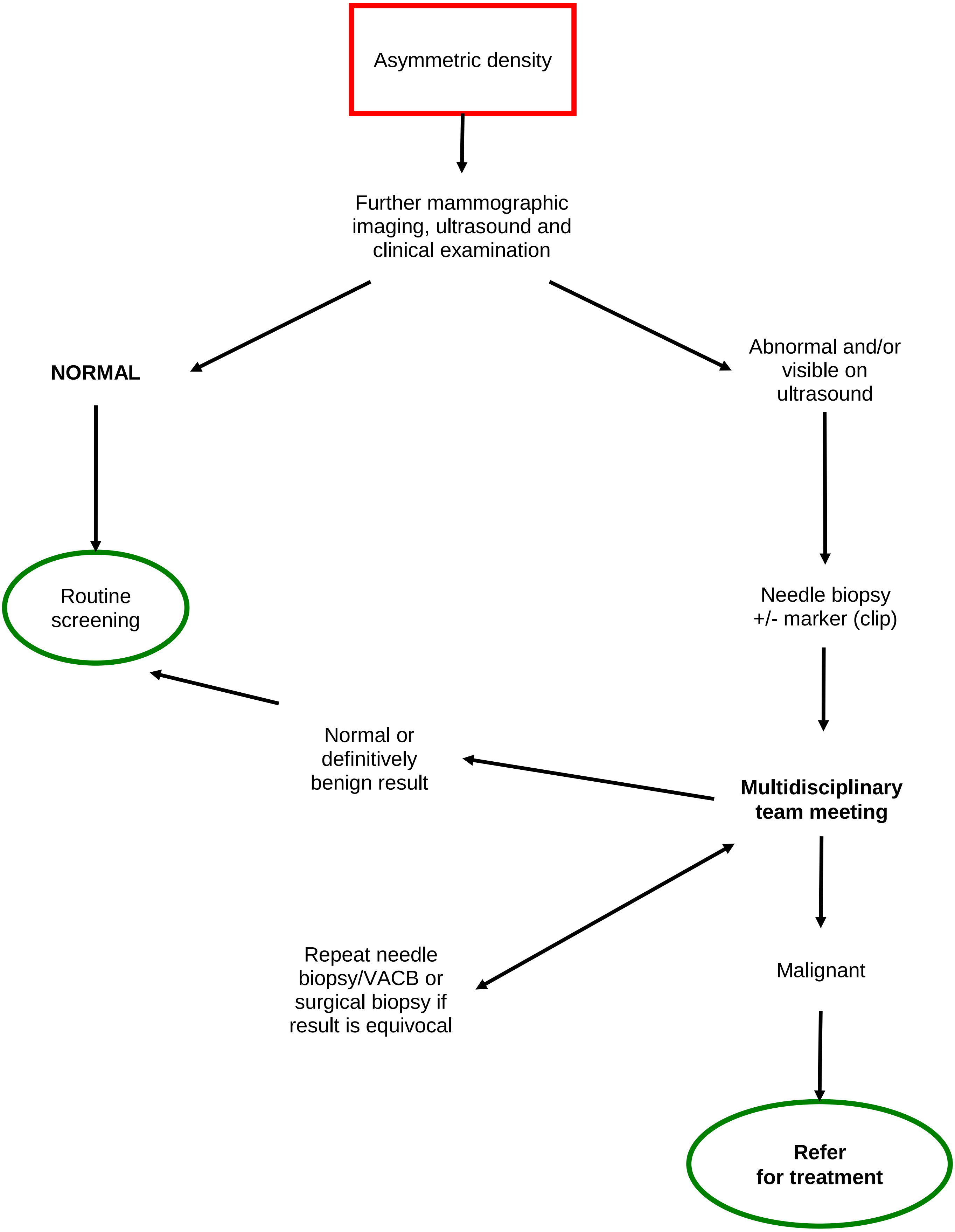
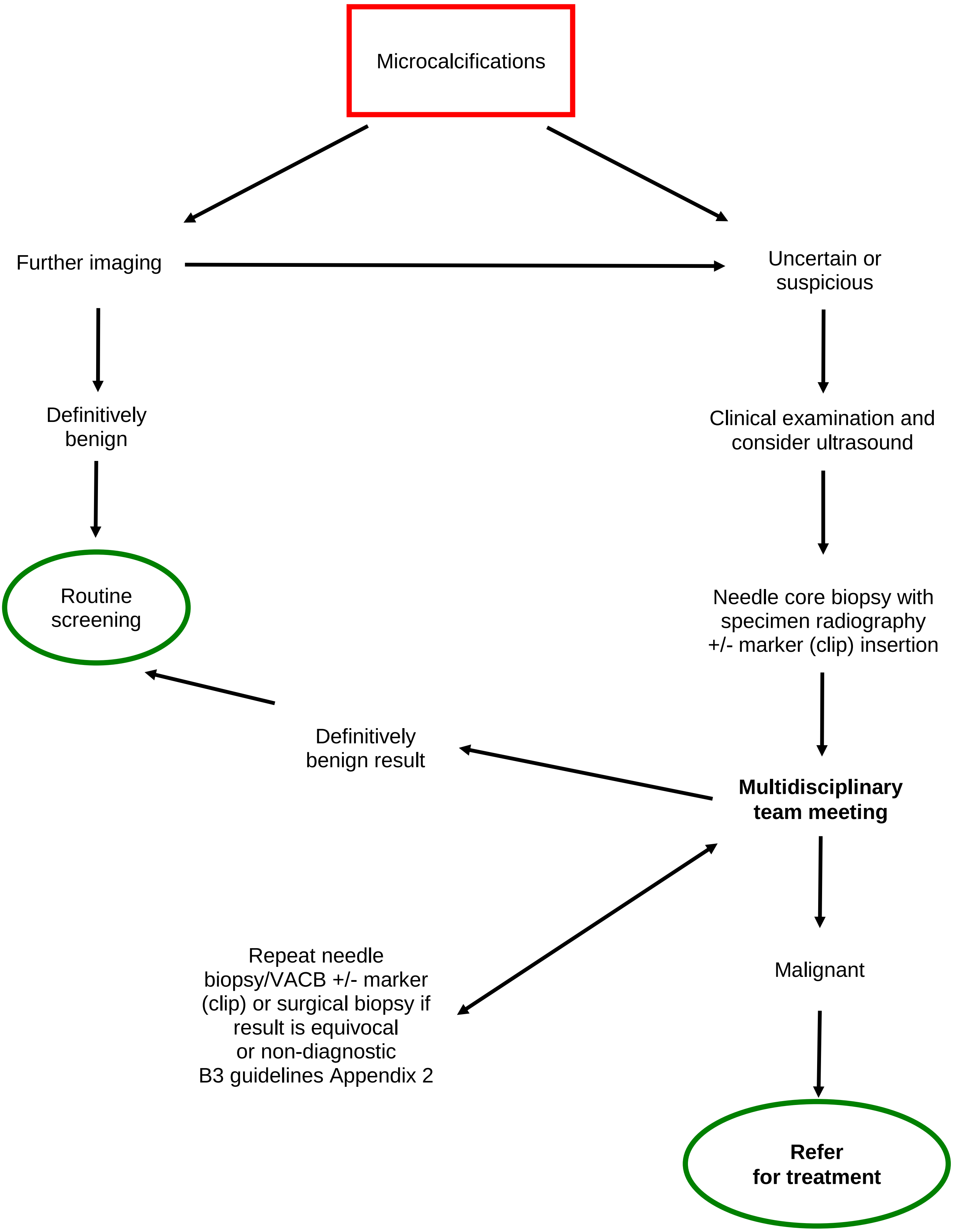


Figure 6 Microcalcifications



References

1 Briggs P, Gray S, Patnick J, Blanks R. Organising a Breast Screening Programme. NHS Cancer Screening Programmes, 2002 (NHSBSP Publication No 52) (under review), section 3.5: p13.

2 Ong G, Austoker J. Recalling women for further investigation of breast screening: women's experiences at the clinic and afterwards. Journal of Public Health Medicine, 1997;19:29–36.

3 Brett J, Austoker J, Ong G. Do women who undergo further investigation for breast screening suffer adverse psychological consequences? A multi-centre follow-up study comparing different breast screening result groups five months after their last breast screening appointment. Journal of Public Health Medicine, 1998; 20:396–403.

4 Ong G, Austoker J, Brouwer A. Guidelines on Improving the Quality of the Written Information Sent to Women Who are Recalled for Assessment. NHS Breast Screening Programme, 1998 (NHSBSP Publication No 38).

5 Austoker J. Breast Cancer Screening. A Practical Guide for Primary Care Teams. NHS Breast Screening Programme, 1990.

6 Quality Assurance Guidelines for Nurses in Breast Cancer Screening. NHS Cancer Screening Programmes, 2002 (NHSBSP Publication No 29). (Currently under review)

7 van Engen RE, Bosmans H, Dance DR, Heid P, Lazzari B, Marshall N, Schopphoven S, Thijssen M, Young KC. Digital mammography update. European protocol for the quality control of the physical and technical aspects of mammography screening. S1, Part 1: Acceptance and constancy testing. In: European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, Supplements. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds.). European Commission, Office for Official Publications of the European Union, Luxembourg, pp. 1–54 (2013).

8 Berg WA, Hruban RH, Kumar D et al. Lessons from mammographic- histopathologic correlation of large-core needle breast biopsy. Radiographics, 1996;16:1111–1130.

9 Liberman L, Evans III WP, Dershaw DD et al. Radiography of microcalcifications in stereotaxic mammary core biopsy specimens. Radiology, 1994,190:223–225.

10 Bagnall MJ, Evans AJ, Wilson AR, Burrell H, Pinder SE, Ellis IO. When have mammographic calcifications been adequately sampled at needle core biopsy? Clinical Radiology. 2000;55:548-53.

11 Clayton, D., C. Davison, and C. Bailey et al. Technical guidelines for magnetic resonance imaging (MRI) for the surveillance of women at higher risk of developing breast cancer. NHSBSP Publication 68 (2012).

12 Familial Breast Cancer. classification, care and managing breast cancer and related risks in people with a family history of breast cancer National Institute for Clinical Excellence, London. (NICE guidelines CG164). Published June 2013 last updated August 2015 https://www.nice.org.uk/Guidance/CG164.

13 Quality Assurance Guidelines for Breast Screening Radiology. NHS Cancer Screening Programmes, Second Edition March 2011 (NHSBSP Publication No 59).

14 Information and Advice for Health Professionals in Breast Screening. NHS Cancer Screening Programmes, 2002 (NHSBSP Publication No 53). (Archived)

15 Quality Assurance Guidelines for Mammography. NHS Breast Screening Programme, 2006 (NHSBSP Publication No 63). (Under review)

16 The Right Results. Guide to the Correct Processing and Issuing of Results. NHS Cancer Screening Programmes, 2003 (NHSBSP Publication No 55). (Under review)

17 Cornford EJ, Turnbull AE, James JJ et al. Accuracy of GE digital breast tomosynthesis versus supplementary mammographic views for diagnosis of screen-detected soft-tissue breast lesions. British Journal of Radiology, 2016;89:1058.

18 Noroozian M, Hadjiiski L, Rahnama-Moghadam S, Klein KA, Jeffries DO, Pinsky RW, Chan HP, Carson PL, Helvie MA, RoubidouxMA Digital breast tomosynthesis is comparable to mammographic spot views for mass characterization.Radiology. 2012;262:61-8.

19 Zuley ML, Bandos AI, Ganott MA, Sumkin JH, Kelly AE, Catullo VJ, Rathfon GY, Lu AH, Gur D.Digital breast tomosynthesis versus supplemental diagnostic mammographic views for evaluation of noncalcified breast lesions.Radiology. 2013;266:89-95.

20 Morel JC, Iqbal A, Wasan RK, Peacock C, Evans DR, Rahim R, Goligher J, Michell MJ The accuracy of digital breast tomosynthesis compared with coned compression magnification mammography in the assessment of abnormalities found on mammography Clinical Radiology, 2014;69:1112-1116.

21 Tennant SL, Yu D Ipsilateral whole breast ultrasound in patients with suspicious breast lesions - a worthwhile practice? Clinical Radiology 2012;67:S8-9. http://www.clinicalradiologyonline.net/article/S0009-9260(12)00280-2/abstract

22 Moon YK, Noh DY, Im JG Multifocal, multicentric, and contralateral breast cancers: Bilateral whole breast US in the preoperative evaluation of patients. Radiology 2002;224:569-576.

23 Wilkinson, L. S., R. Given-Wilson, T. Hall, H. Potts, A. K. Sharma, and E. Smith. Increasing the diagnosis of multifocal primary breast cancer by the use of bilateral whole-breast ultrasound. Clinical radiology, 2005;60:573-578.

24 Ohuchi N, Suzuki A, Sobue T, Kawai M, Yamamoto S, Zheng YF, Shiono YN, Saito H, Kuriyama S, Tohno E, Endo T, Fukao A, Tsuji I, Yamaguchi T, Ohashi Y, Fukuda M, Ishida T; J-START investigator groups. Sensitivity and specificity of mammography and adjunctive ultrasonography to screen for breast cancer in the Japan Strategic Anti-cancer Randomized Trial (J-START): a randomised controlled trial. Lancet. 2016;387:341-8.

25 Brem RF, Tabár L, Duffy SW, Inciardi MF, Guingrich JA, Hashimoto BE, Lander MR, Lapidus RL, Peterson MK, Rapelyea JA, Roux S, Schilling KJ, Shah BA, Torrente J, Wynn RT, Miller DP. Assessing improvement in detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: the SomoInsight Study. Radiology. 2015;274:663-73.

26 Housammi N Turner R Morrow M preoperative magnetic resonance imaging in breast cancer: meta analysis of surgical outcomes. Annals of Surgery 2013;257:249-55.

27 Onega T, Tosteson ANA, Weiss J, Alford-Teaster J, Hubbard RA, Henderson LM, Kerlikowske K, Goodrich ME, O’Donoghue C, Wernli KJ, DeMartini WB and Virnig BA. Cost of diagnostic and preoperative workup with and without breast MRI in older women with a breast cancer diagnosis. BMC Health Serv Res 2016;16:76.

28 Quality Assurance Guidelines for Surgeons in Breast Cancer Screening. NHS Cancer Screening Programmes, 2009 (NHSBSP Publication No 20). (under review)

29 Britton P. Fine needle aspiration or core biopsy. The Breast, 1999;8:1–4.

30 Liberman L, Sarna M P. Cost-effectiveness of stereotactic 11-gauge directional vacuum-assisted breast biopsy. American Journal of Roentgenology; 2000;175:53–58.

31 Bundred SM, Maxwell AJ, Morris J, Lim YY, Harake MJ, Whiteside S, Bundred NJ. Randomised controlled trial of stereotactic 11-G vacumm-assisted core biopsy for the diagnosis and management of mammographic micocalcification. British Journal of Radiology 2016; 1058: 20150504 doi; 10.1259.bjr21050504.

32 Reynolds HE. Core needle biopsy challenging benign breast conditions: a comprehensive literature review. American Journal of Roentgenology, 2000;174:1245–1250.

33 Litherland JC, Evans AJ, Wilson ARM et al. The impact of core-biopsy on pre- operative diagnosis rate of screen detected breast cancers. Clinical Radiology,1996;51:562–565.

34 Wallis MG, Cheung S, Kearins O, Lawrence GM Non-Operative Diagnosis - Effect on repeat operation rates in the UK Breast Screening Programme European Radiology 2009;19:318-312.

35 Early and locally advanced breast cancer; diagnosis and treatment. NICE/National Collaborating Centre for Cancer, 2009 (Nice Clinical Guideline 80), p18

36 Report of the Working Party for Higher- Risk Breast Screening Lars Holmberg. PHE feb 2015. https://www.gov.uk/.../report-working-party-higher-risk-breast-screening.pdf

37 www.sloaneproject.co.uk

38 Alvarez S, Anorbe E, Alcorta P et al. Role of sonography in the diagnosis of axillary lymph node metastases in breast cancer: a systematic review. American Journal of Roentgenology, 2006;186:1342–1348.

39 Britton PD, Goud A, Godward S, Barter S, Freeman A, Gaskarth M, Rajan P, Sinnatamby R, Slattery J, Provenzano E, O'Donovan M, Pinder S, Benson JR, Forouhi P, Wishart GC. Use of ultrasound-guided axillary node core biopsy in staging of early breast cancer. European Radiology. 2009;19:561-9.

40 Britton P, Moyle P, Benson JR, Goud A, Sinnatamby R, Barter S, Gaskarth M, Provenzano E, Wallis M.Ultrasound of the axilla: where to look for the sentinel lymph node. Clinical Radiology. 2010;65:373-6.

41 Houssami N, Turner RM. Staging the axilla in women with breast cancer: the utility of preoperative ultrasound-guided needle biopsy. Cancer Biol Med. 2014;11:69-77.

42 Mayers MM, Sloane JP. Carcinoma and atypical hyperplasia in radial scars and complex sclerosing lesions: importance of lesion size and patient age. Histopathology, 1993;23:225–231.

43 Sandler GP, McGee S, Dallimore NS et al. The role of the FNA and needle biopsy in the diagnosis of lobular carcinoma of the breast. British Journal of Surgery, 1994;81:1315–1317.

44 Spangler ML, Zuley ML, Sumkin JH, Abrams G, Ganott MA, Hakim C, Perrin R, Chough DM, Shah R, Gur D. Detection and classification of calcifications on digital breast tomosynthesis and 2D digital mammography: a comparison. American Journal of Roentgenology. 2011;196:320-4.

45 Michell MJ, Iqbal A, Wasan RK, Evan DR, Peacock C, Lawinski CP, Douiri A, Wilson R, Whelehan PA. Comparison of the accuracy of film-screen mammography, full-field digital mammography and digital breast tomosynthesis. Clin Radiol. 2012;67:976-81.

46 Soo MS, Baker JA, Rosen EL. Sonographic detection and sonographically guided biopsy of breast microcalcifications. American Journal of Roentgenology 2003;180:941–948.

47 Ji-Yeon Han, Jin Hwa Lee, Eun-Kyung Kim, Suyoung Shin, MyongJin Kang, Keun-Cheol Lee, Kyung Jin Nam. Breast US in patients with breast cancer presenting as only microcalcifications on mammography: can US differentiate ductal carcinoma in situ from invasive cancer? Journal of Medical Ultrasonics 2014;41:39-44.

48 Marion E. Scoggins, Patricia S. Fox, Henry M. Kuerer, Gaiane M. Rauch, Ana P. Benveniste, Young Mi Park, Sara A. Lari, Savitri Krishnamurthy, Wei T. Yang. Correlation Between Sonographic Findings and Clinicopathologic and Biologic Features of Pure Ductal Carcinoma In Situ in 691 Patients. American Journal of Roentgenology 2015;204:878-888.

49 The European guide lines for quality assurance in breast cancer screening 4th edition. Editors Perry N, Broeders M, de Wolf C, Tornberg S, Holland R, von Karsa L. European Commissioner for health and consumer protection Brussels 2006. (http://www.euref.org/european-guidelines)

50 The Characteristics of an Effective Multidisciplinary Team (MDT) National cancer action team Feb 2010 http://www.nhsiq.nhs.uk/media/2444560/ncatmdtcharacteristics.pdf

51 Best practice diagnostic guidelines for patients presenting with breast symptoms (DOH 2010) –editors Willett AM Michell MJ Lee MJR Nov 2010.

52 Patkar V, Acosta D, Davidson T, Jones A, Fox J, Keshtgar M Cancer Multidisciplinary Team Meetings: Evidence, Challenges, and the Role of Clinical Decision Support Technology. International Journal of Breast Cancer 2011; Article ID 831605, 7 pages. http://dx.doi.org/10.4061/2011/831605.

53 The Royal College of Radiologists. Cancer multidisciplinary team meetings – standards for Clinical Radiologists, Second edition. London: The Royal College of Radiologists, 2014. https://www.rcr.ac.uk/sites/default/files/bfcr1415_mdtms_revised_web_final.pdf

54 Ong GJ, Austoker J, Brett J. Breast Screening: adverse psychological consequences one month after placing women on early recall because of a diagnostic uncertainty. A multicentre study. Journal of Medical Screening, 1997;4:158–168.

55 Ong GJ, Austoker J, Michell M. Early rescreen/recall in the UK National Health Service breast screening programme: epidemiological data. Journal of Medical Screening, 1998;5:146–155.

56 Guidelines on Quality Assurance Visits. NHS Cancer Screening Programmes, 2000 (NHSBSP Publication No 40). (under review)

57 Boulton R, James R, Kantharuban S, Chin K , Taylor A Improving the service for patients with benign breast biopsy Results: lessons learnt from a busy District General Hospital. Page S14 International Journal of Surgery 2012 Vol 10, Iss 8, Pgs 382-404, S1. http://www.sciencedirect.com/science/journal/17439191/10/

58 Rowley J, Safdar G, Clayton G, Taylor K. Results following a benign breast biopsy – A breast care nurse led “virtual” telephone clinic EJSO 2014;40:664.

59 Krishnan N, Fagerlin A, Skolarus TA Rethinking Patient-Physician Communication of Biopsy Results—The Waiting Game JAMA Oncol, 2015;1:1025-1026.