

**CLINICAL GUIDELINES FOR BREAST CANCER  
SCREENING ASSESSMENT**

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## CONTENTS

	<b>Page No</b>
1. INTRODUCTION	1
1.1 Background	1
1.2 Aim of assessment	1
2. THE ASSESSMENT PROCESS	2
2.1 Introduction	2
2.2 Number of assessment clinics	2
2.3 Method and timing of recall	2
2.4 Number of assessment visits	4
2.5 Personnel for the assessment clinic	4
2.6 Equipment for assessment	4
2.7 Risk management	5
2.8 Indications for assessment	5
3. ASSESSMENT PROCEDURES	6
3.1 Assessment protocols	6
3.2 Further imaging	6
3.3 Clinical examination	6
3.4 Needle biopsy (FNA/core biopsy)	6
4. ASSESSMENT OF MAMMOGRAPHIC ABNORMALITIES	9
4.1 Masses	9
4.2 Architectural distortion	9
4.3 Asymmetric density	9
4.4 Microcalcifications	9
4.5 Exceptional circumstances	14
5. OUTCOMES OF ASSESSMENT	15
5.1 Multidisciplinary meetings	15
5.2 Short-term recall	15
5.3 Results after assessment	16
5.4 Audit	16
APPENDICES	
1 Standards for the NHSBSP (Updated May 2000)	17
2 Example screening assessment protocol	23
3 Audit of screening assessment	29
REFERENCES	30



# 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.<sup>1</sup> When breast screening was introduced in the NHS in 1987, the recommendation was that assessment should be carried out by multidisciplinary teams.<sup>1,2</sup> 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.<sup>2-8</sup> However, no specific clinical guidance on breast screening assessment has been published, and assessment is carried out following a variety of different models of organisation and clinical protocols. 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 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.

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

### 2.2 Number of assessment clinics

The standard is that women should be offered an appointment date that is within three weeks of their screening attendance. 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 the facilities and staff available to carry out the assessment. The average breast screening service with a target population of 40–45 000 (Forrest unit) holds two assessment clinics per week, with 10–15 women attending each clinic.<sup>10</sup> The assessment clinics for women who have been recalled after their initial screening mammogram should operate at a separate time from those for symptomatic women.<sup>11,12</sup> The majority of women attending for screening are asymptomatic and have different clinical needs from those who present through their GP with symptoms.

### 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’ recalled for assessment of a screen-detected abnormality are significantly different from those of women referred to breast clinics with breast problems. Recall for assessment is associated with significant anxiety, particularly as the majority of women have no previous indication that they have a breast problem. 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 the fact that the vast majority of women 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 likely receipt of letters of invitation to assessment.<sup>13</sup> The primary care team should be kept informed about the assessment process.<sup>14</sup>

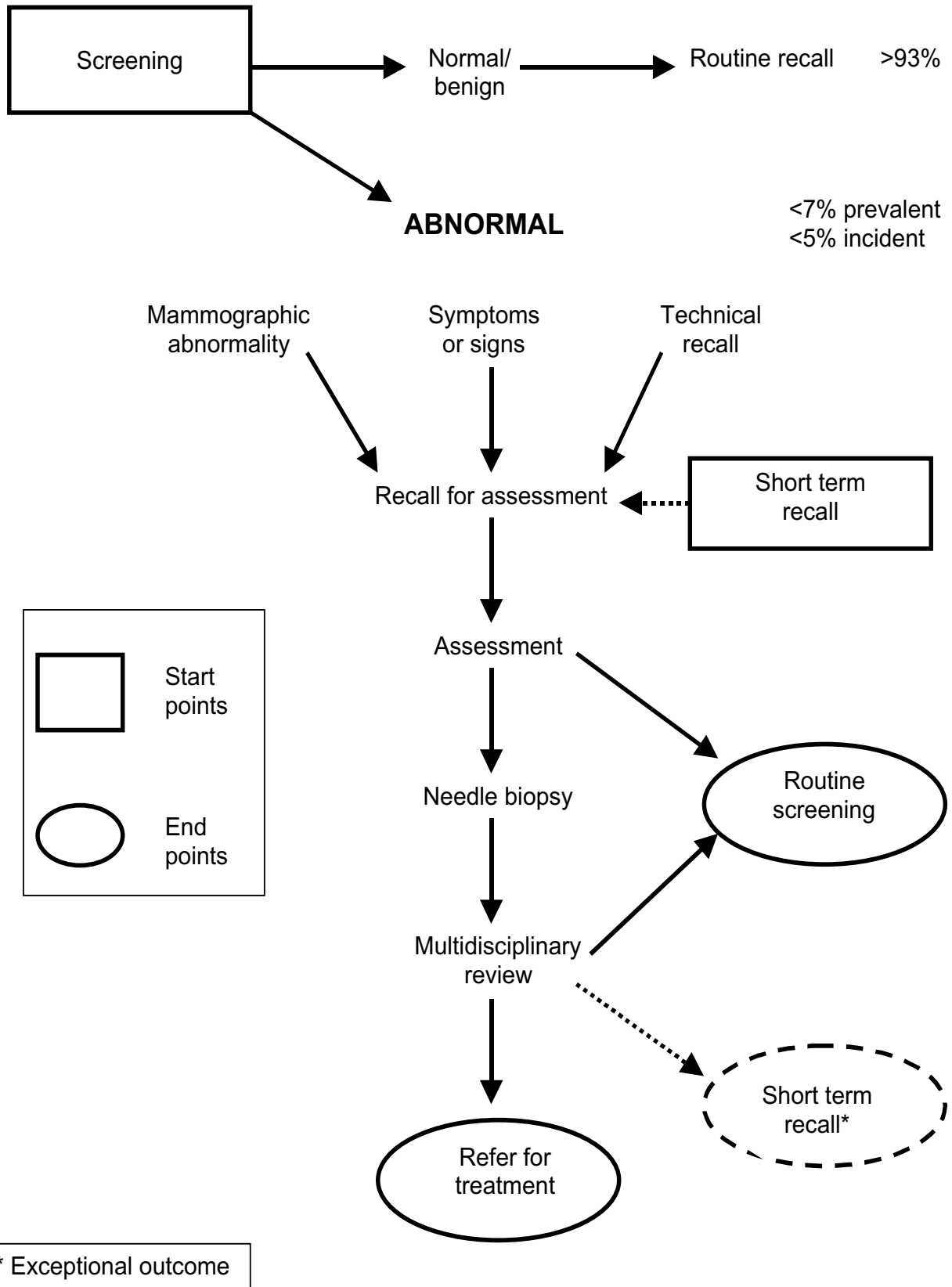


Figure 1 Assessment process.

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.

The minimum standards and targets for the timing of the various stages of breast screening and assessment are set out in the NHS Breast Screening Programme (NHSBSP) Standards Table (Appendix 1). The relevant standards are standards 12–16.

### **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.

### **2.5 Personnel for the assessment clinic**

The core assessment team comprises:

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

The introduction of advanced practitioners in breast screening is currently under development, and it is expected that they would 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. 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.

All those involved in formal screen reading should also attend screening assessment on a regular basis.

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 – equipment capable of magnification mammography, special views and stereotactic x-ray guided biopsy (equipment with digital imaging) may be preferred
- ultrasound equipment with a minimum operating frequency of 7.5 MHz (preferably 10 MHz)<sup>15</sup>

- appropriate materials and devices for fine needle aspiration (FNA) and/or core biopsy.

### 2.7 Risk management

All breast screening assessment clinics should carry out a risk assessment exercise that includes all aspects of staff and patient safety. All clinics should have a written protocol and action plan in the event of a cardiac arrest during an assessment procedure.

### 2.8 Indications for assessment

Indications for assessment include:

- significant mammographic abnormality
- significant breast symptoms identified at screening
- significant breast signs identified at screening
- review of short-term recall
- technical recalls where there is a suspicion of a significant problem being present.

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.<sup>5,16</sup> 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. State registered radiographers 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).

A family history of breast cancer is not an indication for assessment in women of this age. Women suspected to be at increased risk of breast cancer should be managed through a specialist service where appropriate counselling and genetic expertise is available. The NHSBSP must not be used for screening high risk women under the age of 50 or for these women over 50 at more frequent intervals.

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

### 3. ASSESSMENT PROCEDURES

#### 3.1 Assessment protocols

For each assessment clinic, there should be an identified lead medical practitioner responsible for the clinical 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 agreed by all 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 at Appendix 2.

#### 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, where 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. Details of possible abnormalities are discussed in Chapter 4.<sup>17</sup>

For the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), the referrer is the practitioner authorised to read the screening mammograms and to recall women for assessment, the practitioner is the lead clinician present and responsible for the assessment clinic and the operator is the state registered radiographer responsible for supervising mammography performed during the assessment process.<sup>18</sup>

#### 3.3 Clinical examination

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

Clinical examination is required in all women with a mammographic or ultrasound abnormality confirmed by further imaging and in all women 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.<sup>19,20</sup> Current evidence suggests that 14-gauge core biopsy, properly carried out, provides better sensitivity and specificity than FNA for microcalcifications, asymmetry and architectural distortion.<sup>21-23</sup>

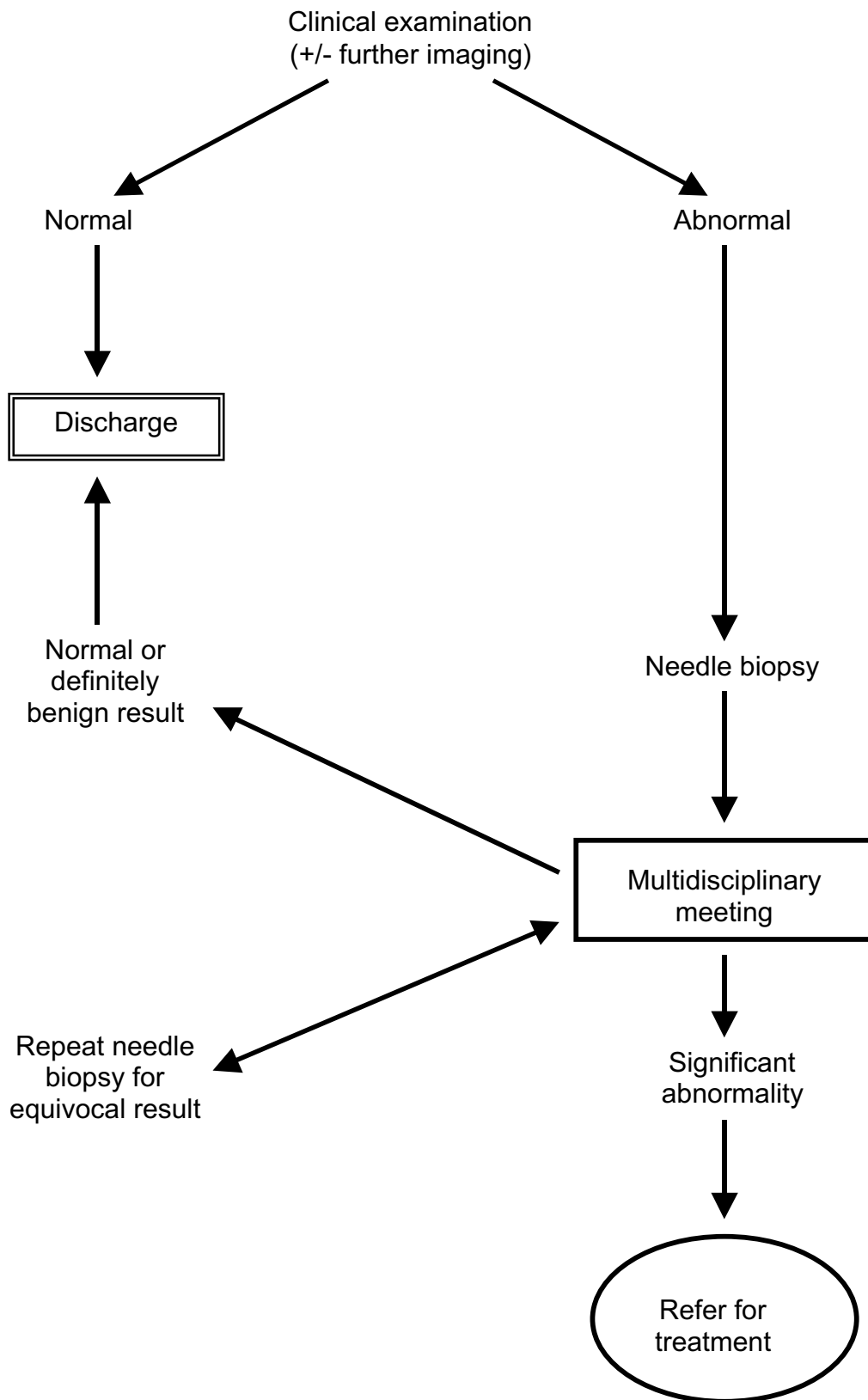


Figure 2 Clinical examination.

Core biopsy also facilitates definitive diagnosis of benign lesions. FNA may be preferred in some centres for sampling mass lesions and obvious carcinoma, but only where a satisfactory standard of excellence has been achieved.<sup>21,22</sup>

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

There should be written local protocols clearly defining the indications for FNA cytology, automated core biopsy and other needle biopsy techniques.<sup>19</sup> Further guidance is given in *Guidelines for Non-operative Diagnostic Procedures*.<sup>24</sup>

## 4. ASSESSMENT OF MAMMOGRAPHIC ABNORMALITIES

### 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 patients with solitary and/or new masses who are recalled for assessment and whose lesions are confirmed as solid on ultrasound and do not have the typical features of an adenolipoma or lymph node should undergo FNA or needle core biopsy (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.

### 4.2 Architectural distortion

Architectural distortion (differential diagnosis of radial scar or complex sclerosing lesion from malignant disease) requires further mammography, including paddle compression views and ultrasound (Figure 4). If the distortion is confirmed, clinical examination should be performed. There is now some evidence that malignant change can be definitively excluded by the use of multiple core biopsies or vacuum-assisted mammotomy (at least nine separate cores).<sup>25</sup> However, until this is confirmed by larger studies, it is currently recommended that all confirmed architectural distortions, not associated with previous surgery or breast abscess, should be surgically excised because of the significant risk with associated malignancy.<sup>26</sup> Needle biopsy should still be considered to attempt a preoperative diagnosis of malignancy as this may influence surgical management. Core biopsy is preferred to FNA for sampling architectural distortion.

### 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). For significant asymmetry found on imaging or clinical examination, core biopsy is preferred because of its increased sensitivity compared with FNA for ductal carcinoma in situ (DCIS) and invasive lobular carcinoma.<sup>27,28</sup>

### 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.<sup>29</sup> Representative microcalcification must be demonstrated in the core specimens on specimen radiography. If it is not, then the procedure should be repeated or localisation surgical biopsy performed.<sup>28-31</sup> Identification of microcalcification on histology alone is not a reliable indicator of adequate sampling (histological microcalcification is

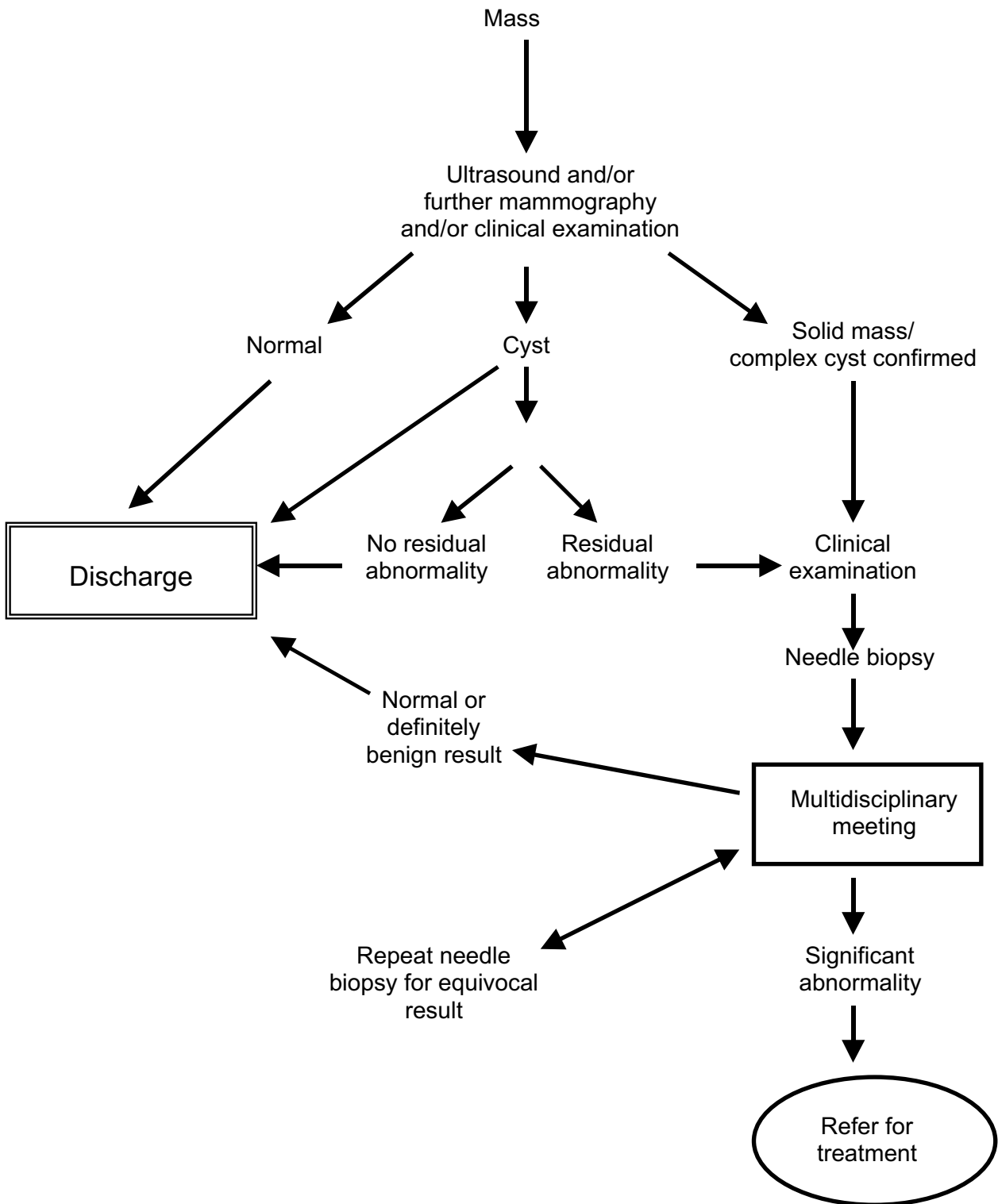


Figure 3 Assessment of breast masses.

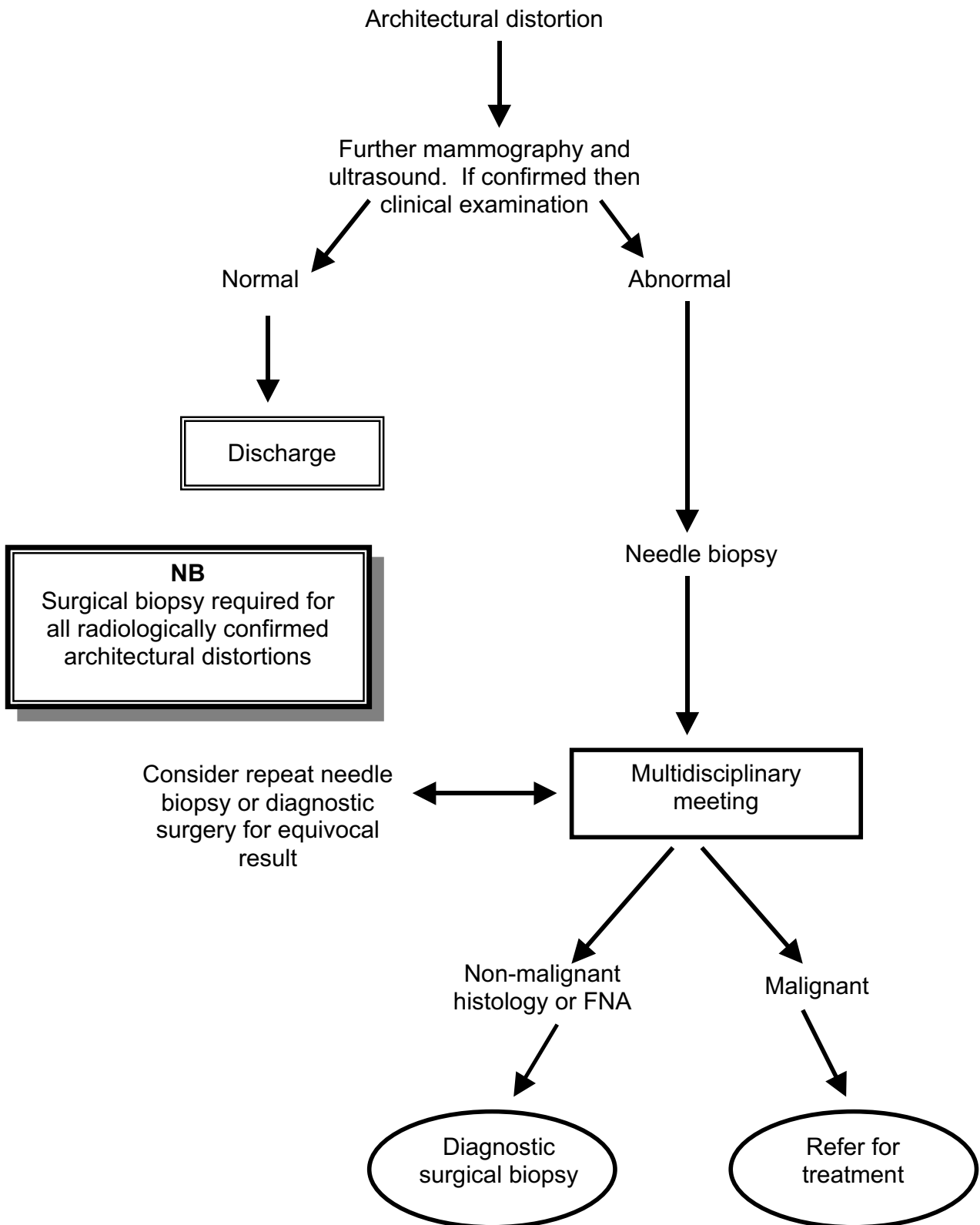


Figure 4 Assessment of architectural distortion.

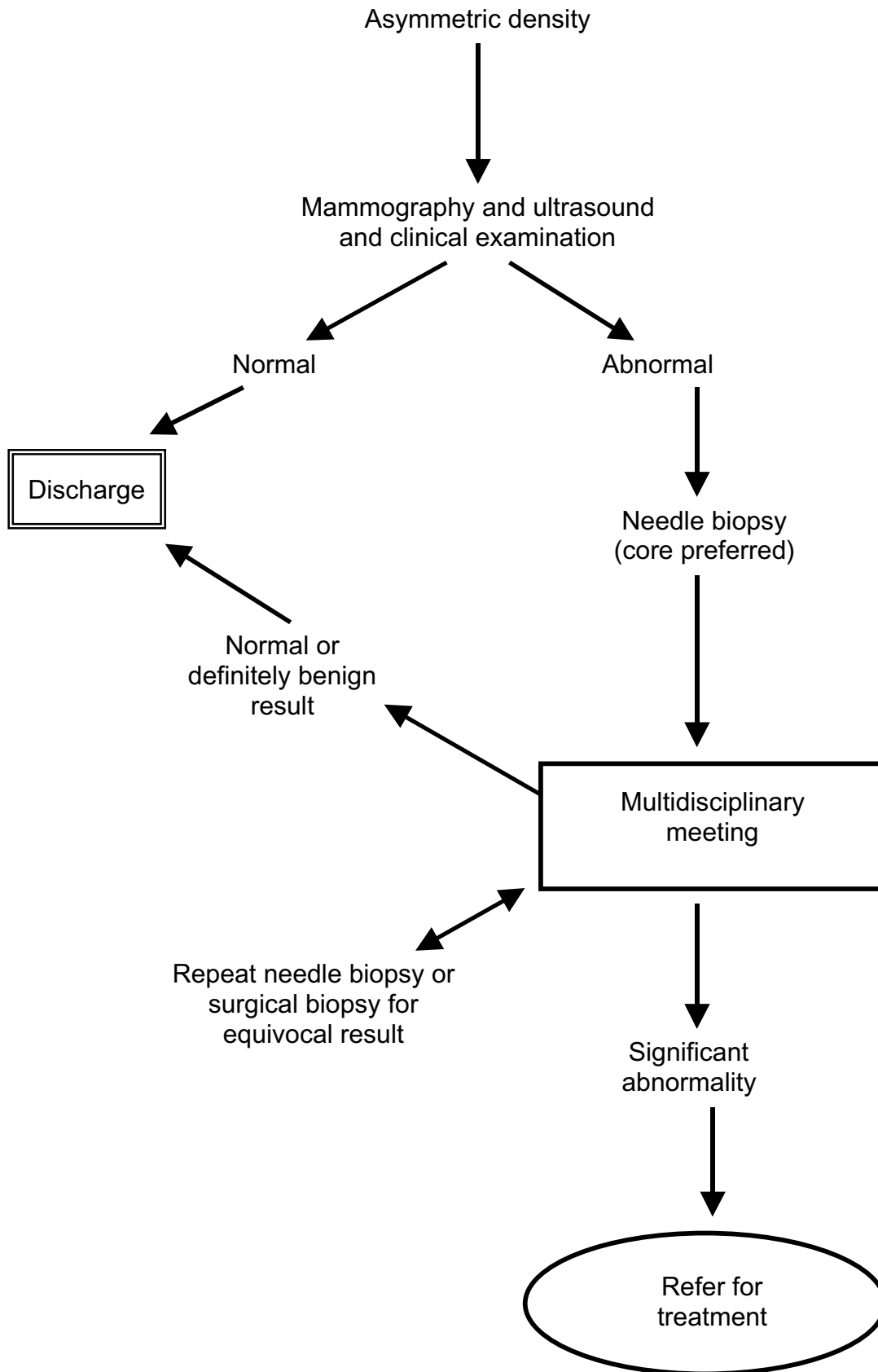


Figure 5 Assessment of asymmetric density.

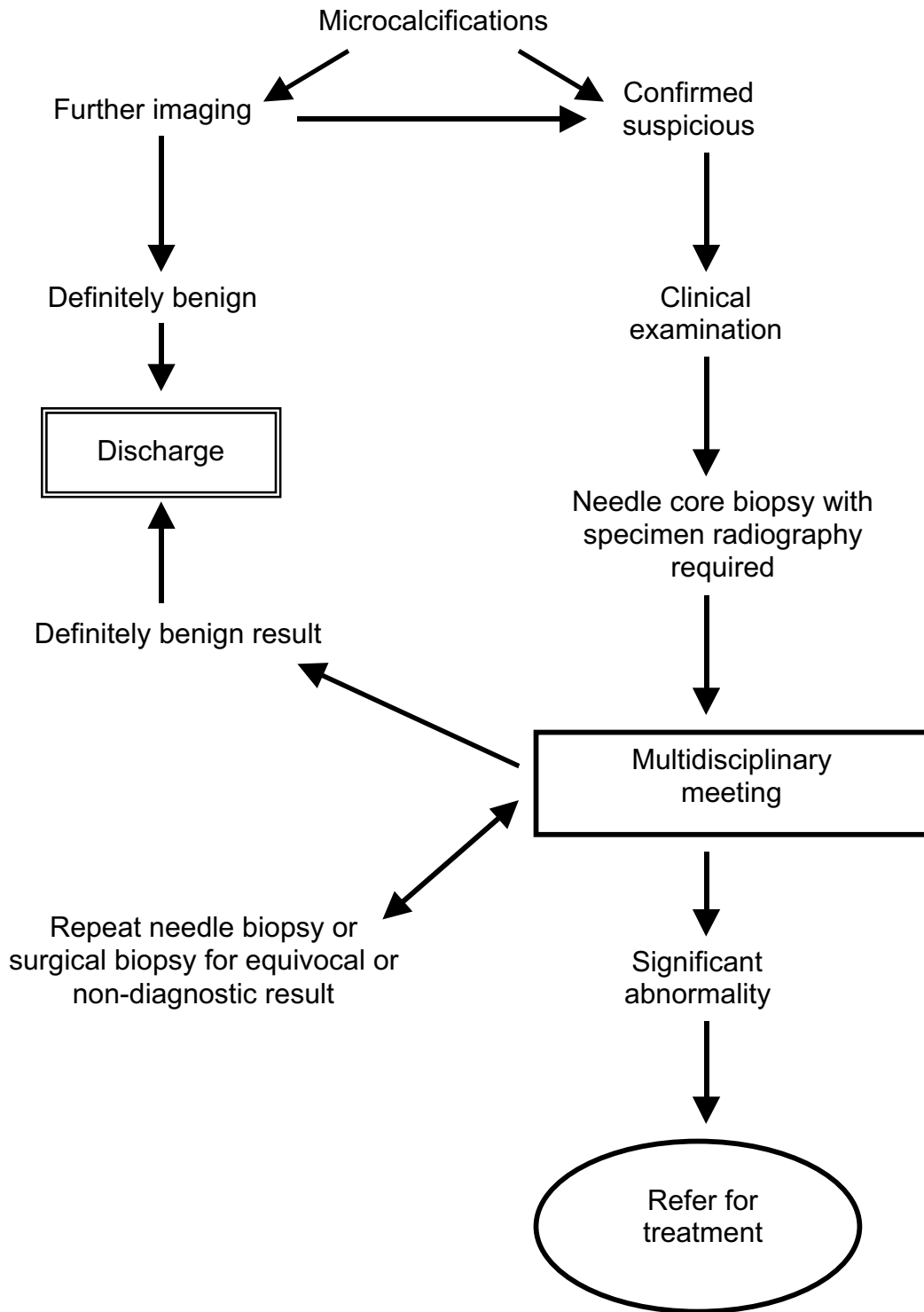


Figure 6 Assessment of microcalcifications.

a common incidental finding and can be present when there is no calcification visible on mammography).<sup>32</sup> Surgical biopsy is not required when histology shows a definitively benign cause for calcifications in core specimens confirmed by specimen radiography to contain calcifications clearly representative of those considered suspicious on mammography. Surgical open biopsy is normally required to exclude frank malignant change in the adjacent tissue where core biopsy demonstrates atypical ductal hyperplasia.<sup>26,30,31</sup> The specificity and absolute sensitivity for sampling microcalcifications is significantly higher with the use of larger bore biopsy devices such as vacuum assisted mammotomy, and such devices may be considered where there is diagnostic uncertainty.<sup>33,34</sup> Vacuum assisted mammotomy can also help to avoid surgery for diagnosis in certain lesions such as papillary lesions and focal fibrosis.

#### **4.5 Exceptional circumstances**

In certain circumstances, it may not be possible or prudent to adhere to the expected assessment practices for specific clinical reasons (such as patient infirmity). In this situation, the clinical circumstances and reasons should be fully documented and preferably reviewed by the multidisciplinary team.

## 5. OUTCOMES OF ASSESSMENT

### 5.1 Multidisciplinary meetings

The outcome of assessment should be decided according to agreed multidisciplinary written protocols (Appendix 2). A provisional opinion as to the nature of the problem and how it may 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 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 medical practitioner.

There are two routine outcomes of assessment:

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

### 5.2 Short-term recall

A short-term recall is defined as a further screening invitation and attendance at less than the routine screening interval. This is also known as 'early recall'. 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. At the latest, under any circumstances, screening episodes (including assessment) should be closed within six months of the first attendance for routine mammography. 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.<sup>5,35,36</sup> 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 multidisciplinary team 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 discussed in detail at the multidisciplinary meeting and then agreed with the woman. 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.<sup>5,8</sup> The NHSBSP standard is that less than 1% of women screened should be placed on short-term recall and 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 with a diagnosis of breast cancer should receive their results in the presence of a doctor and a clinical nurse specialist in breast care with sufficient time allocated to provide the necessary counselling and support. All women assessed must also always receive written confirmation of the outcome of their assessment attendance.<sup>11,13</sup>

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 Appendix 3. Units should expect audit of assessment to be included in quality assurance reviews.

**APPENDIX 1: STANDARDS FOR THE NHS BREAST SCREENING PROGRAMME (UPDATED MAY 2000)**

<b>Domain</b>	<b>Objective</b>	<b>Criterion</b>	<b>Minimum standard</b>	<b>Target</b>
D2	1. To maximise the number of eligible women who attend for screening	The percentage of eligible women who attend for screening	≥ 70% of invited women to attend for screening	
D1	2. To maximise the number of cancers detected <sup>1</sup>	a) The rate of invasive cancers detected in eligible women b) The rate of cancers detected which are in situ carcinoma c) Standardised detection ratio (SDR)	Prevalent screen ≥ 2.7 per 1,000 Incident screen ≥ 3.0 per 1,000 Prevalent screen ≥ 0.4 to ≤ 0.9 per 1,000 Incident screen ≥ 0.5 to ≤ 1.0 per 1,000 ≥ 0.75	Prevalent screen ≥ 3.6 per 1,000 Incident screen ≥ 4.0 per 1,000 ≥ 1.0
D1	3. To maximise the number of small invasive cancers	The rate of invasive cancers less than 15 mm in diameter detected in eligible women invited and screened	Prevalent screen ≥ 1.5 per 1,000 Incident screen ≥ 1.65 per 1,000	Prevalent screen ≥ 2.0 per 1,000 Incident screen ≥ 2.2 per 1,000
D3, D4	4. To achieve optimum image quality	a) High contrast spatial resolution b) Minimal detectable contrast (approx) 5–6 mm detail 0.5 mm detail c) Standard film density	≥ 10 lp/mm ≤ 1% ≤ 5% 1.4–1.8	
D3	5. To limit radiation dose	Mean glandular dose per film to standard breast using a grid	≤ 2 mGy	
D5	6. To minimise the number of women undergoing repeat examinations	The number of repeat examinations	< 3% of total examinations	< 2% of total examinations
D5	7. To minimise the number of women screened who are referred for further tests <sup>1</sup>	a) The percentage of women who are referred for assessment b) The percentage of women screened who are placed on early recall	Prevalent screen < 10% Incident screen < 7% < 1%	Prevalent screen < 7% Incident screen < 5% ≤ 0.25%
D4, D5	8. To ensure that the majority of cancers, both palpable and impalpable, receive a non operative tissue diagnosis of cancer	The percentage of women who have a non operative diagnosis of cancer by cytology or needle histology	≥ 70%	≥ 90%

## Breast Cancer Screening Assessment

Domain	Objective	Criterion	Minimum standard	Target
D4, D5	9. To minimise the number of unnecessary operative procedures	The rate of benign biopsies	Prevalent round < 3.6 per 1,000 Incident round < 2.0 per 1,000	Prevalent round < 1.8 per 1,000 Incident round < 1.0 per 1,000
D3	10. To minimise the number of cancers in the women screened presenting between screening episodes <sup>1</sup>	The rate of cancers presenting in screened women a) in the two years following a normal screening episode b) in the third year following a normal screening episode	<b>Expected standard</b>  1.2 per 1,000 women screened in the first two years  1.3 women per 1,000 women screened in the third year	
D1, D2, D6	11. To ensure that women are recalled for screening at appropriate intervals	The percentage of eligible women whose first offered appointment is within 36 months of their previous screen	≥ 90%	100%
D2, D3, D5	12. To minimise anxiety for women who are awaiting the results of screening	The percentage of women who are sent their result within two weeks	≥ 90%	100%
D2, D3, D5	13. To minimise the interval from the screening mammogram to assessment	The percentage of women who attend an assessment centre within one week of the decision that further investigation is necessary and within three weeks of attendance for the screening mammogram	≥ 90%	100%
D2, D3, D5	14. To minimise the delay before examination by the surgeon who will have care of the woman <sup>2</sup>	Time interval between the first assessment appointment and surgical assessment	≤ 5 working days	Same day (surgeon present at an assessment clinic)
D2, D3, D5	15. To minimise the interval between a surgical decision to operate for diagnostic purposes and the first offered admission date <sup>2</sup>	The percentage of women who are admitted within two weeks of their final assessment visit (which includes a results visit)	≥ 90%	100%
D2, D3, D5	16. To minimise the interval between a surgical decision to operate for therapeutic purposes (i.e. where there is a preoperative definitive diagnosis of cancer) and the first offered admission date <sup>2</sup>	The percentage of women who are admitted within three weeks of informing the patient that she needs surgical treatment	≥ 90%	100%

### DEFINITIONS

#### Domain

In the new NHS national performance framework there are six areas of performance focused upon. They have been selected to capture what really counts for patients and for staff. Each of the standards has been allocated a domain. This covers all the areas listed in *The New NHS: Modern and Dependable*.<sup>5</sup> The domains are:

- D1 Health improvement
- D2 Fair access
- D3 Effective delivery of appropriate healthcare
- D4 Efficiency
- D5 Patient/carer experience
- D6 Health outcomes of NHS care

#### Objective

These are the aims of the NHSBSP in its operation in relation to specific quality issues.

#### Criteria

These are the parameters by which the achievement of the objective (or not) will be measured.

#### Minimum standard

These figures represent the levels of performance which are the minimum acceptable for any breast screening unit. Where the minimum standard is shown as 'greater than or equal to', any level of performance below that standard should be **investigated by the quality assurance team**.

Where the minimum standard is shown as 'less than or equal to', any level of performance above that standard should be **investigated by the quality assurance team**.

#### Targets

These are the quantitative targets that are achievable individually by one-third of units within the NHSBSP. All units should aim to achieve these targets. If the specified cancer detection rates etc are achieved, then the programme will be on target to replicate the mortality reduction achieved in trials.

#### Eligible women

These are women aged 50–64 who are included in the call and recall system.

#### Proportion of women invited who attend for screening

The percentage of women who, having been sent an invitation for screening, attend a screening unit and undergo mammography in response to that invitation. No allowance is made for letters returned or refusals. This is calculated from KC62 and represents uptake not coverage.

#### Cancers detected

This includes both invasive and in situ cancers. For this purpose, multiple cancers in one patient are counted as one cancer.

### **Small cancers**

The size of the cancer is determined by pathological measurement.

### **Repeat examinations**

Repeat examinations include both those films repeated in the same view while the woman is still present in the unit and those occasions where a woman is required to attend a second time to have a film repeated (same view) because of a technical inadequacy.

### **Further tests**

These include all second appointments where further procedures (including further views and/or clinical examination) beyond those normally undertaken at the first appointment are carried out.

### **Assessment**

This is defined as 'further tests' above and does not include repeat examinations (qv).

### **Operative procedures**

These are open surgical biopsies (for diagnostic reasons) where definitive histology proves benign. More than one procedure on the same occasion on one patient will be counted as one biopsy.

### **Benign biopsy**

A benign biopsy is an open surgical biopsy which results in a benign diagnosis histologically.

### **Prevalent screen**

These are women who are being screened for the first time by the NHSBSP (usually those aged 50–52.9).

### **Incident screen**

These are women who have had a previous screening episode within the NHSBSP and are now being rescreened at the routine (three year) interval.

### **Week**

Five working days.

### **Early recall**

A second screening invitation at less than the routine screening interval.

## **Notes**

1. The expected effectiveness of the NHSBSP is based on a target uptake of 70% of eligible women being screened. Current national data indicate that this target is being achieved across the UK. However, it is recognised that in some localities the target is very difficult to attain. Indeed, even in those regions which do attain well over 70% there may be districts or GP practices where to achieve considerably less than 70%, for example 50%, may still be regarded as a considerable achievement. In these cases it could be considered that the objective of maximising the number of eligible women attending for screening in that GP practice has been achieved. This target relates to women aged 50–64 called or recalled for screening as part of the NHSBSP.

2. The criterion used to measure whether the number of cancers detected is being maximised is the rate of invasive cancers detected in women both invited and screened, every three years, in the 50–64 age group. Microinvasive disease is excluded. The numbers of in situ carcinomas expected includes ductal carcinoma in situ (DCIS), lobular carcinoma in situ and microinvasive disease. There is a geographical variation in the incidence of breast cancer, although no consistent pattern has emerged which would allow different standards to be set for different parts of the country.

The standardised detection ratio (SDR) measures a unit's performance and takes into consideration variable age distributions between screening units. For investigative purposes it can be corrected for the geographical variations in background incidence. The minimum standard and the target are a guide to the levels to be achieved based on the underlying incidence and the average age of the women screened.

If a high DCIS rate is reported the overall cancer detection rate and pathology reporting should be investigated.

3. This refers to the number of invasive cancers measuring less than 15 mm in diameter, microinvasive carcinoma is excluded. Size is determined by pathological measurement.
4. For discussion of assessment of image quality, see section 6.5.1 of the Pritchard Report<sup>3</sup> and IPEM Report 59. It should be noted that:

- i) the measurement of image quality is subjective and due allowance should be made for observer variability
- ii) the standards specified are guidelines based on current knowledge and may need to be revised as better methods of measuring image quality are developed
- iii) test films should be evaluated under appropriate viewing conditions with the use of ocular aids where necessary.

- a) The value given refers to the limiting high contrast resolution which would be obtained by radiographing a high contrast resolution grating placed on top of approximately 4 cm Perspex and approximately 6 cm from the chest wall edge.

The value given should be met in directions both parallel and perpendicular to the tube axis. The measured high contrast resolution in the direction perpendicular to the tube axis will normally be greater than that parallel to the tube axis. The test film should have a sufficient dwell time in the cassette prior to exposure to ensure good screen–film contact (the time will depend on the type of cassette but will often be at least five minutes). The film should be evaluated under appropriate conditions with the aid of a high power magnifier.

- b) The figures given for threshold contrast are based on measurements with the TOR(MAS) or TOR(MAX) test object placed on top of 4 cm Perspex and the contrast values are those quoted by the manufacturer (nominal radiation contrast calculated at 28 kVp using a molybdenum target and filter). However, the threshold contrast limits can be applied using different makes of test object provided that due allowance is made for the different definitions of contrast used by the manufacturer and the amount of scatter material used.
- c) Standard film density is taken to mean the gross optical density measured 4 cm from the chest wall edge on the midline of a radiograph of a 4 cm thick Perspex block exposed using the automatic exposure control (AEC) at the current clinical settings. The standard optical density should lie within  $\pm 0.2$  of the target values.

5. Mean glandular dose for a 45 mm thick standard breast. For definition and method of measurement, see section 6.5.2 of the Pritchard Report<sup>3</sup> and IPEM Report 59. The value given should not normally be exceeded and, typically, values are in the range 1–2 mGy. Values lower than 0.8 mGy should be investigated to ensure that the image quality obtained is acceptable.
6. Repeat examinations should be avoided both to minimise radiation dose and, particularly where second appointments are needed, to minimise anxiety.

The decision to repeat a film while the woman is present in the unit is generally the radiographer's decision. The decision to recall a woman for a second appointment in order to repeat a film is the radiologist's decision. Both types of repeat examination need to be monitored, and the combined rate of both types of repeat examination should be less than 3% of total examinations.

7. The minimum standards and targets for the number of women referred for assessment relate to women aged 50–64 called or recalled for screening as part of the NHSBSP.
  9. If a particularly low benign biopsy rate is reported, this might be due to a high non-operative diagnosis rate in the context of an on target cancer detection rate. If this is not the case, then further investigation would be needed particularly looking at cancer detected amongst women placed on early recall. This target relates to women aged 50–64 called or recalled for screening as part of the NHSBSP.
  10. The criterion for measuring whether the number of cancers presenting between screening episodes is being minimised is the rate of cancers which presents in screened women in the first 24 months subsequent to screening. It is recognised that these will not all be false negatives; some will have developed in the interval since screening and some will be mammographically occult cancers. In addition, it is recognised that some false negative cancers will present in the third year after screening. As interval cancers are an expected part of breast screening, and have to be considered over either a number of years or on a regional, large population basis, no minimum or target level is given.
  11. The long term effectiveness of the screening programme is dependent on women in the target age group continuing to be screened at regular intervals. Currently the screening interval is 36 months. Women should be offered an appointment which ensures that they are screened at an interval of not more than 36 months. In order to keep women within their screening batch, this may on occasion necessitate a screening interval of less than 36 months.
- 14, 15 & 16. Where the recommended intervals between the surgical decision to operate and admission are not achieved, this should be drawn to the attention of the appropriate hospital managers and steps taken to improve the situation.

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## APPENDIX 2: EXAMPLE SCREENING ASSESSMENT PROTOCOL

This is an example of a possible protocol that may be adopted by a screening assessment centre. The content in this example is not meant to be prescriptive and should be defined locally. This example can be provided on disk or as an e-mail attachment on request to the national office (nhs.screening@sheffield-ha.nhs.uk).

St Elsewhere Hospital

Date:

### 1. Screening assessment

- 1.1 Screening assessment is carried out to confirm or otherwise the presence of any significant breast abnormality identified at screening.
- 1.2 This is achieved by following the principles of triple assessment (imaging, clinical examination and needle biopsy) carried out by the screening assessment team (minimum of consultant breast radiologist, consultant breast surgeon, nurse specialist and screening radiographers).
- 1.3 All cases recalled are reviewed by the team immediately before the start of the assessment clinic to determine the assessment procedures required.
- 1.4 The reason for recall and the required diagnostic procedures should be discussed with each woman.
- 1.5 All the necessary diagnostic procedures should be carried out at the first assessment clinic visit whenever possible.
- 1.6 The imaging and clinical opinion should be recorded according to the following categories:

*Usually a 1–5 score ('normal' through to 'definitely malignant')*

Local categories vary but should be consistent and agreed by all the members of the clinical breast team

Examples of categories are:

1 <i>normal/definitely benign</i>	1 <i>normal</i>
2 <i>probably benign</i>	2 <i>benign</i>
3 <i>indeterminate</i>	3 <i>indeterminate</i>
4 <i>probably malignant</i>	4 <i>probably malignant</i>
5 <i>definitely malignant</i>	5 <i>definitely malignant</i>

- 1.7 All significant radiological and clinical abnormalities require needle biopsy.
- 1.8 Needle biopsy is reported according to the categories defined in the NHSBSP *Guidelines for Breast Pathology Services* (NHSBSP Publication No 2, currently under revision).

## Breast Cancer Screening Assessment

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- 1.9 All women attending for assessment must be told of their assessment outcome and receive clear details of any further appointments and when and how they will receive their results before leaving the assessment clinic.
- 1.10 The results of all assessment investigations must be reviewed and a clear management decision made at the weekly multidisciplinary screening meeting held before the patient is seen again for results.
- 1.11 There should be only three possible outcomes after complete assessment:
  - no significant abnormality – return to normal screening
  - significant benign abnormality requiring surgery (eg phyllodes tumour)
  - diagnosis of cancer.
- 1.12 All women attending for assessment and their GP must receive written confirmation of the outcome.

### **2. Imaging**

- 2.1 The majority of women recalled for assessment have a mammographic abnormality. Further mammography and/or ultrasound is performed to determine if this is significant.
- 2.2 The imaging assessment performed will depend on the type of lesion being assessed (examples for illustration only):
  - microcalcification only – lateral and craniocaudal magnification views
  - asymmetrical density – craniocaudal and compression magnification views  $\pm$  ultrasound
  - architectural/parenchymal distortion – craniocaudal and compression views and ultrasound
  - mass – ultrasound  $\pm$  craniocaudal  $\pm$  compression views  $\pm$  magnification views.
- 2.3 The imaging opinion (based on both mammography and ultrasound findings) is classified according to the range of categories 1–5 defined in paragraph 1.6 above.
- 2.4 Abnormalities not visible on ultrasound should be managed on the basis of their mammographic and clinical features. Clinical abnormalities with no imaging correlate must be managed on the basis of their clinical features. Needle biopsy should be on the basis of the most suspicious imaging or clinical feature.
- 2.5 Ultrasound guidance is the preferred method for needle biopsy.
- 2.6 For suspicious microcalcifications, core biopsy must be performed and specimen radiography used to confirm satisfactory sampling.
- 2.7 Cysts should be aspirated if there is any doubt about their nature.

### **3. Clinical assessment**

- 3.1 Clinical examination is mandatory for all women recalled for assessment of significant symptoms and/or signs whether or not the screening mammogram is normal.
- 3.2 Clinical assessment must also be performed when a significant radiological lesion is confirmed and before any needle biopsy.

- 3.3 Clinical examination may not be necessary for women who are shown to be entirely normal after further imaging.
- 3.4 Where a significant clinical abnormality has been found, the team should be certain that there is radiological clinical concordance:

*3.4.1 Mammographic/ultrasound abnormality and clinical abnormality*

If there is a discordance in the site of the abnormality, review of mammogram and ultrasound of the clinical abnormality should be performed together by the radiologist and the clinician. Clinical needle biopsy *in addition* to imaging needle biopsy must be performed if the site of the *significant* clinical abnormality does not correspond to the imaging abnormality.

*3.4.2 Mammogram normal with clinical abnormality*

Ultrasound of the abnormal clinical site may be useful particularly in the dense breast (eg cysts found on ultrasound may be aspirated). Where imaging is normal in the presence of clinical abnormality, then a freehand needle biopsy of the abnormality should be considered.

#### 4. Triple assessment

- 4.1 The clinical and radiological opinions are used independently to decide on the significance of any abnormality.
- 4.2 The clinical and radiological opinions are formally documented **before** any further intervention (eg needle biopsy).
- 4.3 The most suspicious opinion prevails – if the radiological opinion is that the abnormality is ‘probably malignant’ and the surgical opinion is that there is ‘no significant abnormality’ then the woman is managed on the basis of the radiological opinion. Similarly, if there is a clinically suspicious lesion and imaging is normal the patient is managed on the basis of the clinical opinion.
- 4.4 The clinical opinion may not downgrade the imaging opinion or vice versa.
- 4.5 The need for needle biopsy is decided by the prevailing opinion:
- needle biopsy is not required for lesions classified as normal or definitely benign
  - needle biopsy is mandatory for all abnormalities classified as indeterminate or more suspicious.
- 4.6 All needle biopsy results must be discussed in the context of the imaging and clinical finding at the multidisciplinary screening assessment meetings. A needle biopsy result not consistent with the clinical/imaging opinion must be discussed fully and a clear management decision reached at this meeting to ensure that either false negative or false positive results are managed appropriately.

### OPTIONAL SECTION

#### 5. Imaging/clinical categories

*The categories listed may vary from unit to unit. For example, it is common for the 'normal' and 'definitely benign' categories to be listed separately.*

##### *Normal/definitely benign*

- 5.1 The patient can be reassured and discharged, eg normal mammography, ultrasound and clinical examination. Needle biopsy is not required.

##### *Probably benign*

- 5.2 This category applies when there is normal imaging but with clinical abnormality that is almost certainly benign (eg a prominent area of 'thickening' that is normal on imaging).
- 5.3 Although the risk of malignancy is low (less than 5%) needle biopsy is required for all cases classified as 'probably benign'.
- 5.4 A result of 'inadequate/benign' on FNA or 'normal breast tissue/benign breast tissue' on core biopsy is acceptable.
- 5.5 With any of these outcomes the woman can be advised that further procedures or surgical biopsy are not required.
- 5.6 With any other diagnosis (C3–C5; B3–B5), a repeat core biopsy should be performed before surgical biopsy.
- 5.7 For C5 or B5 results, definitive therapeutic surgery, especially mastectomy, should only take place after careful re-evaluation in light of the low clinical and imaging suspicions of malignancy.

##### *Indeterminate*

- 5.8 This classification applies to abnormalities that have benign features on either imaging or clinical assessment but a definitive cytological or histological diagnosis of a benign lesion is required to avoid excision biopsy, eg a clinically smooth and mobile 1-cm lump with benign imaging features most likely to represent a fibroadenoma.
- 5.9 The risk of malignancy is 5–50%. FNA must show a good yield of unequivocally benign epithelial cells and core biopsy must provide a benign diagnosis consistent with the clinical and imaging findings – 'normal breast tissue' (B1) should not be accepted as representative where the patient has a discrete lump with a provisional diagnosis of a fibroadenoma.
- 5.10 An 'inadequate' FNA (C1) or 'normal' core biopsy (B1) is not acceptable and, along with an 'equivocal' (C3 or B3) and 'suspicious' (C4 or B4) result requires repeat sampling. If FNA cytology was performed initially the repeat procedure is usually performed as a core biopsy.
- 5.11 With a 'malignant' result (C5 or B5), definitive surgical excision can be planned. Repeat needle biopsy may be considered necessary before performing mastectomy.

##### *Probably malignant*

- 5.12 This classification is used where there is a strong clinical or imaging suspicion of malignancy but the features are not sufficiently characteristic to classify as definitely malignant, eg an area of architectural distortion.

## Breast Cancer Screening Assessment

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5.13 Therapeutic surgery can be performed if needle biopsy shows unequivocal evidence of malignancy (C5 or B5).

5.14 For all other needle biopsy results (C1–C4 or B1–B4), a diagnostic open surgical biopsy should be performed if repeat sampling fails to provide a definitive diagnosis of cancer (C5 or B5). If FNA cytology was performed initially the repeat procedure is usually performed as a core biopsy.

### *Malignant*

5.15 This classification is given where there is unequivocal clinical or imaging signs of malignancy.

5.16 Needle biopsy is performed to obtain a definitive preoperative diagnosis and allow for counselling for therapeutic surgery.

5.17 For all other needle biopsy results (C1–C4 or B1–B4), a diagnostic open surgical biopsy should be performed if repeat sampling fails to provide a definitive diagnosis of cancer (C5 or B5). If FNA cytology was performed initially, the repeat procedure is usually performed as a core biopsy.

### **Assessment outcome**

The outcomes following triple assessment are summarised below:

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<b>Image/clinical classification</b>	<b>FNA/NB result</b>	<b>Management decision</b>
1	Not required	Reassure – RR
2	1/2	RR
	3	Rpt NB, DS
	4	Rpt NB, DS
	5	DS or TS
3	1	Rpt NB, DS
	2	RR
	3/4	Rpt NB, DS
	5	DS or TS
4, 5	1	Rpt NB, DS
	2	Rpt NB and DS
	3/4	Rpt NB and DS
	5	TS

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RR, return to routine screening; Rpt, repeat; NB, needle biopsy; DS, diagnostic surgical excision; TS, therapeutic surgery.

## **OPTIONAL SECTION**

### **6. Short-term recall**

6.1 Properly applied, the assessment procedure should result in a definitive result with the woman either discharged back to normal screening or referred for treatment.

- 6.2 Short-term recall should only be recommended where needle biopsy is not possible and the risk of malignancy is low or if the woman refuses to undergo either needle biopsy or diagnostic surgery.
- 6.3 This outcome should only be decided after attendance at an assessment clinic and/or full discussion at the multidisciplinary screening assessment meeting.
- 6.4 Women placed on short-term recall should have the reasons fully explained in the presence of the nurse specialist.
- 6.5 The short-term recall attendance should be to the assessment clinic.
- 6.6 No woman should be placed on short-term recall more than once in each screening round.

### **7. Managing the needle biopsy result**

- 7.1 A pathological result of C1/B1 is acceptable where needle biopsy has been performed for a category 2 (probably benign) imaging/clinical opinion.
- 7.2 A result of C2/B2 is required for all category 3 (indeterminate) lesions before the woman can be discharged back to normal screening.
- 7.3 For microcalcifications, specimen radiography of the core specimens should be performed and must demonstrate representative microcalcification. In the absence of representative calcification, the presence of histological calcification should not be accepted as indicating that a representative sample has been obtained. In these circumstances, the core biopsy should be repeated or open surgical biopsy performed.
- 7.4 A diagnosis of atypical ductal hyperplasia (ADH) on needle biopsy necessitates surgical excision to definitively exclude DCIS in the adjacent tissue.
- 7.5 A diagnosis of radial scar or complex sclerosing lesion necessitates surgical excision to definitively exclude associated malignant change.
- 7.6 A C5 or B5 result is required before definitive therapeutic surgery can take place.
- 7.7 C3, C4, B3 and B4 results should result in a repeat needle biopsy (preferably core biopsy) or open surgical biopsy to obtain a definitive result.

### APPENDIX 3: AUDIT OF SCREENING ASSESSMENT

1. Time from screen reading to first offered screening assessment appointment  
Standard: Within 10 working days
2. Number of assessment visits required to achieve a definitive diagnosis  
Standard: No more than three
3. Preoperative diagnosis rate for breast cancer  
Standard: At least 70%
4. Benign surgical biopsy rates  
Standard: Prevalent Less than 3.6 per thousand women screened  
Incident Less than 2.0 per thousand women screened
5. Attendance at multidisciplinary screening assessment review meetings.
6. Records kept of assessment cases and outcomes.

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