

CLINICAL GUIDELINES FOR BREAST CANCER SCREENING ASSESSMENT

Third edition

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PREFACE

The guidelines for breast screening assessment were last revised in 2005. Since then there have been further changes in practice, prompting this third revision. Today the optimal management of screen detected breast cancer requires pre-operative assessment with image guided needle biopsy to obtain a non-operative diagnosis. The new guidelines include recommendations for the use of vacuum assisted core biopsy (VACB), reflecting its increased use in tissue sampling. They also acknowledge that sentinel node biopsy of axillary lymph nodes has become established as an alternative to dissection for assessing the axilla, and that routine pre-operative assessment of axillary nodes is now expected to include ultrasound with needle sampling of morphologically abnormal nodes. Another significant change has been the integration of higher risk screening into the NHSBSP, requiring the inclusion of guidance on the assessment of women with magnetic resonance imaging (MRI) detected breast abnormalities.¹

1. INTRODUCTION

1.1 Background

The 1986 report to the Chief Medical Officers of England, Wales, Scotland and Northern Ireland on breast cancer screening (the 'Forrest Report') recognised the importance of high quality, comprehensive assessment of screen detected abnormalities in reducing mortality from breast cancer.² When breast screening was introduced in the NHS in 1987, the recommendation was that assessment should be carried out by multidisciplinary teams.^{2,3} Since then, guidance has been published on the organisational support that this requires and a number of standards have been included in breast screening quality assurance guidelines to ensure that this assessment is carried out satisfactorily.³⁻⁹ The present guidance sets out the minimum standards for breast screening assessment.

1.2 Aim of assessment

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), plus clinical examination, plus 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.

2. THE ASSESSMENT PROCESS

2.1 Introduction

Depending on the age of the women screened and the screening round, some 5% of women screened are recalled for assessment.¹⁰ The minimum NHSBSP standard is that no more than 10% of women screened for the first time or 7% of women who have been screened before should be recalled for assessment.¹¹ Those attending for their first screen are more likely to be recalled. Around 1% of women screened will undergo needle biopsy to confirm either a benign process or a clinical/radiological suspicion of malignancy.¹² Figure 1 shows the assessment process in further detail, including the possible start and end points.*

The Director of Screening is responsible for verifying that failsafe mechanisms are in place to ensure that decisions to recall for assessment are actioned.¹³ If a recalled woman fails to attend there should be protocols in place for issuing a second recall appointment and, if she fails to attend a second time, for contacting the woman and her primary care team to agree on appropriate further management.

2.2 Organisation of assessment clinics

The standard is that 90% of women to be assessed should be seen within three weeks of screening.¹¹ There should be enough assessment capacity to ensure that assessment takes place well within this standard period. The number of assessment clinics needed will vary according to the size of the population being screened, the facilities available, and the staff and skill mix available to carry out the assessment.

2.3 Method and timing of recall

Most women who participate in the breast screening programme have no breast symptoms or signs. 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 clinics with breast problems.¹⁴ Recall for assessment is associated with significant anxiety, particularly as most women have had no previous indication of a breast problem.^{14,15} For this reason, the time between receipt of the appointment for the assessment clinic and actual attendance should be as short as is practically possible. It should take into account that most women recalled for assessment do not prove to have breast cancer. Recall by letter is the recommended method; it should convey the basic minimum information, including a contact telephone number for women seeking more detail. With this in mind the posting of invitations to assessment should be timed to avoid their arriving at weekends.¹⁶ The primary care team should be kept informed about the outcome of the assessment process.¹⁷

Telephoning women to invite them for assessment may unnecessarily 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.

*To facilitate reproduction, all figures appear on separate sheets at the end of the document.

2.4 Number of assessment visits

The number of diagnostic assessment visits needed to achieve a definitive outcome should be as low as possible. The minimum standard is that 95% of women should require no more than three separate visits for diagnostic assessment (including visits to receive results). The number of visits will depend on the structure of the assessment process; however, no more than two needle biopsy procedures, carried out on separate occasions, should normally be needed to achieve a non-operative diagnosis.

2.5 Personnel for the assessment clinic

The core assessment team may include

- consultant radiologist (or equivalent)
- clinician (radiologist, surgeon, breast clinician)
- clinical nurse specialist in breast care
- advanced radiographer practitioner
- radiographer
- assistant radiographer practitioner
- administrative staff.¹⁸

The assessment clinic must be led by a consultant radiologist or consultant radiographer or breast clinician who should be present in the clinic to direct the assessment process.

Professionals involved in screening assessment are expected to fulfil the requirements for individual professional training and for their continuing medical education and development. Those involved in formal screen reading should also participate regularly in screening assessment.

The service should ensure that 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 when required to provide this.⁷

2.6 Equipment for assessment

The equipment needed for breast assessment includes

- digital mammography equipment. This should be capable, as a minimum, of magnification mammography, special views and small field digital stereotactic x-ray guided biopsy, and able to undertake specimen radiography during a core biopsy procedure¹⁹
- ultrasound equipment that meets the standard set by the National Institute for Health and Clinical Excellence's Medical Technologies Assessment Committee.²⁰ At the time of publication, a minimum operating frequency of 10 MHz is required²¹
- the consumables and devices necessary for core biopsy and VACB, including biopsy site markers.

2.7 Indications for assessment

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).^{1,22}

Mechanisms must be in place to identify and record significant signs and symptoms of breast problems in women attending for screening, and this information must be made available at the time of screen reading.^{6,23} Radiographers and assistant practitioners should be trained to recognise them at the time of screening.¹⁸ Recall for assessment of signs and symptoms may be appropriate even if the screening mammograms appear normal and each unit should have a clear written protocol for recall in these circumstances. 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 reason for the recall clearly identifiable to those undertaking the assessment.

2.8 Right Results protocol

All screening units must have in place externally verified protocols and procedures for ensuring that each decision to recall a woman for assessment results in an appropriate invitation and that attendance and outcomes are formally recorded.²⁴

3. ASSESSMENT PROCEDURES

3.1 Assessment protocols

Each assessment clinic should include, as a minimum, a consultant radiologist, a consultant radiographer or an appropriately trained breast clinician to take responsibility for the clinical and imaging processes (see section 2.5). Local risk management policies should state whether a woman's formal written consent to assessment procedures is needed.

Assessment should follow the triple assessment model: appropriate further imaging with mammography and ultrasound plus clinical assessment and, where indicated, needle sampling. Each assessment unit should have written protocols for triple assessment and they 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.

3.2 Further imaging

The majority of 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) and/or ultrasound where indicated. Depending on the nature of their breast abnormality, some women will not need further imaging. Where they do, it should be directed by the individual(s) in charge of imaging. If ultrasound is used at least the relevant breast quadrant should be imaged, and ultrasound of the ipsilateral axilla should be performed if a cancer is suspected.

Breast screening assessment units should meet the requirements of the Ionising Radiation (Medical Exposure) Regulations 2000 and staff involved must be clear about their specific responsibilities under these regulations.^{25,26}

3.3 Clinical examination

The clinical examination of women recalled for assessment should be carried out by an individual recognised by the breast team as having the necessary clinical skills.

A clinical examination is mandatory for every woman with a confirmed mammographic or ultrasound abnormality that needs needle sampling and for all women recalled because of clinical signs or symptoms (Figure 2). It is not mandatory for women whose further imaging is entirely normal.

3.4 Needle biopsy of breast

Significant breast abnormalities should be assessed by needle core biopsy or VACB.^{5,27} Current evidence suggests that 14-gauge core biopsy, properly carried out, achieves greater sensitivity and specificity for microcalcifications, asymmetry and architectural distortion than does fine needle

aspiration (FNA).²⁸⁻³² Core biopsy provides information on tumour type, invasive status, grade and receptor status. It also aids the definitive diagnosis of benign lesions. If a rapid diagnosis is needed fine needle aspiration cytology (FNAC) may be used in addition to core biopsy but not instead of it. In rare 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 will inform discussion at the multidisciplinary team (MDT) meeting.

VACB is now available in many screening centres and can be used with ultrasound and stereotactic x-ray guidance. Published evidence shows that its use is associated with higher rates of calcium retrieval and lower rates of underdiagnosis of both ductal carcinoma in situ (DCIS) and invasive tumour.^{33,34} Where it is available, VACB may be considered the sampling method of choice for

- microcalcifications (see section 4.4)
- following a B1/B3/B4 result at 14-gauge core biopsy
- diagnostic excision of papillary lesions and radial scars/complex sclerosing lesions without atypia that have been diagnosed at core biopsy.

Practitioners undertaking biopsy procedures in assessment clinics should ensure that they have the necessary skills to carry out cyst aspiration and needle biopsy under stereotactic and ultrasound control.

There should be written local protocols clearly defining the indications for FNAC, core biopsy and VACB.³⁵ Further guidance is given in the *Guidelines for Non-operative Diagnostic Procedures and Reporting in Breast Cancer Screening*.⁴ Specifically, it is emphasised that a B3 or C3 result does not automatically indicate the need for either repeat needle biopsy or surgical open biopsy. All needle biopsies carried out as part of screening assessment should be reviewed at the MDT meeting and management of each case should be agreed by the team.³⁶

3.5 Needle biopsy of axilla

If one or more abnormal axillary lymph nodes are seen with ultrasound in a woman with suspected breast cancer, needle sampling is required to establish whether there is evidence of metastatic disease. Pre-operative diagnosis of lymph node metastases will identify patients for whom sentinel node biopsy is inappropriate. Ultrasound of the axilla should be carried out at the time of assessment in all women with suspected invasive breast cancer. The criteria for proceeding with lymph node sampling should be agreed locally; however, a node that is entirely hypoechoic or that has a cortex > 2 mm, a focal cortical bulge or a short-long axis ratio > 0.5 should be considered as potentially abnormal.³⁷ The criteria and procedure for sampling should be agreed locally. FNAC and core biopsy of axillary nodes are recognised techniques and staff involved in assessment should have the necessary skills to carry out node biopsy under ultrasound guidance. If the breasts are normal and lymphoma is suspected, local protocols should be followed to obtain a tissue diagnosis.

4. ASSESSMENT OF MAMMOGRAPHIC ABNORMALITIES

4.1 Masses

Ultrasound is the preferred imaging method for establishing the nature of a breast mass (Figure 3). Further mammography, including focal compression views, 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 or 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 cytology of the aspirate if appropriate. If a mass is confirmed on mammography but is not visible on ultrasound it should be managed according to its mammographic features and not necessarily 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 either a second core biopsy or VACB should be considered.

4.2 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 as well as ultrasound to establish whether there is a persistent localised abnormality. The initial assessment may also include clinical examination to check for relevant clinical findings such as a mass or scarring from previous surgery (Figure 4a and b). If surgical scarring is ruled out, architectural distortion may indicate malignancy and needle biopsy should always be performed.^{33,38} Recommendations for the management of architectural distortion depend on the local availability of VACB. If VACB is not available conventional core biopsy is recommended as the initial diagnostic test for all distortions that are not a result of surgical scarring.³¹ If this shows malignant change then therapeutic surgery should be performed. For all other diagnoses, diagnostic surgical open biopsy should be performed. If VACB is available and the result is benign or shows radial scar with no evidence of epithelial atypia, a choice of either open surgical excision or excision with VACB plus clip insertion may be offered. VACB can be performed under ultrasound or stereotactic x-ray guidance and a minimum of twelve 11-gauge cores should be obtained. The site of the cavity may be marked using an ultrasound visible clip to aid localisation if subsequent surgical excision is required. The VACB findings should be discussed at an MDT meeting. Surgical excision is usually recommended if atypia is reported in the VACB specimens. Where VACB histology again shows either benign changes or radial scar with no evidence of epithelial atypia then further excision is unnecessary. In all cases management should be discussed prospectively by the MDT. If there is any doubt regarding the concordance of the imaging and histology findings, diagnostic surgical excision is recommended.

4.3 Asymmetric density

Further mammography, 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 asymmetry found on imaging or clinical examination.³⁹⁻⁴¹

4.4 Microcalcifications

It is often difficult to distinguish between benign and malignant microcalcifications from their mammographic appearance alone (Figure 6). Cranio-caudal and lateral magnification views aid further characterisation and help in assessing the probability of malignancy. Magnification views are also useful in defining the extent of DCIS if conservation surgery is being considered. 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.⁴² Ultrasound assessment of large areas of microcalcification may identify focal areas of altered echotexture, indicating possible invasive foci within DCIS. Assessment of the axilla with ultrasound should also be considered in these cases. Representative microcalcification must be demonstrated in the core specimens on specimen radiography. If it is not, the procedure should be repeated. Ideally, this 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. The identification of microcalcification on histology is not of 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. Where core biopsy demonstrates atypical epithelial proliferation, surgical open biopsy or VACB is normally needed to exclude malignant change in the adjacent tissue.^{34,42}

The specificity and absolute sensitivity for sampling microcalcifications is significantly increased when larger bore biopsy devices such as VACB are employed, and their use may be considered where there is diagnostic uncertainty.^{33,43}

Where available, VACB is the preferred method for sampling microcalcifications in the following circumstances

- very small clusters of microcalcification that are likely to be difficult to sample (< 5 mm)
- failed conventional core biopsy
- a B3 or B4 result after conventional core biopsy
- indeterminate microcalcification where it is likely that large tissue volumes will be required for accurate histological assessment
- microcalcifications at a site that is likely to be difficult to sample with conventional core biopsy.

If there is little residual calcification a marker with a metal component should be inserted to mark the site.

4.5 Multidisciplinary meetings

The diagnosis and management of all women who have undergone needle biopsy procedures at a breast screening assessment clinic should be discussed at a prospective MDT meeting.

All separate suspicious lesions should be biopsied unless the patient is clear that she wants a mastectomy. Multifocality should not be assumed from imaging results alone, and patients should not be told they need a mastectomy without a tissue diagnosis confirming that separate lesions are malignant.

4.6 Exceptional circumstances

In certain circumstances, clinical factors, such as patient infirmity, may make it neither possible nor prudent to adhere to the 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.

5. OUTCOMES OF ASSESSMENT

5.1 Multidisciplinary meetings

The outcome of assessment should be decided according to agreed multidisciplinary written protocols (see section 3.1). A provisional opinion as to the nature of the problem and its possible management may be discussed with the woman at the time of assessment. A woman who has undergone needle biopsy should have her result discussed in a multidisciplinary clinical meeting and the management of her case agreed. This should happen prior to any treatment and ideally before the patient receives her result. A multidisciplinary forum to discuss the results of screening assessment should occur at least weekly. Even when normal, the provisional and final results of assessment should be given to the patient by a clinical practitioner.

There are three outcomes of assessment

- return to the routine screening programme
- refer for open surgical biopsy
- refer for treatment.

5.2 Short term recall

A short term recall is defined as a further invitation to assessment. Short term recall for screening at less than the routine screening interval (also known as 'early recall') is not recommended.⁶ 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; it is not a delayed screening assessment follow-up. Women placed on short term recall should be invited to the assessment clinic for bilateral two view mammography and may be given their result immediately. They should not be given a routine mammography screening appointment.

Short term recall must not be considered a routine outcome of assessment.^{6,44} The use of triple assessment makes it possible to reach a definitive conclusion in the great 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 these few cases, short term follow-up is required. A woman should be placed on short term recall only if there is clear justification and after the decision has been discussed in detail at the multidisciplinary meeting, agreed and documented. This option should not be used as an alternative to proper assessment. 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.^{6,9}

5.3 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; sufficient time should be allocated to provide the necessary counselling and support. All women assessed without a diagnosis of cancer should receive written confirmation of the outcome of their assessment.^{14,16}

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

In addition to the NBSS computer record, a written record should be kept of the assessment process and outcome.

5.4 Audit

Audit should be regarded as a fundamental part of effective screening. Recommendations for audit criteria are listed in the Appendix. Units should expect audit of their assessment processes to be included in quality assurance reviews.

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APPENDIX

AUDIT OF SCREENING ASSESSMENT

Non-operative diagnosis rate for breast cancer	Minimum standard 90% (invasive) 85% (non-invasive)	Target 95% (invasive) 90% (non-invasive)
Benign diagnostic surgical biopsy rates	Minimum standard Prevalent < 1.5 per 1000 women screened	Target Prevalent < 1.0 per 1000 women screened
	Incident < 1.0 per 1000 women screened	Incident < 0.75 per 1000 women screened
Attendance at multidisciplinary screening assessment review meetings	Minimum standard Colleagues involved in decision making and further diagnostic procedures (ultrasound and biopsy) should attend multidisciplinary meetings at which screening cases are discussed (twice per month on average) and/or should ensure that a formal process is in place for auditing their practice and outcomes	
Pre-operative assessment of lymph nodes in screen detected cancers	Lymph node biopsy outcomes must be audited	
Individuals should provide audit of their recalls plus assessment outcomes including needle biopsy results	Examples % of cases recalled at first reading which prove to be malignant number of women assessed per year B1/2/3/4/5 rates	
False negative assessment	To ensure that the assessment processes prescribed in these guidelines have been adhered to, interval cancers or screen detected cancers must be formally audited if the same lesion, or a precursor lesion at the same site, has previously been assessed	

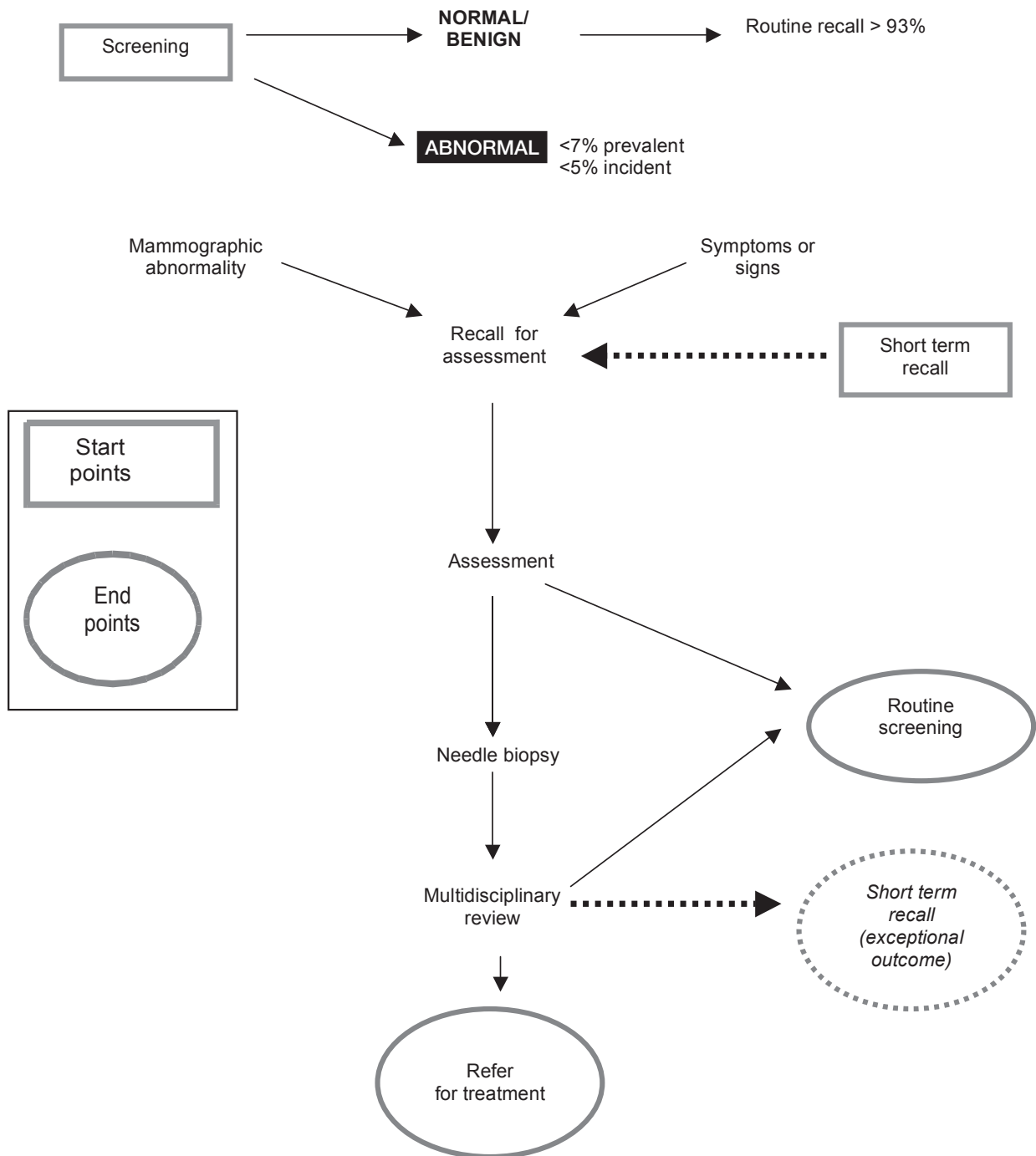


Figure 1 Assessment process

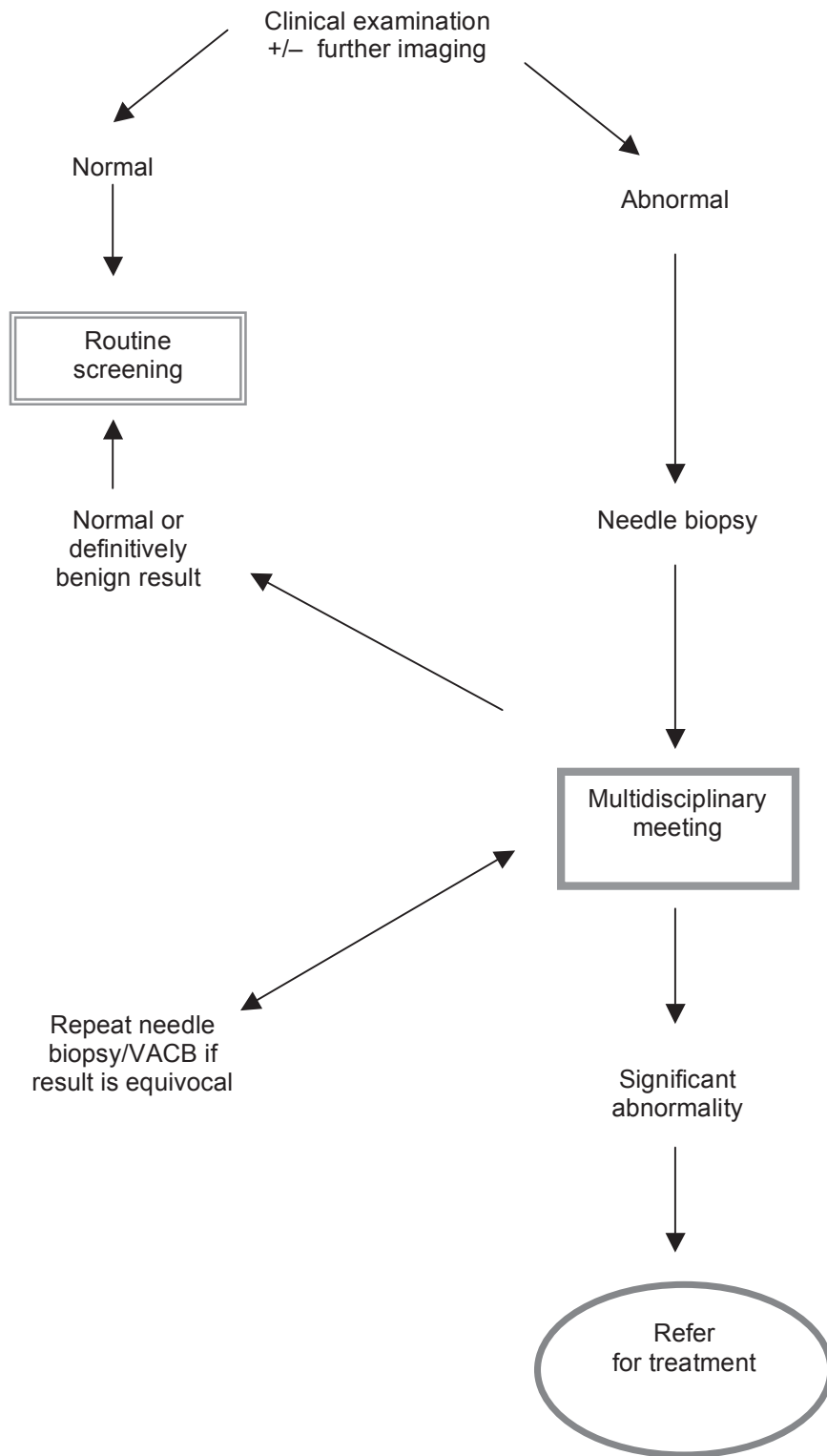


Figure 2 Assessment of clinical signs/symptoms

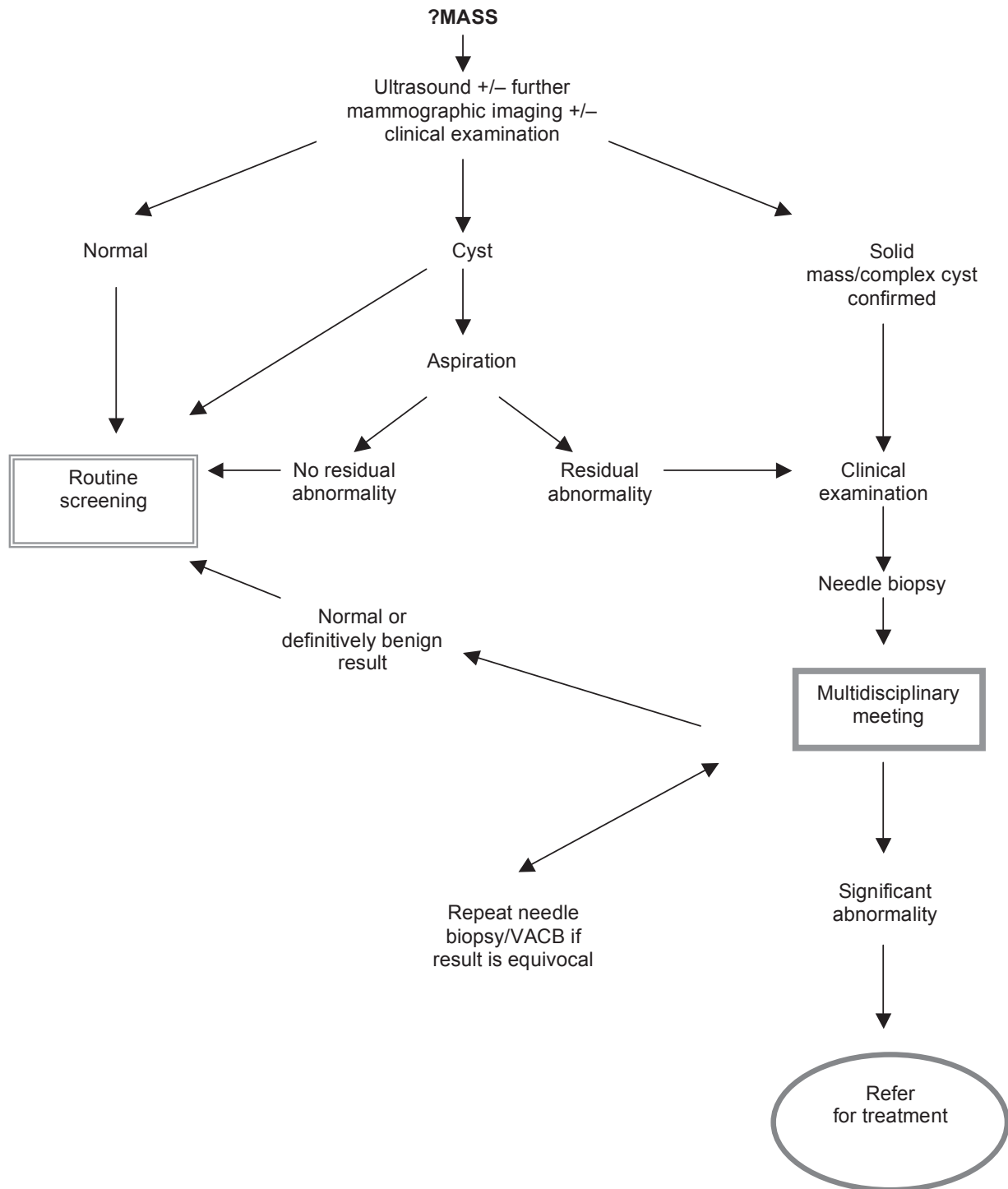


Figure 3 Assessment of breast masses

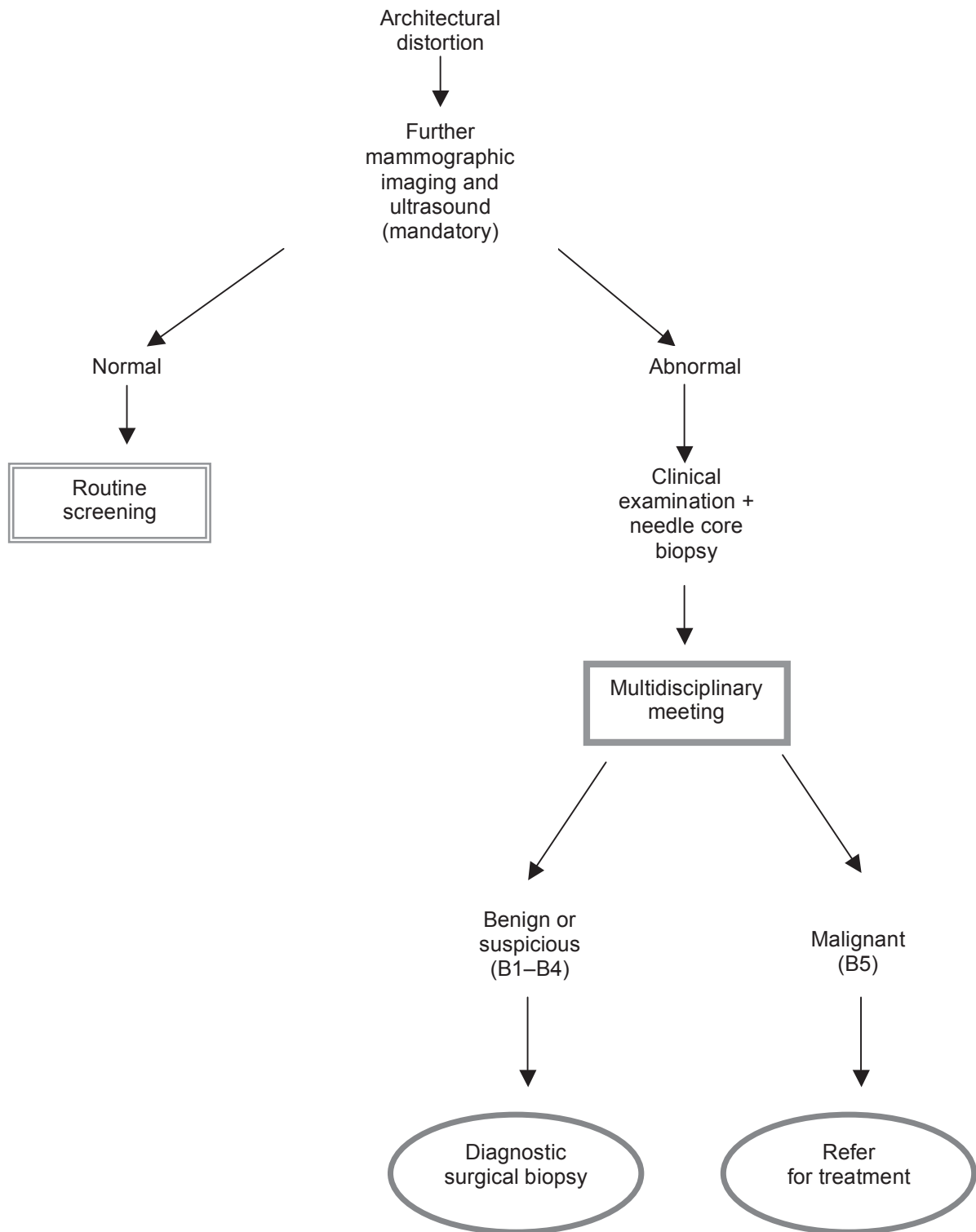


Figure 4a Architectural distortion: core biopsy only available

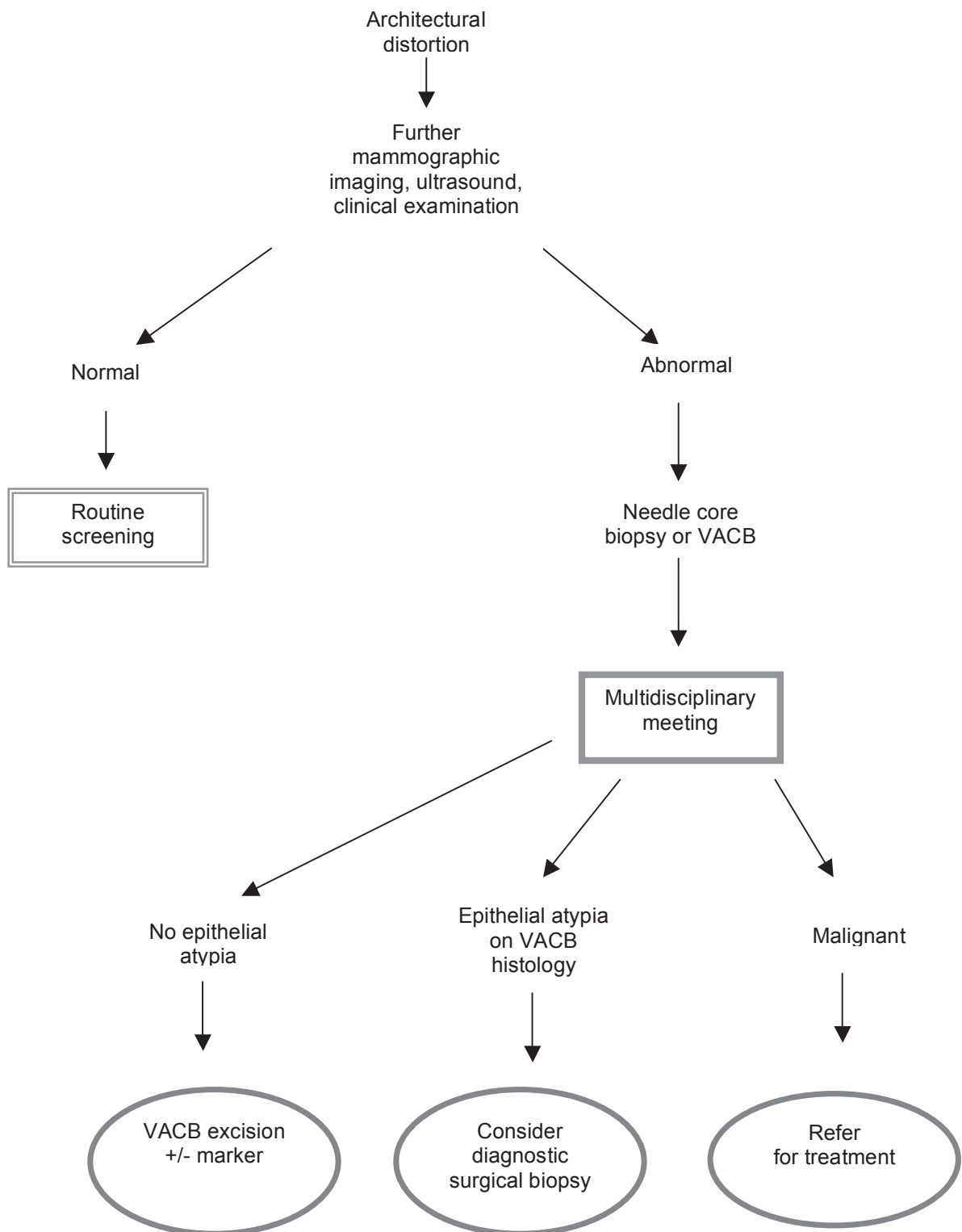


Figure 4b Architectural distortion: vacuum assisted core biopsy only available

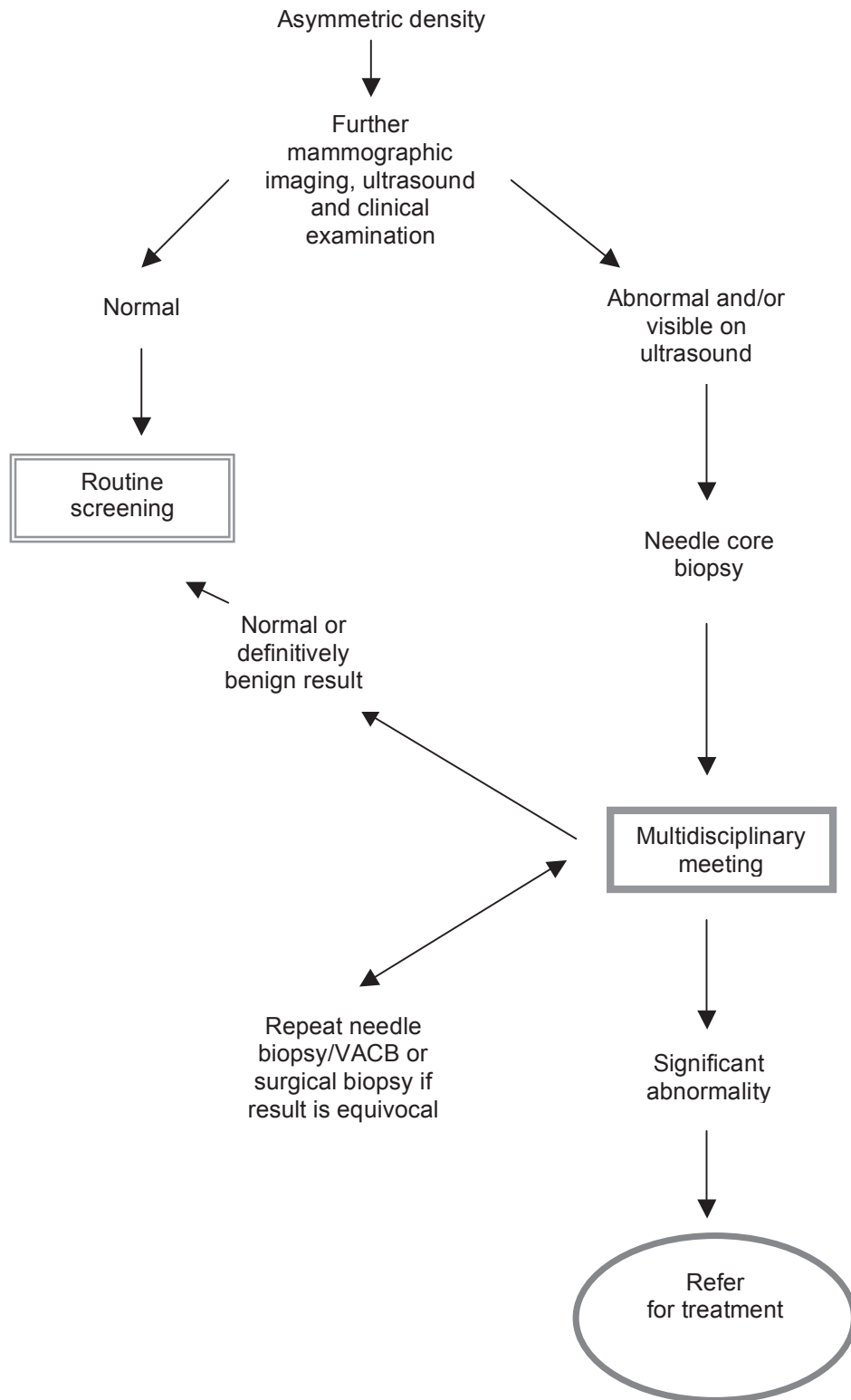


Figure 5 Asymmetric density

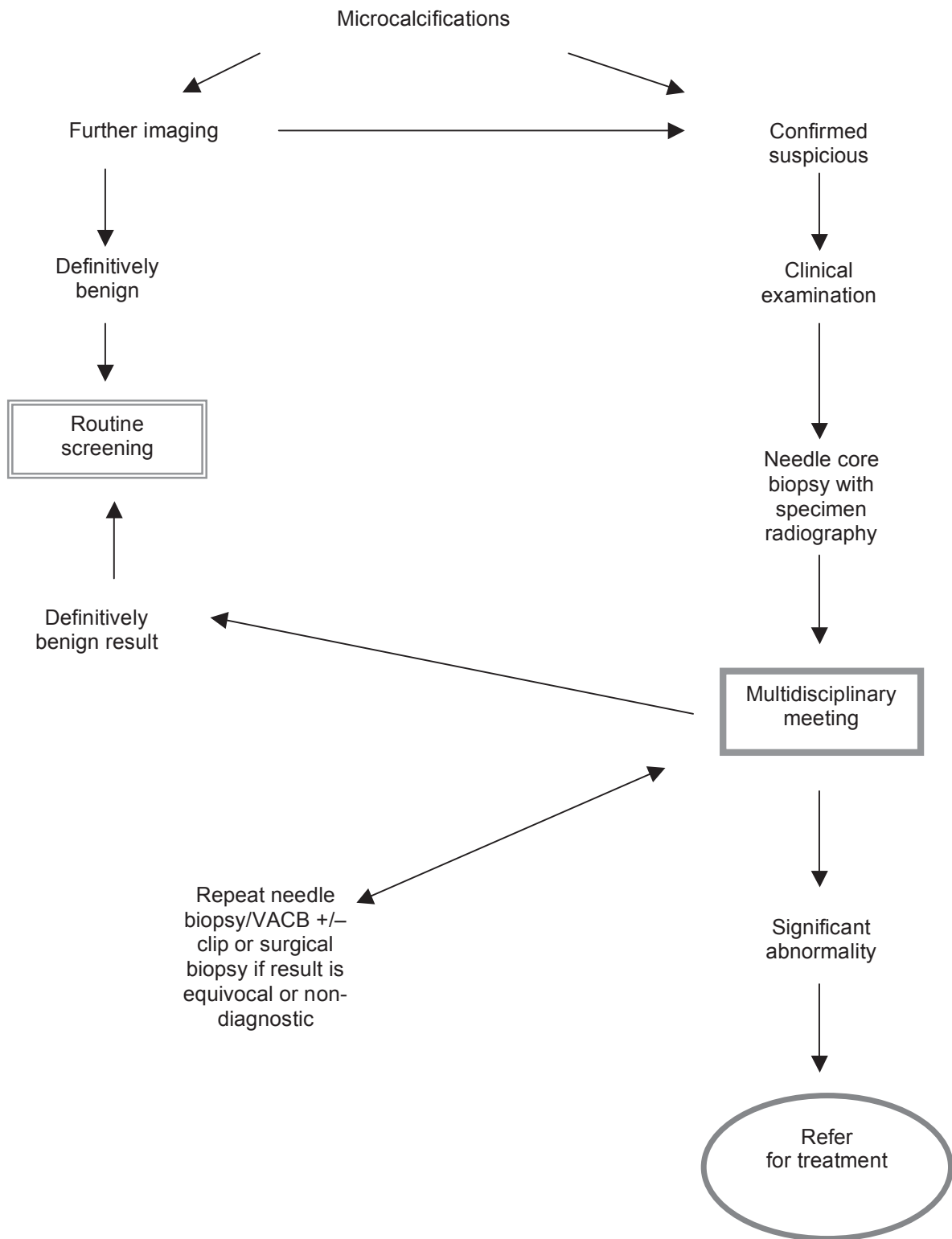


Figure 6 Microcalcifications

