

**CLINICAL GUIDELINES FOR BREAST CANCER
SCREENING ASSESSMENT**

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An example screening assessment protocol is available for download on the NHS Cancer Screening Programmes web site (www.cancerscreening.nhs.uk).

PREFACE

The first guidelines for breast screening assessment were published in 2001. In the three years since then there have been a number of changes in practice that warrant inclusion in updated guidelines. Most units have now moved from fine needle aspiration (FNA) for cytology to automated core biopsy as the method of first choice for non-operative diagnosis. The guidelines also include recommendations on the indications and use of vacuum assisted mammotomy (VAM), reflecting the increasing use of this method of biopsy in many screening assessment units.

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 to achieving the aim of reducing mortality from breast cancer.¹ When breast screening was introduced in the NHS in 1987, the recommendation was that assessment should be carried out by multidisciplinary teams (MDTs).^{1,2} Since then, guidance has been published on the appropriate organisation to support such assessment, and a number of standards have been included in the various breast screening quality assurance guidelines to ensure that this assessment is carried out satisfactorily.²⁻⁸ This guidance sets out the minimum standards required for satisfactory breast screening assessment.

1.2 Aim of assessment

The aim of assessment is to obtain a definitive diagnosis of all potential screen-detected abnormalities in a timely way. Women with no significant breast problems should be reassured as quickly as possible, and women with cancer should be diagnosed without delay. This is best achieved by the 'triple approach' using, where indicated, imaging (usually mammography and ultrasound), clinical examination and needle sampling for cytology or histology.

2. THE ASSESSMENT PROCESS

2.1 Introduction

Assessment of potential screen-detected abnormalities is best carried out at clinics that are dedicated for this purpose, as the majority of women attending are asymptomatic and have different clinical needs from those who present through their general practitioner (GP) with symptoms.¹

Depending on the age of the women screened and the screening round, about 5% of women screened are recalled for assessment.⁹ The minimum NHS Breast Screening Programme (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.¹⁰ Younger women and those who are attending for their first screen are more likely to be recalled. About 1% of women who are screened will undergo needle biopsy to confirm either a benign process or a clinical/radiological suspicion of malignancy.¹¹ Figure 1 shows the assessment process in further detail, including the possible start and end points.

The director of screening is responsible for ensuring that failsafe mechanisms are in place to ensure that a decision to recall for assessment is actioned. If a woman who is recalled fails to attend, there should be protocols for issuing a second recall appointment and, should the woman fail to attend for a second time, protocols 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 women should be offered an appointment date that is within three weeks of their screening attendance.¹⁰ There must be sufficient assessment clinics per week to ensure that assessment takes place well within this standard for all women screened. The number of assessment clinics required will vary according to the size of the population being screened and to the facilities and staff available to carry out the assessment.

2.3 Method and timing of recall

Most women participating in the breast screening programme have no breast symptoms or signs. The expectations and needs of 'well women' who are recalled for assessment of a screen-detected abnormality are significantly different from those of women referred to breast clinics with breast problems.¹² Recall for assessment is associated with significant anxiety, particularly as the majority of women have no previous indication that they have a breast problem.^{12,13} 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. This takes into account that the vast majority of women who are recalled for assessment have no significant breast problems and can be returned to routine screening. Recall by letter is the recommended method and should include the basic minimum information, including a contact telephone number for women who require further information. For this reason weekends should be avoided for the likely receipt of letters of invitation to assessment.¹⁴ The primary care team should be kept informed about the assessment process.¹⁵

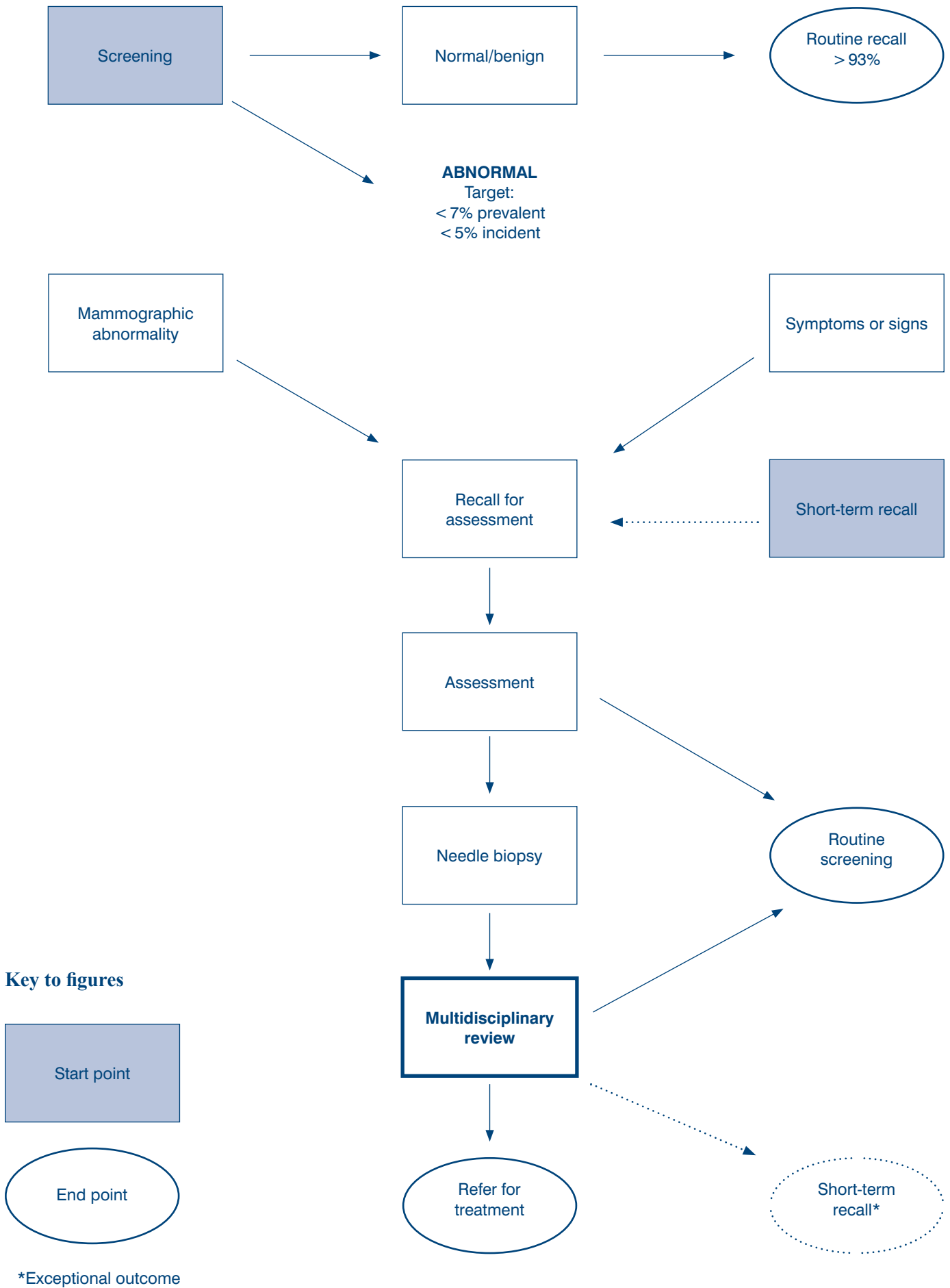


Figure 1 Assessment process.

Telephoning women to invite them to attend for assessment may cause unnecessary increased anxiety. If this method of recall is used in exceptional circumstances, it must be done only by suitably trained individuals following appropriate written local guidelines.

2.4 Number of assessment visits

The number of diagnostic assessment visits required to achieve a definitive outcome should be kept to a minimum. 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 assessment visits required will depend on the structure of the assessment process, but normally women should not undergo more than two needle biopsy procedures carried out on separate occasions in an attempt to achieve a non-operative diagnosis.

2.5 Personnel for the assessment clinic

The core assessment team comprises:

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

The assessment clinic must be led by a consultant radiologist or clinician, who should be present in the clinic and review the care of each case that is assessed. The clinician and clinical nurse specialist should be available when required and need not necessarily attend the whole clinic.

The introduction of advanced practitioners in breast screening is currently under development, and it is expected that they will also be part of the core assessment team. It is expected that the professionals involved in screening assessment comply with their individual professional training, continuing medical education and development requirements. Advanced practitioners are expected to comply with the relevant occupational standards and work to the guidance on skill mix.¹⁶ Those involved in formal screen reading should attend screening assessment on a regular basis.

Additional team members may be included according to local practice. Some screening units that use cytology for diagnosis have a medical laboratory scientist or pathologist in attendance to assess the cellularity of aspirates.

The service should ensure that all women who are recalled for assessment receive information, advice and support appropriate to their needs from a clinical nurse specialist in breast care.

2.6 Equipment for assessment

Equipment for assessment includes:

- mammography equipment that is capable of magnification mammography, special views and spot digital stereotactic x-ray guided biopsy, and the facility to undertake specimen radiography during a core biopsy procedure (minimum requirements)

- ultrasound equipment with a minimum operating frequency of 10 MHz¹⁷
- appropriate materials and devices for core biopsy and fine needle aspiration (FNA).

2.7 Indications for assessment

Indications for assessment are:

- significant mammographic abnormality
- significant breast symptoms identified at screening
- significant breast signs identified at screening
- review of short-term recall.

Mechanisms must be in place to identify and record significant signs and symptoms of breast problems in women who are attending for screening and this information must be made available at the time of screen reading.^{5,18} Radiographers should be trained to recognise significant breast signs and symptoms and there should be a written protocol for clinical recall. Recall for assessment of signs and symptoms may be appropriate, even when the screening mammograms appear normal and each unit should have a clear written protocol for recall in these circumstances. Radiographic practitioners may instigate recall for assessment according to local protocols, but the ultimate responsibility for recall for the assessment of signs and symptoms rests with the authorised mammography film reader(s).

Family history of breast cancer is not an indication for assessment in women of screening age. Women suspected to be at increased risk of breast cancer should be managed by a specialist service through which appropriate counselling and genetic expertise is available. The NHSBSP must not be used for screening high risk women under the age of 50 years, or for those women over 50 at more frequent intervals, unless specific additional funding and resources are provided. The National Institute for Clinical Excellence (NICE) guidelines on screening women at increased risk of breast cancer should be followed.¹⁹

Screen-detected mammographic abnormalities should be clearly documented in a way that the reason for recall for assessment is clearly identifiable to those carrying out the subsequent assessment.

2.8 Correct results protocol

All screening units must have externally verified protocols and procedures in place to ensure that all women about whom a decision has been made to recall for assessment are indeed recalled for assessment and that their attendance is recorded.²⁰

3. ASSESSMENT PROCEDURES

3.1 Assessment protocols

For each assessment clinic, there should be a consultant radiologist or appropriately trained breast clinician who is responsible for the clinical and imaging processes. Requirement for formal written consent for assessment procedures should be determined by local risk management policies.

Assessment should follow the principles of the triple approach. Each assessment unit should have written protocols for triple assessment, which are agreed by all of the members of the local breast assessment team. These protocols should clearly define the methods of assessment and the diagnostic and referral pathways that apply for all possible assessment outcomes. An example of a screening assessment protocol is given on the NHS Cancer Screening Programmes web site (www.cancerscreening.nhs.uk).

3.2 Further imaging

A mammographic abnormality is the reason for recall for the majority of women. Unless there is likely to be an obvious clinical abnormality, further imaging is carried out to assess the nature of the lesion. This should include the minimum imaging required to confirm or exclude any abnormality, including further mammography (repeat routine views, magnification or special views) and ultrasound when indicated. The need for further imaging is dictated by the nature of the abnormality being assessed and not all women will require further imaging. The imaging carried out should be directed by the consultant radiologist (or other doctor in charge of imaging) and should include at least the minimum required to establish the presence or absence of any abnormality.²¹ Details of possible abnormalities are discussed in Chapter 4.

For the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), the referrer is the practitioner who is authorised to read the screening mammograms and to recall women for assessment, the practitioner is the lead clinician present and is responsible for the assessment clinic, and the operator is the state registered radiographer who is responsible for supervising mammography that is performed during the assessment process.²²

3.3 Clinical examination

Clinical examination of women who are recalled for assessment should be carried out by a clinician who is recognised by the breast team to have the necessary clinical skills.

Clinical examination is required in all women who have a mammographic or ultrasound abnormality confirmed by further imaging and in all women who are recalled because of clinical signs or symptoms (Figure 2). Clinical examination is not mandatory in women whose further imaging is entirely normal.

3.4 Needle biopsy (FNA/core biopsy)

Significant breast abnormalities should be assessed by needle core biopsy or FNA.^{3,23} Current evidence suggests that 14-gauge (14G) core biopsy, properly carried out, provides better sensitivity and specificity than FNA

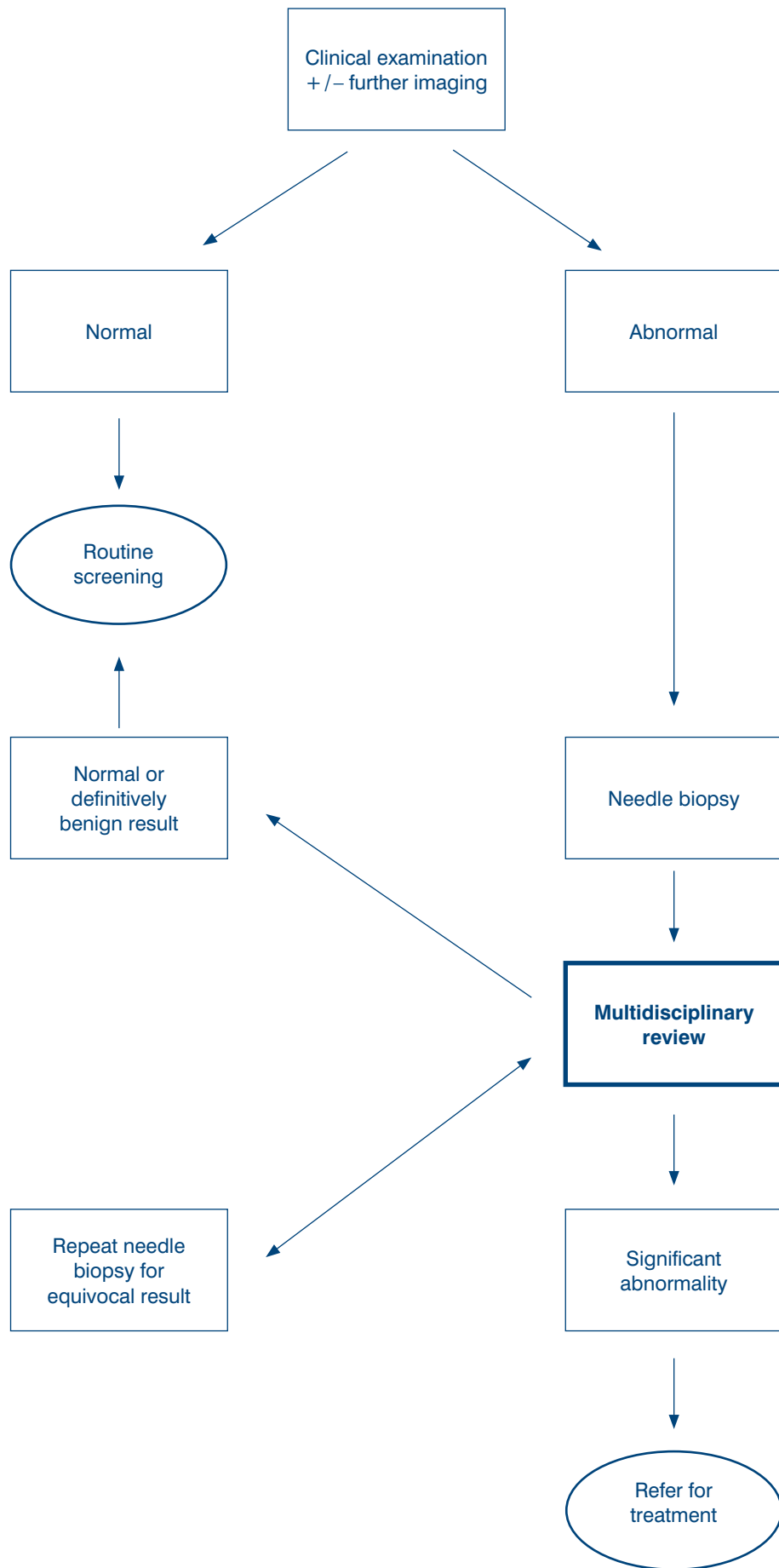


Figure 2 Clinical examination.

for microcalcifications, asymmetry and architectural distortion.²⁴⁻²⁸ Core biopsy also facilitates definitive diagnosis of benign lesions.

Vacuum assisted core biopsy (VACB) is now available in many screening centres and can be used with either standard upright or prone stereotactic apparatus. Published evidence shows that the use of VACB is associated with higher rates of calcium retrieval and lower rates of underdiagnosis of both ductal carcinoma in situ (DCIS) and invasive tumour.^{29,30} When available, VACB may be considered the sampling method of choice:

- for microcalcifications (see section 4.4)
- following B1/B3/B4 result on 14G core biopsy
- for diagnostic excision of papillary lesions and radial scars/complex sclerosing lesions previously diagnosed at core biopsy.

FNA may be preferred in some centres for sampling mass lesions and obvious carcinoma, but only when a satisfactory standard of excellence of both sampling and cytology interpretation has been achieved.³⁰⁻³²

Although some screening units provide immediate reporting of FNA during assessment for geographical reasons, it is not essential.²³ Radiologists who are involved in assessment should ensure that they have the necessary skills required to carry out core biopsy and FNA under stereotactic and ultrasound control.⁵

There should be written local protocols clearly defining the indications for FNA cytology, automated core biopsy and other needle biopsy techniques. Further guidance is given in the *Guidelines for Non-operative Diagnostic Procedures and Reporting in Breast Cancer Screening*.³ 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. B3 and C3 results should be reviewed at the MDT meeting, and management of each case should be agreed by the team.

4. ASSESSMENT OF MAMMOGRAPHIC ABNORMALITIES

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

4.1 Masses

Ultrasound is the imaging method of choice for establishing the nature of a breast mass (Figure 3). Further mammography, including focal paddle compression and craniocaudal views, may be required to confirm the presence, morphology and site of the mass. All solitary and/or new masses recalled for assessment, confirmed as solid on ultrasound and which do not have the typical features of a hamartoma, fibroadenoma, lipoma or lymph node should undergo needle core biopsy (or FNA), usually performed under ultrasound guidance. Cysts that do not have the typical features of a cyst 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; stereotactic core biopsy should be performed if the mammographic features are not definitely benign. If a B1, B3 or B4 result is reported at initial core biopsy of a solid lesion then repeat core biopsy or vacuum assisted mammotomy (VAM) should be considered.

4.2 Architectural distortion

Possible architectural distortion found on screening mammography initially requires imaging work up, which should include both standard mammography views and localised compression/magnification views and ultrasound to establish whether there is a persistent localised abnormality. The initial assessment may also include a clinical consultation and examination to establish the presence of relevant clinical findings such as a mass or scarring from previous surgery (Figure 4a and b).

In total, 20–50% of cases of architectural distortion are due to malignancy.^{29,33} Data from several published series now show that image guided core biopsy is accurate in distinguishing cases due to malignancy from benign causes, for example radial scar, if targeting is accurate and sufficient material is obtained.^{33–36} A recent series has shown that the most accurate results are obtained by taking more than 12 11G samples using a vacuum assisted core biopsy device.³⁵ Recommendations for the management of architectural distortion depend on the local availability of VAM. If VACB is not available, it is recommended that conventional core biopsy is performed as the initial diagnostic procedure on all distortions that are not due to surgical scarring.²⁷ If this shows malignant change then therapeutic surgery should be performed (a minimum of three cores are targeted to sample different areas of the imaging abnormality).

For all other diagnoses, diagnostic surgical open biopsy should be performed. If VACB is available, it is recommended that initial diagnosis is carried out using conventional automated core biopsy. Again, a malignant result should be managed by therapeutic surgery. However, if the result

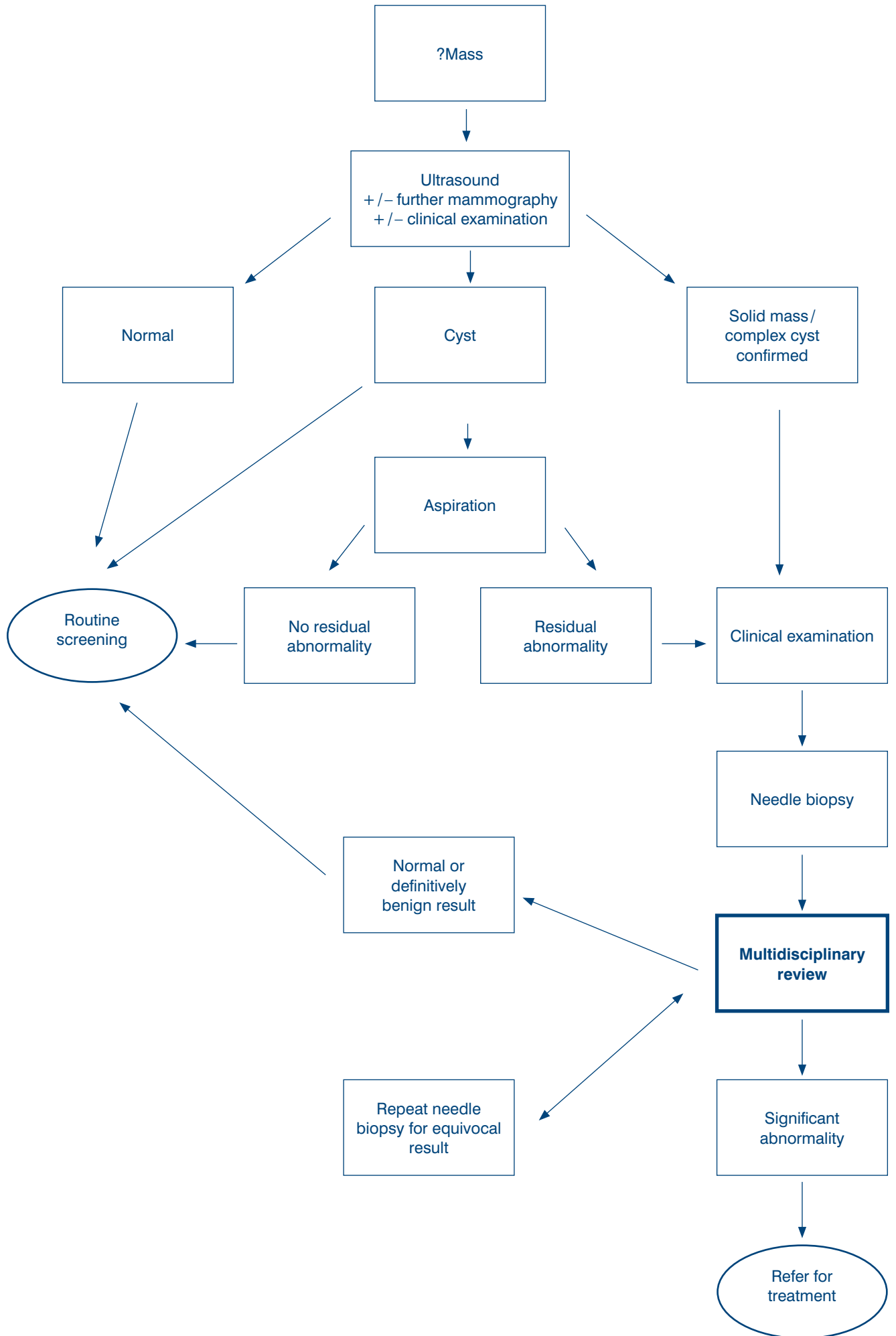


Figure 3 Assessment of breast masses.

is benign or shows radial scar with no evidence of epithelial atypia, a choice of either open surgical excision or excision with VAM may be offered. VAM can be performed under ultrasound or stereotactic x-ray guidance and a minimum of 12 11G cores should be obtained. The VAM findings should be discussed at an MDT meeting. When VAM histology again shows either benign changes or radial scar with no evidence of epithelial atypia then further excision is not required. In all cases, management should be discussed prospectively by the MDT. If there is a doubt regarding the concordance of the imaging/histology findings, diagnostic surgical excision should be recommended.

4.3 Asymmetric density

Further mammography, ultrasound and clinical examination should be performed for all asymmetric densities that are considered significant enough to warrant recall (Figure 5). For significant asymmetry found on imaging or clinical examination, core biopsy is preferred because of its increased sensitivity compared with FNA for DCIS and invasive lobular carcinoma.³⁷⁻³⁹

4.4 Microcalcifications

It is often difficult to distinguish between benign and malignant microcalcifications from their mammographic appearances alone (Figure 6). Craniocaudal and lateral magnification views are helpful in the further characterisation of microcalcifications and assessing the probability of malignancy. Magnification views are also helpful for defining the extent of DCIS if conservation surgery is being considered. Microcalcifications with definitely benign features do not require needle biopsy. If there is considered to be any risk of malignancy, image guided core biopsy with specimen radiography should be performed.^{40,41} Representative microcalcification must be demonstrated in the core specimens on specimen radiography. It is recommended that as a minimum at least three flecks are obtained or calcification is seen in at least two cores. However, to achieve a high absolute sensitivity for malignancy, five flecks of representative calcification or calcium seen in three separate cores are required. This requirement is lessened in those lesions with fewer than 10 flecks of calcification.⁴⁰ If it is not, then the procedure should be repeated or localisation surgical biopsy performed.

Identification of microcalcification on histology alone is not a reliable indicator of adequate sampling (histological microcalcification is a common incidental finding and can be present when there is no calcification visible on mammography).⁴⁰ Surgical biopsy is not required when histology shows a definitively benign cause for calcifications in core specimens confirmed by specimen radiography to contain calcifications that are clearly representative of those considered suspicious on mammography. Surgical open biopsy is normally required to exclude malignant change in the adjacent tissue when core biopsy demonstrates atypical epithelial proliferation.^{30,40,41}

The specificity and absolute sensitivity for sampling microcalcifications is significantly higher with the use of larger bore biopsy devices, such as VAM. These devices may be considered when there is diagnostic uncertainty.^{29,42}

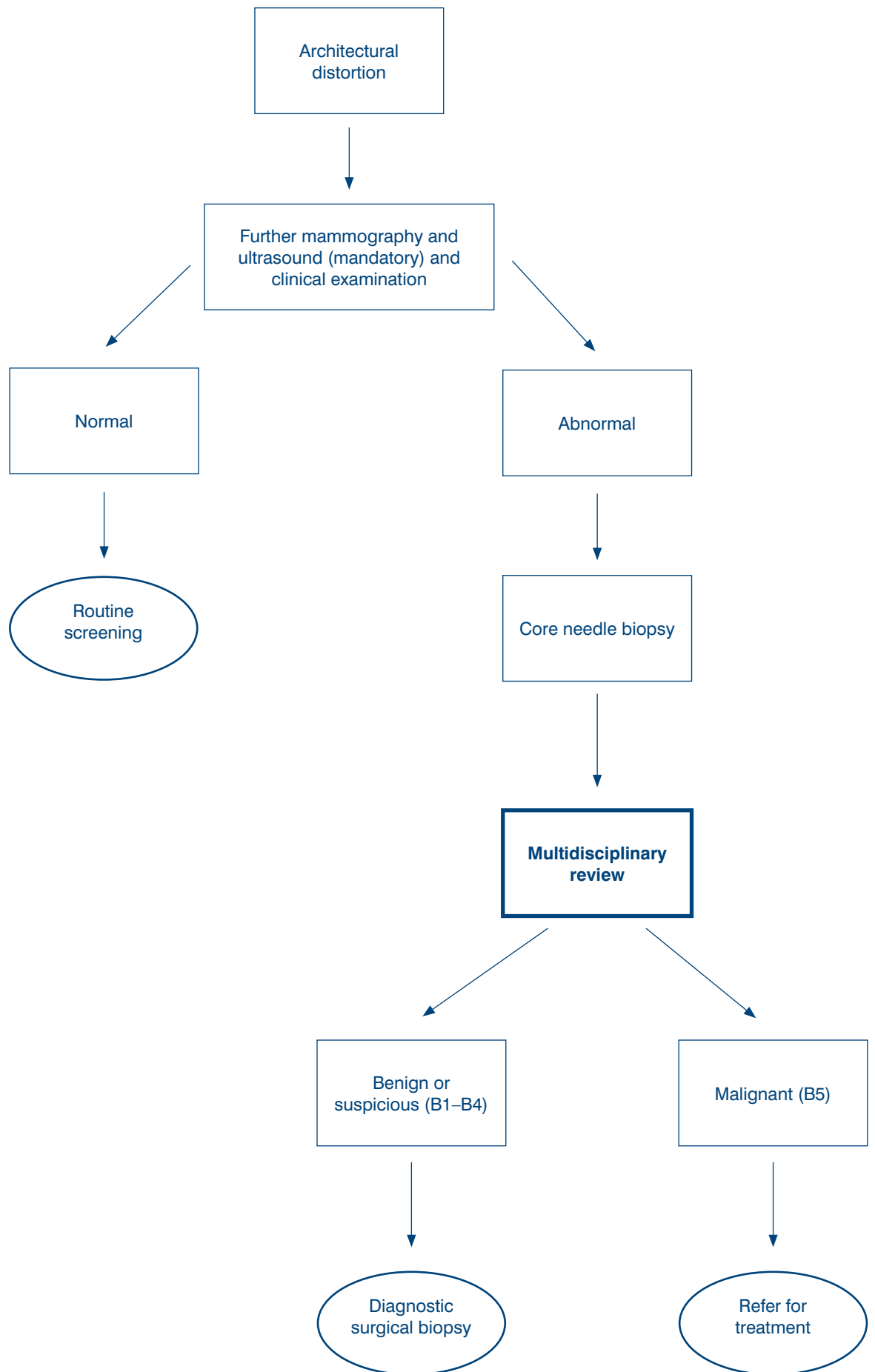


Figure 4. Architectural distortion. (a) Core biopsy only available.

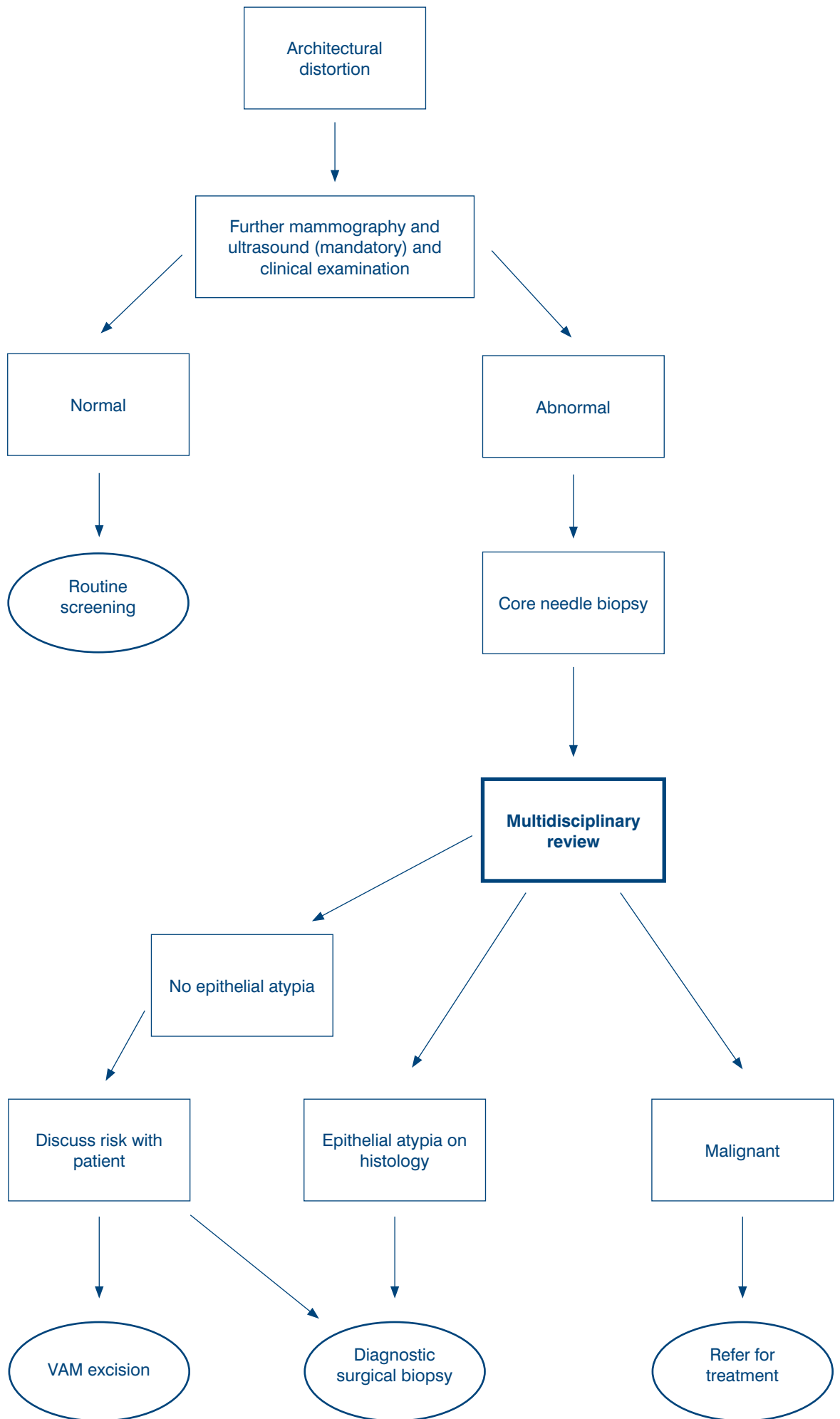


Figure 4. Architectural distortion. (b) Vacuum assisted core biopsy available.

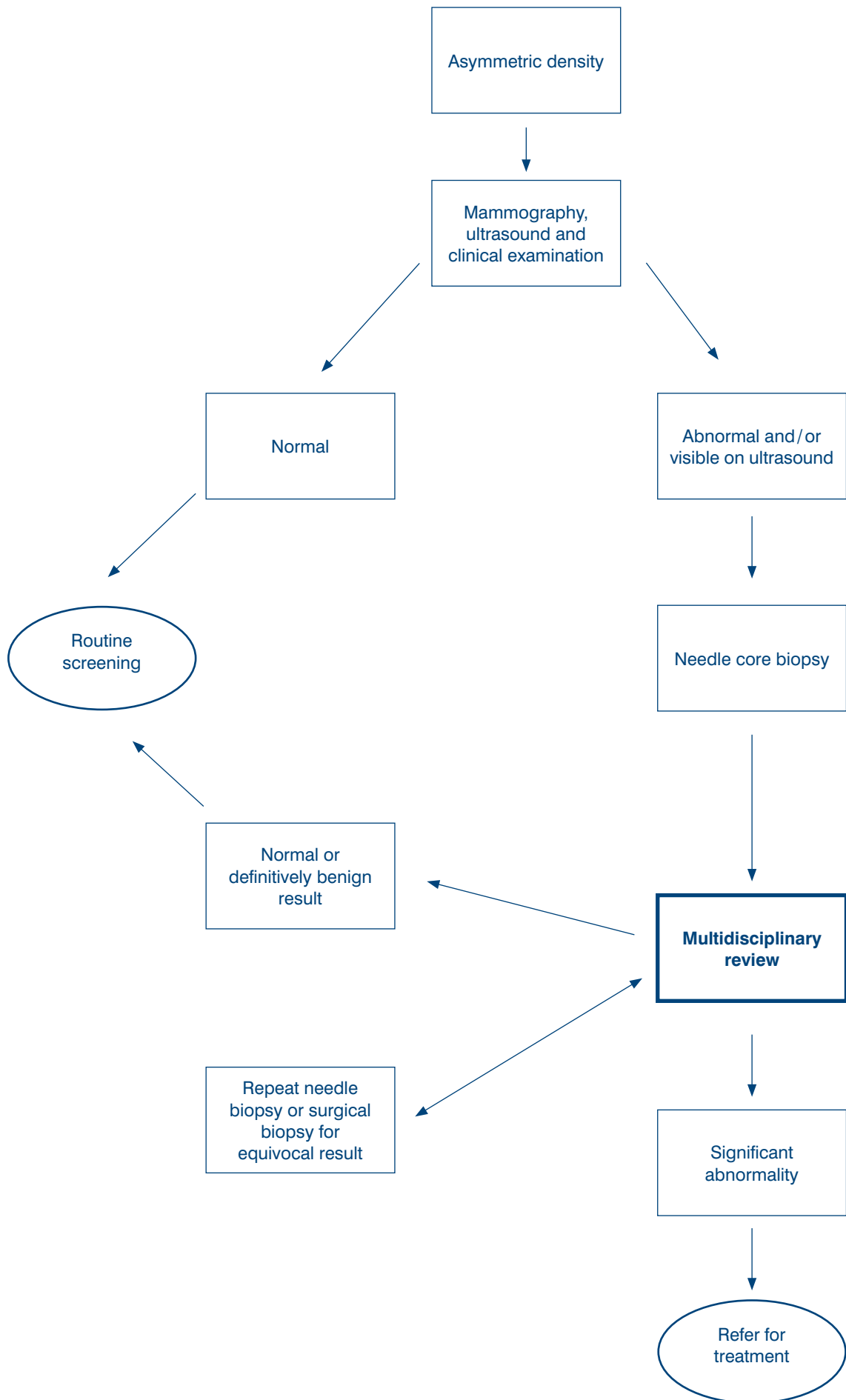


Figure 5 Asymmetric density.

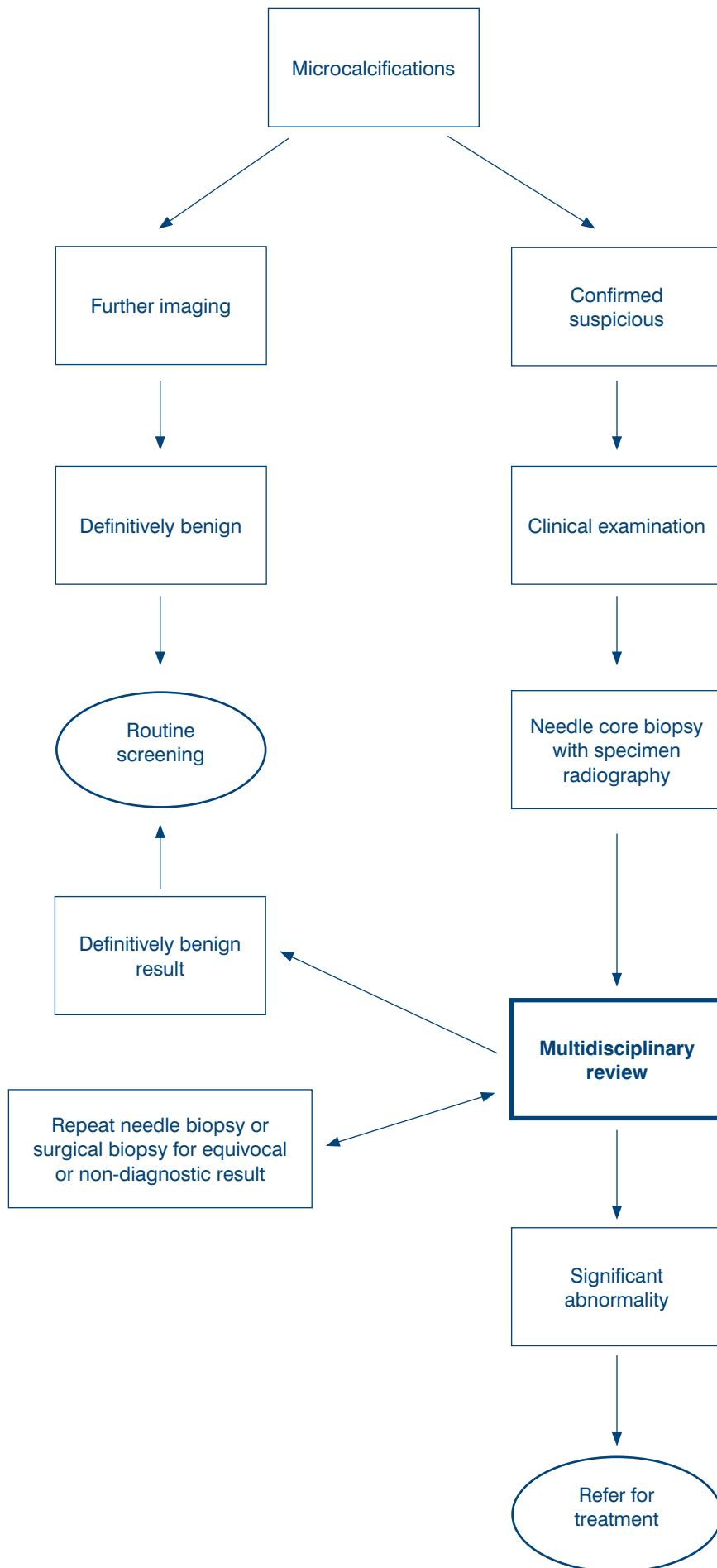


Figure 6 Microcalcifications.

When available, large core vacuum biopsy should be considered as preferable for sampling microcalcifications in the following circumstances:*

- very small clusters of microcalcification that is likely to be difficult to sample (< 5mm)
- failed conventional core biopsy
- B3 or B4 result after conventional core biopsy
- indeterminate microcalcification when 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 using conventional automated core biopsy.

*Recommended by the UK Mammotome Users Group, 17 October 2002.

4.5 Exceptional circumstances

In certain circumstances, it may not be possible or prudent to adhere to the expected assessment practices because of specific clinical reasons, for example patient infirmity. These cases should be reviewed by the MDT and the reasons documented.

Magnetic resonance imaging should be considered for the further assessment of difficult cases for which conventional triple assessment is inconclusive and for the occasional case when 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 the NHS Cancer Screening Programmes web site). A provisional opinion as to the nature of the problem and how it can be managed may be discussed with the woman at the time of assessment. Women who have undergone needle biopsy should have their results discussed in a multidisciplinary clinical meeting and management should be agreed prospectively in advance of any treatment, and preferably before the patient receives her result. A multidisciplinary forum to discuss the results of screening assessment should occur at least weekly. Provisional and final results of assessment, even when the result is normality, should be given to the patient by a clinical practitioner.

There are two routine outcomes of assessment:

- return to the routine screening programme
- refer for treatment.

5.2 Short-term recall for assessment

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.⁵ 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 not a delayed screening assessment follow-up. Women placed on short-term recall should be invited to the assessment clinic, where they can be given their result immediately, and not to a routine mammography screening appointment.

Short-term recall must not be considered to be a routine outcome of assessment.^{5,43,44} By applying the triple approach to assessment, it is possible to reach a definitive answer in the vast majority of patients. In a small number of cases, it may not be possible to reach a definitive decision at assessment and the MDT may consider surgical biopsy to be inappropriate. For these few cases, short-term follow-up is required. A woman should only be placed on short-term recall if there is a clear reason to do so and this decision has been subsequently discussed in detail and agreed at the multidisciplinary meeting. This option should not be used as an alternative to proper assessment when it may represent a failure of clear decision making. 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.^{5,8} The NHSBSP standard is that less than 0.5% of women screened should be placed on short-term recall.¹⁰ In practice, considerably lower short-term recall rates are being achieved (less than 0.25% of women screened).

5.3 Results after assessment

All women who have a diagnosis of breast cancer should receive their results in the presence of a clinician and a clinical nurse specialist in breast care, with sufficient time allocated to provide the necessary counselling and support. All women assessed must receive written confirmation of the outcome of their assessment attendance.^{12,14}

Some women with a benign outcome, and most of those with a diagnosis of cancer requiring treatment, will seek and require support for themselves and their families from their primary care team. Primary care teams must be kept informed of the outcome of assessment in a timely way.

A written record of the assessment process and outcome should be kept with the film packet as well as on any computer record.

5.4 Audit

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

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APPENDIX: AUDIT OF SCREENING ASSESSMENT

1. Time from attendance at screening to first offered screening assessment appointment
 - Minimum standard 90% within 3 weeks
2. Number of assessment visits required to achieve a definitive diagnosis
 - Standard: no more than two for interventional procedures
3. Preoperative diagnosis rate for breast cancer
 - Minimum standard 80%
 - Target 90%
4. Benign diagnostic surgical biopsy rates
 - Minimum standard
 - Prevalent < 3.6 per thousand women screened
 - Incident < 2.0 per thousand women screened
 - Target
 - Prevalent < 1.8 per thousand women screened
 - Incident < 1.0 per thousand women screened
5. Attendance at multidisciplinary screening assessment review meetings
6. Records kept of assessment cases and outcomes.

