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Position Paper

Quality assurance in the diagnosis of breast disease

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1. Introduction

The diagnosis of breast disease has been subject to a sustained and widespread drive for quality control and quality improvement across Europe over the last ten years. Much of this has been confined to the provision of breast cancer screening services. Professionals working in the field have long since recognised that women using symptomatic breast services should be confident of receiving similar standards of diagnosis available in the screening sector.

Published guidelines for quality assurance in mammography screening already exist at a European level and at a national level in several Member States. Guidelines for quality assurance in symptomatic breast diagnostic activity are not so well established. Their existence, however, is essential as symptomatic services potentially affect considerably more women than take part in screening programmes. This document attempts to lay out in a setting suitable for European usage, those aspects of quality assurance, quality objectives and outcome measures that are necessary to further these aims.

As far as possible we have tried to avoid screening or treatment issues unless of particular relevance to diagnostic activity. We have also chosen not to attempt to define clinical protocols.

Modern diagnosis of breast disease is a multidisciplinary activity requiring trained and experienced professionals using specialised equipment with up-to-date sampling and other diagnostic techniques. Screening is predominantly a radiological procedure with particular emphasis placed on the optimal balance of sensitivity and specificity. Many abnormalities are impalpable and priority is given to maximising the cancer detection rate while minimising anxiety and reducing the benign biopsy rate. The radiologist has the role of prime responsibility in screening. In symptomatic activity the clinician has the role of prime responsibility, this person is usually the referring General Practitioner or the surgeon that the patient is referred on to. The clinician may also be regarded as any medical professional who is trained and skilled specifically in clinical examination of the breast. In these circumstances, however, the role of imaging, interpretation and cytological/histological sampling procedures will still be paramount as supportive diagnostic activities.

Practices are likely to vary across the Member States according to healthcare environments and availability of trained personnel; however, these variations must not be allowed to interfere with the achievement of set targets and outcome measures.

If possible, all women requiring breast diagnosis should be referred to a specialist breast unit, the requirements for which have already been laid out by EUSOMA. However, it is important to recognise that in a decentralised healthcare setting many women will not undergo more than basic imaging following a General Practitioner referral, and the benefits of full multidisciplinary assessment will not be available to them, or indeed necessary for many of them. These guidelines will, therefore, attempt to cover all pertinent aspects of basic diagnosis as well as assessment and underline the importance of ensuring that women who do require further assessment are not denied it. In order to ensure this, agreed protocols should be set up between diagnostic clinics and assessment centres, if the two are run as separate entities. Throughout this text the terms 'patients' and 'women' are referred to at various points as appropriate. It is recognised that on occasions, male patients will also require the services of a diagnostic breast clinic.

Asymptomatic women do not necessarily require initial clinical examination or other imaging investigation apart from mammography if taking part in a breast screening programme. However, it is regarded as good practice that all women with breast symptoms undergo a clinical examination prior to any further investigation requested, and that this be performed by a suitably trained and experienced clinician.

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2. Training and quality assurance

The key professional personnel involved in breast diagnosis are the surgeon (clinician), radiologist, radiographer, histo/cytopathologist, nurse counsellor and physicist. All such personnel must hold the requisite professional qualifications in their own country and have undergone specific training in the field of diagnosis/diagnostic imaging of the breast. They should regularly participate in Continuing Medical Education and update courses, also taking part in any existing external quality assessment schemes and being in possession of any necessary Certificate of Competence.

It is to be hoped that over the next few years there will be a move towards certification/accreditation for all professional staff and units participating in this activity.

A full and comprehensive quality assurance programme must be in place with clearly documented local quality control procedures and quality assurance manuals. As far as the imaging aspects of breast diagnosis are concerned — i.e. radiographic and radiological — these must comply with the technical and professional requirements laid out in the European Guidelines for Quality Assurance in Mammography Screening [1].

It is essential that there be a nominated person with responsibility for the physico-technical quality control aspects of every unit participating in breast diagnosis, at whatever level. Similarly, each service must have a Clinical Director or one member of the professional team acting as Lead Clinician with responsibility for overall performance and quality of the service, and with the requisite authority to make changes or suspend equipment if necessary.

3. Imaging procedures

Breast units, diagnostic clinics or assessment units must be in possession of local imaging protocols agreed by and made available to all clinic staff and forming part of the local quality assurance (QA) manual.

Mammography and ultrasound either alone or in combination are the primary diagnostic imaging methods used for the breast. If mammography is required, a two view examination should be performed using the standard lateral oblique and cranio caudal projections. The use of mammography prior to the age of 35 years is of limited diagnostic use and carries a higher theoretical risk from ionising radiation. Mammography in this age group should only be used in particular circumstances such as a strong clinical suspicion of malignancy and when specifically authorised by the radiologist in charge. If breast imaging is required below the age of 35 years, ultrasound is the method of choice. Other imaging techniques such as magnetic resonance imaging (MRI) of the breast have specific indications and do not form part of the initial diagnostic investigation at present.

Mammography is associated with a variable false-negative rate in the order of 10–20%, but this may be as high as 50% if the image quality is compromised for any reason including the age of the patient and the density of the breast. If a woman complains of, or is found to have a discrete mass or other significant clinical sign in her breast which is not demonstrable mammographically, it is essential that she be referred for an ultrasound examination as part of standard triple assessment procedures. This will reduce the possibility of missed malignancy with negative mammography.

Women with breast implants should be advised that these may significantly reduce the efficacy of subsequent mammography and that mammographic imaging should be performed in clinics where ultrasound is available as it may frequently be required as an additional imaging technique. MRI is now recognised as the method of choice for investigating significant abnormalities in the breast in the presence of implants and for the assessment of possible intracapsular or extracapsular implant rupture.

Assessment of microcalcification is likely to require magnification views, and these should be performed in orthogonal projections, i.e. true lateral and cranio caudal in order to maximise the diagnostic information available.

It is preferable to perform clinical examination prior to any image-guided interventional sampling procedure so that subtle clinical signs are not disturbed by haematoma formation. For similar reasons, it is preferable to perform any necessary basic imaging procedures such as mammography/ultrasound prior to any clinically guided sampling. If facilities and staffing allow, it may be logistically advantageous to perform sampling of clinically palpable lesions under image-guided control.

Communication at all times is an essential part of the process and this must exist between the members of the imaging team, e.g. radiographer/radiologist, as well as with the patient and the referring clinician.

4. Diagnostic imaging clinic

In a decentralised healthcare setting, there may be multiple clinics or offices present within a geographical area offering mammography and/or ultrasound examination of the breast. Some of these may be operating to significantly lower volume levels than that currently regarded as acceptable by specialist units. There are numerous problems with low volume throughput in breast imaging and a decentralised approach must not be allowed to jeopardise production of examinations

having adequate image quality. The highest possible image quality is necessary to maximise diagnostic information and provide suitable levels of sensitivity and specificity. Inadequate quality of equipment, inadequate processing facilities, under-used processing facilities, lack of a quality control programme and poorly trained and experienced radiological or radiographic staff will adversely affect optimum performance and interpretation of breast images. Minimum standards must be set in place so that this is not allowed to happen.

This section will describe certain requirements to be provided by any clinic offering diagnostic imaging services. This should be regarded as the most basic level of quality needed for adequate service provision. The next section will describe requirements for a fuller and more comprehensive breast assessment centre.

The endpoint of the Diagnostic Imaging Clinic is to correctly identify and classify imaging characteristics, and should not include further formal assessment with tissue/cytology sampling, with the exception of simple cyst aspiration. Further investigations should be performed at or in conjunction with a breast assessment centre as laid out in the next section. This will ensure that cellular or tissue samples are analysed by a trained and recognised pathologist adhering to pathology quality assurance requirements.

4.1. Mammography equipment

Dedicated mammographic and film processing equipment must be available with the facility to produce low dose with high contrast and spatial resolution examinations. An adequately high optical density is required for satisfactory image interpretation due to the proven relationship between optical density and small cancer detection rates. Equipment should be up to date, from a recognised manufacturer, suitable for its purpose, and subject to regular maintenance and quality control checks as laid out in the European Guidelines for Quality Assurance in Mammography Screening [1]. For example, it is not suitable to use a mammography machine without a foot-operated compression system. All equipment in the clinic must be subject to regular radiographic quality control checks and performance tests by a medical physicist suitably trained and experienced in mammography. Consistent breaching of quality control levels should lead to suspension of the equipment from use by the nominated person charged with the overall responsibility for quality assurance of the unit.

4.1.1. Targets

The following are essential targets to be achieved, fuller requirements are laid out in the European Guidelines.

High contrast/spatial resolution >10 lp/mm
Optical density 1.4–1.8
Mean glandular dose per film <2 mGy
Daily processor control maintenance 100%

4.2. Ultrasound equipment

Breast ultrasound should only be carried out by members of medical staff specifically trained and experienced in this procedure. It should not be carried out by General Practitioners, gynaecologists, surgeons, radiologists or radiographers who have not undergone such specific training and who do not participate in the regular performance of this task. The operating frequency of the ultrasound machine must be at least 7.5 MHz, and should preferably operate at 10 MHz or higher. Suitable recording facilities for sonographic images must be available.

4.3. Radiographic staff

Mammograms should be performed by suitably trained and experienced radiographic staff fulfilling all necessary training and working professional requirements and holding any relevant Certificate of Competence as previously described. In clinics where no mammographically trained radiographer is employed, the member of staff performing the mammograms must have undergone full training in the radiographic aspects of mammography, comply with all requirements as laid down for radiographic staff, including any necessary external quality assessment schemes and update courses and take the lead in regular radiographic quality control procedures. For the purpose of this document such a person will be referred to as the radiographer.

It is the radiographer's responsibility within the team to produce an optimum image with regard to positioning and technical aspects and in a manner acceptable to women. The radiographer must inform the woman about the procedure, how it is to be performed, how the woman will get her result, and in what timescale. The radiographer in charge of the unit is responsible for ensuring that a regular quality control programme is carried out and is responsible for reporting breaches of quality to the radiologist in charge of the clinic. Such a quality control programme will include both regular radiographic- and physicist-performed checks as listed in the European Guidelines [1].

In order to limit unnecessary exposure to ionising radiation and the creation of unnecessary anxiety, the technical retake level where repeat mammograms are necessary for positioning or technical faults must be kept to an absolute minimum, preferably below 1%, but no more than 3%. All such retakes should be documented for audit purposes. Positioning performance requirements for adequate mammographical examinations are

laid out in the European Guidelines and must be adhered to. The minimum requirements for positioning of the standard lateral oblique projection are that the pectoral muscle must be displayed down to nipple level, the inframammary fold should be visible and the nipple should be in profile. Skin folds, movement and other artefacts should be absent. An external quality assessment scheme should be in place so that peer review of adequate positioning is performed and satisfactory results obtained in at least 97% of images. All films must be appropriately named and marked correctly for side.

In order to maintain the skills and expertise required to carry out optimum mammography and be a useful member of the multidisciplinary team, the radiographer must be involved in performing at least 20 mammographic studies per week.

4.3.1. Targets

Technical repeat rate minimum level $<3\%$ — expected $<1\%$.
More than 97% of women will have an acceptable examination according to the positioning and exposure criteria given.
100% of women will be informed by the radiographer of the method and time-scale for receiving her results.
Minimum 20 mammographic studies per week to be performed by each radiographer.

4.3.2. Basic quality control

The following is a basic summary of routine quality control tests to be performed by the radiographer, fuller details are available in the European Guidelines [1].

Daily
Mechanical, safety and function checks
Standard density consistency tests
Reproducibility of mAs values
Sensitometry
Clean X-ray crossover rollers
Screen inspection and cleaning
Cassette inspection for wear and tear

Weekly
Thickness variation
Image quality

Quarterly
Sensitivity and radiation absorption of cassettes
Film screen contact
Calibration of densitometer

4.4. Radiological staff

The radiologist must be specifically trained and experienced in breast imaging. This should include a knowledge of the technical requirements of mammography equipment, processing, exposure factors and all those other factors of importance that are necessary in the production of good image quality. If possible, radiologists involved in symptomatic activity should also participate in local screening programmes.

A dedicated mammographic film viewer must be available and films should be read in a suitable room with control of background lighting. It is the responsibility of the radiologist to ensure that the mammograms are of adequate diagnostic standard, particularly with regard to positioning and film density. Where films are inadequate, they must be repeated. The radiologist must also ensure that feedback is provided to the radiographer on image quality. The report provided by the radiologist must state quite clearly the nature of any abnormality present, its side, site, size, description and extent. The radiologist should make clear the implication of the imaging findings and should recommend the most suitable necessary further investigation.

If a significant finding is present, carrying a high risk of malignancy, it is the responsibility of the reporting radiologist to ensure that the woman is aware that further investigation or management will be required. For this reason it is recommended that wherever possible the radiologist should be available within the clinic during the mammographic examination so that any necessary procedure such as an ultrasound can be performed while the woman is still present. This will avoid the need for a separate return visit, and allow the radiologist to pass on any necessary information to the woman, with due regard paid to the importance of not creating unnecessary anxiety.

4.5. Basic requirements

Ultimately it is hoped that all clinics offering breast diagnostic services will be subject to accreditation/certification procedures. Until that time the following criteria are proposed in line with the European Reference Organisation for Quality Assured Breast Screening and Diagnosis (EUREF) Certification Protocols.

The following basic criteria will be required from a Diagnostic Mammography Unit, which should:

(a) Perform at least 1000 mammograms per year.
(b) Have dedicated equipment specifically designed for application in diagnostic mammography, e.g. mammography system with magnification ability and dedicated processing, and be able to provide adequate viewing conditions for mammograms.
(c) Comply with the physico-technical protocol in the European Guidelines.
(d) The radiographer, technologist or other member of staff performing the mammographic examination must have had at least 40 h of training specific to the radiographic aspects of mammography and regularly

participate in External Quality Assessment Schemes where available and radiographic update courses. This person must also take the lead in the radiographic aspects of quality control.

(e) Employ a trained radiologist, i.e. a person who has had at least 60 h of training specific to mammography and who in volume requirements reads at least 500 mammograms per year.

(f) Keep a record of mammogram results and monitor the numbers of women referred for further assessment.

(g) Provide feedback of further assessment outcomes to the unit radiologists.

NB: Volume requirements as stated in this section and the following section are regarded as the absolute minimum required to allow the production of adequate diagnostic quality images. Greater numbers may not guarantee higher quality, but are more likely to be associated with a significantly higher level of professional skill and physico-technical excellence. For this reason, higher volume throughputs are strongly recommended, and have been specified in the EUSOMA guidelines for a specialist breast unit.

In all cases, a mammogram refers to a full set of mammograms performed on a woman, and should not under any circumstances for the purposes of numerical advantage be counted in terms of individual mammographic exposures.

5. Breast assessment centre

While basic diagnostic imaging in the form of mammography/ultrasound may be sufficient for many women, those with significant symptoms, clinical findings, or mammographic findings need further follow-up which will require more specialist equipment and staff. A protocol should be in place with the referring General Practitioners so that women with a clinical finding carrying a significant risk of malignancy should be referred directly to the breast assessment centre at a specialist breast unit. Such clinical findings will include a discrete new palpable mass, nipple discharge — particularly if single duct and unilateral, nipple retraction, nipple eczema, skin distortion such as tethering, dimpling or a change in breast shape, palpable axillary lymphadenopathy or inflammatory change. In this setting, the woman will undergo a process of triple assessment, i.e. clinical, imaging and cytological/histological investigation, performed by a specialist multidisciplinary team with access to more sophisticated imaging equipment and preoperative diagnostic techniques.

Breast assessment centres which are not functioning as part of a specialist breast unit must have written protocols available for triple assessment techniques. Additional mammographic techniques must include the ability to perform paddle compression and microfocus magnification views. Image-guided sampling techniques must be available with the ability to perform these either under ultrasound or stereotactic control. Whether fine needle aspiration cytology (FNAC) procedures or core biopsy (CB) procedures are carried out will depend upon the local radiological and cytological expertise, and audit of results obtained. Immediate cytological reporting or checking for adequacy of cellularity can be performed. Core biopsy in expert hands can provide increased sensitivity and specificity compared with FNAC. Radiographic, radiological and histo/cytopathological staff must be fully conversant with the accurate carrying out and interpretation of all these procedures. Specific standards of performance in sampling procedures must be adhered to, particularly with regard to insufficiency of results and preoperative diagnosis.

If abnormalities are visible sonographically, it is more suitable for sampling to be performed under ultrasound control. It is generally advisable for image-guided sampling to be performed for any solid sonographically detected lesion. If required, microcalcification may occasionally be sampled under ultrasound control, but more usually stereotactic procedures will be required. CB is preferred for lesions of architectural distortion and microcalcifications, and may also allow definitive diagnosis of a benign lesion which will then not require surgical excision biopsy. If core biopsy is performed for microcalcification, it is essential that specimen radiography of the cores be obtained to demonstrate the presence of calcification. Sampling techniques should be carried out with due regard to the imaging or clinical modality carrying the most suspicious features. Where there is a possibility of discordant clinical and imaging findings with regard to any lesion, it is advisable to carry out sampling under both imaging and clinical guidance. Very occasionally there may remain a significant discordance between suspicious radiological features and benign sampling where no reasonable pathological correlation can be made. Under these circumstances, open surgical excision is advisable.

It is regarded as good practice that lesions which are predominantly architectural distortion should be subject to excision biopsy following preoperative diagnostic procedure due to a significant risk of associated malignancy which may not be demonstrated even under ideal sampling conditions. In addition, lesions that are proven to contain atypical ductal hyperplasia should be subject to excision due to the risk of associated malignancy.

Where resources allow, mammotomy offers significant advantages for percutaneous biopsy in a proportion of patients in achieving definitive preoperative diagnosis and reducing the need for surgical intervention.

5.1. Diagnostic classification

A standard classification system is used as follows in addition to the normal descriptive methods.

Radiology	
R1	Normal/benign
R2	A lesion having benign characteristics
R3	An abnormality present of indeterminate significance
R4	Features suspicious of malignancy
R5	Malignant features
Ultrasound	
U1	Normal/benign
U2	A lesion having benign characteristics
U3	An abnormality present of indeterminate significance
U4	Features suspicious of malignancy
U5	Malignant features

A negative or benign clinical examination must not be allowed to downgrade the importance of suspicious imaging features unless the radiologist has been fully consulted.

Fine needle aspiration cytology	
C1	Inadequate
C2	Benign epithelial cells
C3	Atypia probably benign
C4	Suspicious of malignancy
C5	Malignant
Core biopsy/histology	
B1	Unsatisfactory/Normal
B2	Benign
B3	Benign, but of uncertain malignant potential
B4	Suspicious of malignancy
B5	Malignant

5.2. Targets

% of image-guided FNAC procedures with an insufficient result	
Minimum standard	<25% Expected <15%
% of image-guided FNAC procedures from lesions subsequently proven to be malignant having an insufficient result	
Minimum standard	<10%
% of women with breast cancer having a preoperative diagnosis of malignancy (FNAC/CB reported as definitely malignant)	
Minimum standard	>70% Expected >90%

5.3. Cytology/histology quality assurance

These figures are based on screening targets currently in use. Symptomatic requirements may well need to be reset higher in the light of experience [2].

Absolute sensitivity	⩾60%
Complete sensitivity	>80%
Specificity	>60%
Positive predictive value C5	>95%
False-negative rate	<5%
False-positive rate	<1%

5.4. Audit

For audit purposes, it is proposed that the standard assessment data set be used as recommended in the QT audit document approved by EUSOMA (See Appendix B).

5.5. Cytology/core biopsy reporting standards

These should be based upon examples given in Appendices C and D.

5.6. Basic requirements

These are also based on the EUREF certification protocols. In addition to the standards achieved by the diagnostic mammography unit, a centralised system of diagnostic assessment for mammographically or clinically detected lesions must be available. There should be a full range of assessment facilities provided in order to allow complete and adequate work-up by the centre without necessarily having to refer the woman on for further investigation elsewhere.

The breast assessment centre should:

(a) Perform at least 2000 mammograms a year.
(b) Be able to perform physical examinations and ultrasound examinations as well as the full range of radiographic procedures. Provide cytological examination and/or core biopsy sampling under radiological (including stereotactic) or sonographic guidance.
(c) Employ a trained radiologist reading at least 1000 mammograms a year.
(d) Have organised and specialist cytological and histopathological support services.
(e) Participate in multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services.
(f) Monitor data and feedback of results.
(g) Keep a formal record of the assessment process and outcomes.

The requirements placed upon a breast assessment centre as part of a specialist breast unit may be even more rigorous than these (see EUSOMA Breast Unit document).

6. Multidisciplinary activity

All breast assessment centres or breast units engaged in diagnostic excision biopsy must ensure the formation

of proper multidisciplinary teamwork involving the following personnel: Radiographer, radiologist, histo/cytopathologist, surgeon/clinician, nurse–counsellor.

Ideally, before a woman is considered for surgical excision biopsy her case and results should have been discussed in the setting of a full multidisciplinary meeting. By so doing the surgeon will be best appraised of the likelihood of malignancy, the extent of abnormality on imaging and any discordant results which may have been obtained upon review of the case, which might lead to an alteration of surgical planning. Similarly, all biopsy results should be discussed in a multidisciplinary audit setting to establish the nature of disease, its extent, completeness of excision and the appropriateness of the histology compared with the preoperative diagnosis. Unexpected results should be discussed in this setting to establish their veracity, to confirm that the correct lesion has been excised and to provide a source of learning and experience.

7. Surgical aspects

The surgeon is a member of the multidisciplinary team and should participate in regular multidisciplinary review for case management and audit purposes. The surgeon should be fully involved in the assessment of women and should always see the patient before accepting her for surgery.

It should be agreed surgical policy that mammography is carried out prior to breast surgery providing the woman is in an appropriate age group. Firstly, as a matter of good practice to demonstrate the nature and extent of any disease that is identifiable, secondly, to ensure that full imaging information is available in the case of interval cancers arising in any local screening programme.

The surgeon should be discouraged from cutting specimens open after removal in theatre before sending them to pathology. All specimens should be marked and orientated according to recognised local protocols. The surgeon should ensure completeness of excision, which may be assisted by the use of two-plane specimen radiography. At operation, the use of frozen sectioning is generally inappropriate, particularly in the assessment of clinically impalpable lesions. It may occasionally be justified to enable a firm diagnosis of invasive malignancy to be made in order to allow definitive surgery to be carried out in one operative procedure. In general terms, surgeons should adhere to the European Guidelines for Quality Assurance in the Surgical Management of Mammographically Detected Lesions [3], and in particular the monitoring of surgical outcome measures as defined in the European Guidelines on Quality Assurance in Mammography Screening [1].

7.1. Preoperative localisation

Lesions that are either impalpable or difficult to locate with certainty on clinical examination will require some form of preoperative localisation marking procedure provided by the radiologist. The most usual form is by wire placement either under X-ray or ultrasound guidance. The wire should be placed within 1 cm of the lesion if possible in at least 90% of cases, or a second wire should be inserted. It is acceptable under certain circumstances if the lesion is superficial for skin marking to be provided under ultrasound control. The surgeon must be provided with a full and accurate description of the procedure performed and a precise report of the relative placement of the wire compared with the lesion. Relevant images, correctly marked should also be provided.

Specimen radiographs must be available in, or in very close proximity to, the operating theatre so that confirmation of excision of the lesion can be confirmed without delay and prior to skin closure. Successful excision of impalpable lesions is, therefore, a combination of surgical, as well as radiological, skill and the proportion of impalpable lesions successfully excised at the first operation should be in excess of 95%. Specimen radiographs must also be made available to the pathology department.

In order to limit the number of unnecessary biopsy procedures performed, it is recommended that the ratio of benign to malignant excision biopsies performed for diagnostic purposes should not exceed 0.5:1. Already diagnosed benign lesions and lesions removed due to patient choice are excluded. For cosmetic reasons it is important to minimise the extent of benign biopsies for impalpable lesions, and at present, the most suitable discriminatory factor used is the weight of the specimen. Over 90% of diagnostic biopsies for impalpable lesions which subsequently prove benign should weigh less than 30 g.

7.2. Targets

Proportion of wires placed within 1 cm of an impalpable lesion prior to excision Minimum standard >90%
Proportion of impalpable lesions successfully excised at the first operation Minimum standard >95%
Proportion of benign diagnostic biopsies on impalpable lesions weighing less than 30 g Minimum standard >90%
The rate of benign to malignant operations performed for diagnostic biopsy purposes (see text) Minimum standard 0.5:1
No frozen section performed if tumour diameter <10 mm Minimum standard 95%

7.3. Histopathology reporting forms

It is recommended that a minimum dataset for reporting be established by a form based on the example in Appendix E.

8. Anxiety and delays

Delays at any stage of the diagnostic process may result in anxiety for the woman, which sometimes may be considerable. Targets should be set in terms of working days (w.d.) at every stage where delay may arise.

Delay between mammography and result
Minimum standard < 5 w.d.

Delay between result of imaging and offered assessment
Minimum standard < 5 w.d.

Delay between assessment and issuing of results
Minimum standard < 5 w.d.

Delay between decision to operate and date offered for surgery
Minimum standard < 15 w.d. Ideally < 10 w.d.

95% of women should receive full and adequate assessment in three appointments or less.

80% of women with symptoms and signs strongly suggesting the presence of breast cancer should be seen within two weeks of referral.

Unnecessary distress may be caused not only by delays as listed above, but also by failure of efficient communication between the diagnostic team and the woman. Failure to reach a definitive diagnosis due to imprecise methods of assessment also results in anxiety.

If possible the radiologist should be present in the clinic at the time when a woman has her mammogram so that any necessary further investigation, e.g. ultrasound examination, can be performed without delay. It is also important that full verbal information on the status of her investigations and diagnosis be given to the woman at suitably relevant stages throughout the diagnostic process. As far as possible the woman should be informed of the result of her examination before she leaves the clinic and of the need for any necessary further investigation to be performed.

The failure of the assessment process to make a definitive diagnosis of either a benign or a malignant condition is an undesirable outcome of assessment and further increases anxiety. For this reason, the use of early recall for a repeat examination at a time shorter than that normally specified for a routine follow-up is to be avoided. Women must be informed of when to expect results and should be provided with written information at appropriate stages in the diagnostic procedure. However, women should not be informed by letter or telephone of the likelihood of malignancy being present. Such information should be given verbally to her in the presence of a nurse–counsellor.

8.1. Rapid diagnostic/one stop clinics

There is considerable advantage to the formation of rapid diagnostic clinics, set up in breast units, where the diagnostic team may work together in a multidisciplinary setting. Women may receive a diagnosis and management plan in the quickest time possible, either during the same clinic, or having all necessary investigations at the same time and returning for results within 24–48 h. The main advantages of this system are to reduce anxiety, and to provide a certain level of skill and teamwork not otherwise available. For this reason, as previously recommended, all women with discrete masses or significant signs or symptoms must be referred directly to a breast unit, and not to a basic diagnostic clinic.

9. Pathology QA

Pathologists providing a breast histopathology and/or cytopathology service should have had specialist training and participate in a continuing education programme. They should follow recommended reporting guidelines and diagnostic protocols. They should participate in relevant external QA schemes where available. Diagnostic cytology and needle core biopsy histology performance can be assessed using QA statistical methods. All pathology laboratories should be accredited according to national standards.

10. Magnetic resonance imaging (MRI) and other diagnostic methods

As previously stated MRI is not yet part of the initial diagnostic procedures. The full role and place of MRI in breast diagnosis is still being evaluated. However, when indicated, it already has an established role in the evaluation of breast implants and in the differentiation of recurrent disease from post-surgical scarring, where it has a very high negative predictive value. There is, however, no evidence at present for its usefulness or cost effectiveness as routine follow-up after breast cancer surgery. It is probably better than conventional techniques in assessing the full extent of malignant disease present within a breast, certainly in selected cases such as dense breasts. The technique is not sufficiently specific for routine use in younger women with dense breasts.

The precise place of sentinel node biopsy, scintimammography and positron emission tomography is still under evaluation for breast diagnostic purposes.

Similarly, appraisal of the usefulness of invasive diagnostic procedures such as Mammotome and Advanced

Breast Biopsy Instrumentation (ABBI) compared with FNAC/CB is underway. There is evidence that mammotomy has a better sensitivity and specificity than other percutaneous biopsy methods. It appears to be well tolerated with a low complication rate and may hold significant advantages for patient management decisions.

Comparison will need to be made on the role, availability and cost effectiveness of all these techniques compared with more standard investigations.

Appendix A. List of attendees

EUSOMA Working Party
L. Cataliotti, Surgeon, Florence (President of EUSOMA)
N.M. Perry, Radiologist, London (Chairman)
A.R.M. Wilson, Radiologist, Nottingham
I.O. Ellis, Pathologist, Nottingham
M. Blichert-Toft, Surgeon, Copenhagen
M. Rosselli del Turco, Radiologist, Florence
I. Garas, Surgeon, Athens
M. Greco, Surgeon, Milan

EORTC attendees
J.P. Julien, Surgeon, Rouen
R. Christiaens, Surgeon. Leuven
C.J.H. van de Velde, Surgeon, Leiden

Nottingham attendees
R. Holland, Nijmegen, Radiologist
C. Elston, Pathologist, Nottingham
Z. Pentek, Radiologist, Budapest

Appendix B

Report no._____ **Surname**_____ **Forename**_____

Date of birth /__/__/____/ **Place of birth** _____ **Personal ID no.**_____

Address_____ **Town**_____ **District**_____ **Tel.**___/_____

Trial_____

Assessment Section

Source of referral
(1) - Screening
_____
(2) - Other
_____
(9) - Unknown

Palpable lesion
(0) - No
(1) - Yes
(9) - Unknown

Other clinical findings
_____

Imaging/clinical size
_____ mm

Breast side
(R) - Right
(L) - Left
(U) - Unknown

Size-method (priority as follows)
(1) - Ultrasound
(2) - Mammographic
(3) - Clinical
(9) - Unknown

Lesion site
(1) - Superior-external
(2) - Central-external
(3) - Inferior-external
(4) - Inferior-central
(5) - Inferior-internal
(6) - Central-internal
(7) - Superior-internal
(8) - Superior-central
(9) - Areolar
(88) - Diffuse
(99) - Unknown

Mammogram finding
(0) - Not done
R1 - Negative / Benign
R2 - Benign lesion
R3 - Abn., indetermined significance
R4 - Suspicious of malignancy
R5 - Malignant features
(9) - Unknown

Mammogram pattern
(0) - No opacity or asymmetry
(1) - Well defined opacity
(2) - Poorly defined opacity
(3) - Spiculate opacity
(4) - Distortion / Stellate opacity
(5) - Asymmetry
(8) - Other .....
.....
(9) - Unknown

Ultrasound finding
(0) - Not done
U1 - Negative / benign
U2 - Benign lesion
U3 - Abn., indetermined significance
U4 - Suspicious of malignancy
U5 - Malignant features
(9) - Unknown

Microcalcifications
(0) - Absent
(1) - Predominantly punctate
(2) - Predom. pleomorphic / granular
(3) - Predom. linear branching
(9) - Unknown

Ward Stamp

Disease extent
(0) - Localized
(1) - Multifocal (more foci in the same quadrant)
(2) - Multicentric (syncr. lesions in different quadrants: use 1 form per lesion)
(9) - Unknown

Fine Needle Aspiration
(0) - Not done
C1 - Inadequate
C2 - Benign epithelial cells
C3 - Atypia probably benign
C4 - Suspicious of malignancy
C5 - Malignant
(9) - Unknown

Core Biopsy
(0) - Not done
B1 - Unsatisfactory/Normal
B2 - Benign
B3 - Benign, uncertain
B4 - Suspicious of malign.
B5 - Malignant
(9) - Unknown

If malignant
(a) - In situ
(b) - Invasive

Date of cytology or histology sample
/___/___/_____/

Department
_____

Nipple discarge
(0) - Absent
(1) - Present
(9) - Unknown

Nipple discharge cytology
(0) - Not done (4) - Suspicious
(1) - Benign (5) - Malignant
(2) - Papillary (8) - Unsatisfactory
(3) - Dubious (9) - Unknown

T N M by imaging or physical examination
T _____
N _____
M _____

Menstrual status
(1) - Fertile
(2) - Pregnancy
(3) - Post-menopause
(4) - Hormone replacement therapy
(9) - Unknown

This lesion with respect to any other lesions in the same patient
(0) - Single lesion (4) - Metachronous, contralateral
(1) - Main lesion (5) - Metachronous, ipsilateral
(2) - Double, contralateral (9) - Unknown
(3) - Double, ipsilateral

First malignant lesion
(0) - No
(1) - Yes
(9) - Unknown

First treatment
(1) - Surgery (4) - RT + CT
(2) - Radiotherapy (9) - Unknown
(3) - Chemotherapy

Date of referral
/___/___/_____/

Notes

Appendix C

PROPOSED CYTOLOGY REPORTING FORM

Surname_____ **Forenames**_____

Date of birth_____ **Screening no**_____

Hospital no_____ **Report no**_____

Side	☐ **Right**	☐ **Left**
Specimen type	☐**FNA (solid lesion)**	☐**FNA (Cyst)**
	☐**Nipple discharge**	☐**Nipple or skin scrapings**
Localisation technique	☐**Palpation**	☐**X-ray guided**
	☐**Ultrasound guided**	☐**Stereotaxis**
Opinion	☐**1 Unsatisfactory**	
	☐**2 Benign**	
	☐**3 Atypia probably benign**	
	☐**4 Suspicious of malignancy**	
	☐**5 Malignant**	
		☐**Case for review?**

PATHOLOGIST **NAME OF ASPIRATOR** **DATE**

Appendix D

PROPOSED WIDE BORE NEEDLE BIOPSY FORM

Surname..... Forenames..... Date of birth.....

Screening no..... Hospital no.....

Centre..... Report no.....

Side ☐ Right ☐Left Number of cores.....

Calcification present on specimen x-ray? ☐Yes ☐No ☐Radiograph not seen

Histological calcification: ☐Absent ☐Benign ☐Malignant ☐Both

Localisation technique: ☐Palpation ☐x-ray guided ☐Ultrasound guided ☐Stereotaxis

Opinion:

- ☐ B1 Unsatisfactory/normal tissue only
- ☐ B2 Benign
- ☐ B3 Benign but of uncertain malignant potential
- ☐ B4 Suspicious of malignancy
- ☐ B5 Malignant ☐ a. In-situ ☐ b. Invasive

Pathologist ..... Operator taking biopsy..... Date.....

Comment.....

.....

.....

Appendix E

Pathology Section

Histopathology report no._____
Date diagnostic report /__/__/__/__/
Department _____
Pathologist _____
Date last report /__/__/__/__/
Date lymph nodes report /__/__/__/__/

Specimen cut
(0) - no
(1) - yes
(2) - unknown

Specimen orientation
(0) - no
(1) - yes
(9) - unknown

Weight of specimen _____ gm
Marker distance _____ mm

Main diagnosis
(1) - benign
(2) - in situ
(3) - microinvasive
(4) - invasive
(5) - non - epithelial
(6) - other
.....
(9) - unknown

BENIGN (Type)
(1) - atypical ductal hyperplasia
(2) - atipical lobular hyperplasia
(3) - other
.....
(9) - unknown

IN SITU (Type)
(1) - ductal
(2) - lobular
(9) - unknown

Growth pattern (DCIS)
(1) - solid (6) - clinging
(2) - comedo (7) - other
(3) - papillary .....
(4) - micropapillary (9) - unknown
(5) - cribriform

Histological grade (DCIS)
(1) - low (0) - not done
(2) - intermediate (9) - unknown
(3) - high
Classification
_____

INVASIVE (Type)
(1) - ductal NST (7) - mixed ductal NST and other types
(2) - lobular (8) - mixed tubular / lobular
(3) - medullary (10) - metastatic
(4) - mucinous (11) - other
(5) - tubular, cribriform .....
(6) - mixed ductal / lobular (88) - not assessable
(99) - unknown

DCIS Component
(0) - absent
(1) - present
(9) - unknown

DCIS _____%

Histological grade (Invasive)
(1) - I (0) - not done
(2) - II (9) - unknown
(3) - III
Classification
(1) - WHO (3) - other
(2) - Elston-Ellis (9) - unknown

Vascular invasion
(0) - not seen
(1) - yes
(8) - not evaluated
(9) - unknown

Paget's disease
No Yes Unknown

Pathological size
_____ mm
Whole size (Invasive + DCIS)
_____ mm

Disease extent
(0) - localized
(1) - multiple
(9) - unknown

Specimen excision margins (at the definitive report)
(1) - T does not reach margin (4) - CIS focally reaches margin
(2) - inv. T focally reaches margin (5) - CIS reaches margin (extens.)
(3) - inv. T reaches margin (extensive) (9) - unknown

Margins: minimum distance (Invasive) _____ mm
minimum distance (DCIS) _____ mm
maximum distance _____ mm

pT

X 0 is mic 1 1a 1b 1c 2 3 4 4a 4b 4c 4d unknown

Lymph nodes
(0) - negative
(1) - positive
(9) - unknown

Examined nodes (No.) _____
Positive nodes (No.) _____

pN

X 0 1 1a 1b 1bI 1bII 1bIII 1bIV 2 3 unknown

ER
(0) - not done
(1) - negative
(2) - positive
(9) - unknown

PR
(0) - not done
(1) - negative
(2) - positive
(9) - unknown

ER/PR method **Date of report** /__/__/__/__/
(1) - immunohistochemical (3) - other
(2) - biochemical (9) - unknown
Antibody used _____
Antigen retrieval
(0) - no (1) - yes

Other markers
(0) - no
(1) - yes
(9) - unknown

Notes

References

1. Perry N, Broeders M, de Wolf C, Tomberg S, eds. *European Guidelines for Quality Assurance in Mammography Screening* (3rd edn.) European Commission Publication, 2001.
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3. O'Higgins N, Linos D, Blichert-Toft M. European Guidelines for Quality Assurance in the Surgical Management of Mammographically Detected Lesions. *Eur J Surg Oncol* 1998, **24**, 96–98.